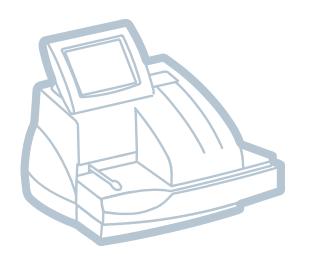
## **CLINITEK Advantus®** Analyzer



# Operator's Guide

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# **Using this Guide**

The *CLINITEK Advantus® Operator's Guide* provides information for clinical laboratory professionals who use the CLINITEK Advantus system.

The following table describes how this guide is organized:

If you want to	Then see
learn about the system principles, the hardware, and the operating sequence	Section 1, Introduction
process samples and manage sample results	Section 2, Operating the System
learn about calibration and how to print the calibration status	Section 3, Calibration
process QC samples	Section 4, <i>Quality Control</i>
perform maintenance activities	Section 5, Maintenance
investigate and correct system problems	Section 6, Troubleshooting
learn about file and data management	Section 7, File Management
install the system or modify system parameters	Section 8, System Configuration
review additional information such as the glossary or the supplies list	Appendices

## Conventions

The CLINITEK Advantus Operator's Guide uses the following text and symbol conventions:

Convention	Description
BIOHAZARD	Biohazard statements alert you to potentially biohazardous conditions.
MARNING WARNING	Warning statements alert you to conditions that may cause personal injury.
<b>A</b> CAUTION	Caution statements alert you to conditions that may cause product damage or loss of data.
Note	Note statements alert you to important information that requires your attention.
Bold	Bold type indicates text or icons on the user interface. For example, if the word save appears as <b>Save</b> , it refers to the <b>Save</b> button on the user interface.
	System icons are also indicated by words in bold type.
	For example, the words <b>Next Screen</b> refer to the system icon .
	A complete list of system icons and their equivalents is in <i>Appendix G, Symbols</i> .
Italic	Italic type refers to the title of a document or a section title in this guide.

## 1 Introduction

#### Intended Use

The CLINITEK Advantus urinalysis analyzer is a semi-automated, bench top analyzer. It is designed to read Siemens Healthcare Diagnostics Reagent Strips for Urinalysis, such as Multistix® 10 SG and Multistix PRO®Reagent Strips.

This analyzer is intended for the measurement of the following: Bilirubin, Blood (occult), Creatinine, Glucose, Ketone, Leukocytes, Nitrite, pH, Protein, ProteintoCreatinine ratio, specific gravity, and Urobilinogen.

These measurements are used to assist diagnosis in the following areas:

- Kidney function
- · Urinary tract infections
- Metabolic disorders, such as diabetes mellitus
- Liver function

Tests performed using the CLINITEK Advantus urinalysis analyzer are intended for *in vitro* diagnostic use.

As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, and should only be made by the physician after all clinical and laboratory findings have been evaluated. The analyzer is for professional use in centralized laboratory settings.

#### Overview

The analyzer is a reflectance spectrophotometer that analyzes the color and intensity of the light reflected from the reagent area and reports the results in clinically meaningful units. The analyzer can determine and report the color of the urine. You can enter clarity for each specimen. You are not required to make any calculations. Calibration is performed automatically each time a urine strip is analyzed.

Figure 1-1: CLINITEK Advantus Analyzer



## **Hardware Overview**

#### **User Interface**

By default, interaction with the CLINITEK Advantus analyzer is via an integrated touch screen. Messages, options, and requests for information display, and responses are made by touching the appropriate key symbol on the screen.



#### **CAUTION**

Do not use anything hard or pointed on the touch screen. It may damage the screen.

You can also use a computer keyboard or a handheld barcode reader to interact with the analyzer. Some analyzer screens may not accept input from these devices.

#### **Testing and Printing Areas**

All testing takes place on the fixed platform.

The fixed platform consists of 3 sections: the strip loading station, the incubation/read station, and the waste bin. Strips are placed on the strip loading station. The push bar moves the strips to the incubation/read station, where they are tested. When testing is complete, the strips drop into the waste bin.

When testing is complete, an internal thermal printer prints the test results.

Figure 1-2: User Interface, Testing and Printing Areas



- 1. Display
- 2. Printer
- 3. Waste bin
- 4. Fixed platform
- 5. Incubation/read station
- 6. Strip loading station
- 7. Push bar

#### **Connections and Power**

The line cord is connected into the line cord receptacle. Turn the analyzer on by pressing the power switch to the on position. You can connect a computer, printer, ethernet connection, keyboard, and handheld barcode reader to the analyzer using the interface connectors.

#### Memory

The analyzer software is stored in internal flash memory. When necessary, you can update the software using an electronic memory card located on the back of the interactive touch display.

The analyzer stores the operating parameters, including those selected by the user, and up to 500 patient results and 200 quality control results. This information is in a RAM with a battery backup, and is held in memory regardless of whether the analyzer power is on or off.



Figure 1-3: Connections, Power, and Memory

- 1. Memory card slot
- 2. Cooling fan
- 3. Power switch
- 4. Line cord receptacle
- 5. Ethernet interface connector

6 5

- 6. Serial interface connector
- 7. Printer interface connector
- 8. Keyboard and barcode reader interface connector

#### **Software Overview**

The CLINITEK Advantus provides an easy-to-navigate and intuitive user interface.

When the analyzer is not in use, the screen saver or the Ready/Run screen displays. If the screen saver displays, touch the screen to access the Ready/Run screen. You can access all tests through the Ready/Run screen. You can also navigate from this screen to any point in the software.

Figure 1-4: Ready/Run Screen



- 1. Information and instructions area
- 2. Inactive action key
- 3. Active action key
- 4. Inactive cycle key
- 5. Active cycle key
- 6. System status area

The information and instructions area shows system settings or user input, and provides instructions for the user. The Help, Stop Run, and Return to Ready/Run keys display in this area.

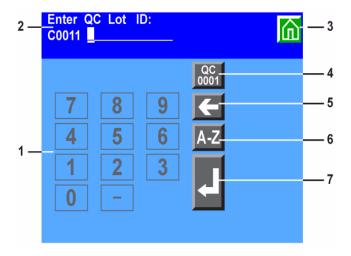
Many options are next to an Action Key. Select this key to select the option.

Some options are next to a Cycle key. Use the cycle key when several options are available. Each time you select the key, a different option displays for the selection.

If an option is active, the key symbol is fully lit. If it is not active, it is dimmed, and a tone will sound when you touch the key.

The system status area displays only on the Ready/Run screen. It shows the current date and time, and the Technician ID, if Technician IDs are active on your system.

Figure 1-5: Input Screen



- 1. Numeric keypad
- 2. Information and instructions area
- 3. Return to Ready/Run screen key
- 4. Reset QC Lot ID key
- 5. Move Left key
- 6. Alphabet key
- 7. Enter key

Some options require that you enter information. If selected, a numeric keypad will display. If available, you can select the Alphabet key to access an alphabetic keypad. If a handheld barcode reader or keyboard is connected to the system, you can scan or enter information for some values. The instrument will only recognize keyboard input that is equivalent to the keypads available on the instrument display.

See *Appendix G, Symbols* for a complete list of key symbols used on the CLINITEK Advantus.

## **Operating Sequence**

If specimen IDs are not used and color/clarity results are reported and displayed, the analyzer automatically enters the Run mode when you place a strip on the fixed platform. A sensor detects the strip's presence and activates the strip movement and reading cycle.

If the push bar is positioned at the left side of the loading station, the analyzer is ready to accept placement of a strip. If the bar is positioned to the right, the analyzer is not ready and ignores any strip placed on the platform.

If the analyzer is already in the Run mode and you place a strip on the platform, there may be delay of up to 7 seconds before the push bar moves. The amount of delay depends on the status of the timing cycle for the strips currently being analyzed.

The push bar moves the strip along the loading station to the read area. The sequence number increments. A series of pins move the strip across the platform at a rate of about 1.3 cm (1/2 inch) every 7 seconds.

Two readheads, located inside the read area, scan the length of each urine strip at a specific time in the incubation cycle. The first readhead reads the reagent areas requiring shorter incubation times. The second reads those requiring longer incubation times.

Each of the 2 readheads contains an incandescent lamp and photodiode pack. When a strip moves into position under the readhead, the analyzer performs a calibration cycle. The readhead then scans the entire length of the strip, measuring the light reflectance of each reagent pad. A portion of the light striking the pad is reflected back to the photodiode pack. The light reflected at specific wavelengths from the test pad is dependent upon the degree of color change in the pad and is directly related to the concentration of the particular constituent in the urine.

The photodiode pack contains 4 filters, one each at 400 to 510 nm (blue), 510 to 586 nm (green), 586 to 660 nm (red), and 825 to 855 nm (IR). The light intensity detected by the photodiode pack is converted into electrical impulses, which are processed by the analyzer's microprocessor and converted into clinically meaningful results.

The pins continue to move the strip along the platform until it drops into the waste bin.

An internal thermal printer prints the test results, if this option is selected. You can also send the results to a computer and a form or 80-column printer.

## 2 Operating the System

Leave the CLINITEK Advantus analyzer on at all times, except during maintenance and cleaning procedures.

#### Overview

You can test without a loadlist or specimen ID. Put a strip on the analyzer. The analyzer automatically assigns a Sequence Number and begins testing.

You can manually assign specimen IDs to tests. You can enter specimen IDs immediately prior to testing each specimen.

You can enter a loadlist of up to 200 specimen IDs before starting the run. You can enter the IDs from the analyzer display, a computer keyboard, a host computer, or Laboratory or Hospital Information System (LIS/HIS).

You can interrupt processing to run a STAT test when using a loadlist. After the STAT test the analyzer will continue testing specimens from the loadlist.

If necessary, you can stop a run before all readings are complete.

Results transmit to the printer and computer as soon as all reagent areas on the strip are read.

## Preparing for a Run

When you place the first strip on the fixed platform the analyzer begins a run. Before starting each run, perform the following procedures.

#### Select a Urine Strip

Siemens urine strips have identification (ID) bands, which can be white or colored. When using these strips, this procedure is not required unless you want to identify strip lot information.

When a urine strip has an ID band, the analyzer reads the ID band and automatically recognizes the strip type. This automatic identification overrides the preset urine strip setting.

Use this procedure to select a primary and alternate urine strip.

1. Check that the primary and alternate urine strip correspond to the strip types you are using.



#### **CAUTION**

Only use Siemens brand urine strips. Use of other strips may cause erroneous results.

- 2. If required, select the cycle key next to Choose Strip to use the alternate strip.
- 3. If the primary and alternate strip types selected for your analyzer do not correspond to the strip types you are using, change the selected strips before beginning testing.

Select the new strip types through the Setup Routine.

See Section 8, System Configuration for more information.

**Note** If you enable automatic color detection and use one of the following reagent strips for urinalysis, no result for color is reported:

- Multistix
- Multistix SG
- Uro-Hema-Combistix<sup>TM</sup>
- Uro-Labstix<sup>TM</sup>
- Hema-Combistix® LONG

#### **Enter Strip Lot and Expiration Information**

Lot and expiration information can only be entered for the primary and alternate strip types selected for your analyzer.

If you want to identify strip lot information, you must identify a primary and alternate strip type.

Use this procedure to enter Strip Lot and Expiration information:

- 1. At the Ready/Run screen, select Menu.
- 2. Select **Primary** or **Alternate**.

A numeric keypad displays.

- 3. Enter an identification number of up to 6 digits:
  - a. Select A-Z to enter alphabetic characters.
  - b. Select **Enter** to return to the numeric keypad.

You can also enter the ID from a computer keyboard, or scan it from a barcoded label using the handheld barcode reader. If you scan a combined lot and expiration barcode, the analyzer enters the expiration date at the same time as the Strip Lot ID.

c. Select **Enter** to save the Strip Lot ID.

A numeric keypad displays.

- 4. Enter the Expiration year in the format YYYY.
- 5. Enter the Expiration month in the format MM.

Select **Enter** to save the expiration date.

You can also enter the date from a computer keyboard, or scan it from a barcoded label using the handheld barcode reader.

6. Confirm the information entered, and select **Next Screen**.

#### **Check the Strip Loading Station**

Ensure that the strip loading station and push bar are clean and in the correct position. If contaminants are present, remove and clean the push bar, the platform, and the moving table.

#### **Change the Starting Sequence Number**

This number increments with each strip placed onto the analyzer. If necessary, use this procedure to change the number.

1. Select **SEQ #**.

A numeric keypad displays.

2. Enter the new sequence number.

Change individual digits as needed:

- Select Move Left or Move Right to move the cursor to the digit to change.
- b. Enter the correct number.

Select **00001** to reset the number.

#### Select Enter.

#### **Change the Technician Identification**

You can activate the Tech ID option during analyzer setup. See *Tech ID*, page 128 for more information.

- 1. At the Ready/Run screen, select **Menu**.
- 2. Select Tech ID.

A numeric keypad displays.

- 3. Enter an identification number of up to 13 digits.
  - a. Select A-Z to enter alphabetic characters.
  - b. Select **Enter** to return to the numeric keypad.
- 4. Select Enter to save the Tech ID.

#### **Print Information**

Use this procedure to print information:

- 1. At the Ready/Run screen, select **Menu**.
- 2. Select Print to print:
  - The ID list if a loadlist exists in memory
  - Confirmation of the last calibration
  - A report of the setup parameters

#### **Run Controls**

At the Set options menu, select **QC** to run controls before processing patient samples. See Section 4, *Quality Control*, for more information.

## Auto-Checks: Detect Urine Strip Humidity Over-Exposure

Urine strips with identification (ID) bands and a leukocyte pad are checked to ensure quality.

After dipping and placing the strip in the analyzer, the analyzer checks to ensure that the urine strip was stored at the proper humidity prior to testing. If humidity over-exposure is detected, the analyzer generates an error message and does not report test results.

## **Testing Routine Specimens**

#### **Testing Without a Specimen ID or Loadlist**



#### **BIOHAZARD**

Wear personal protective equipment. Use universal precautions. See *Appendix A, Safety Information* for recommended precautions when working with biohazardous materials.

Use this procedure to test routine specimens:

1. Select a urine strip.



#### **CAUTION**

Only use Siemens brand urine strips. Use of other strips may cause erroneous results.

2. If you are entering color or clarity, use the cycle key to set color and clarity for each specimen.

You can also enter the color and clarity by scanning the barcoded symbols provided with the handheld barcode reader.

**Note** If Use default COL/CLA during run is set to on, the default values of YELLOW and CLEAR display.

Enter the color and clarity of each specimen before dipping the urine strip.

You can change the color and clarity until the strip moves.

- 3. Completely immerse all of the reagent pads on a Siemens urine Strip in fresh, well-mixed, uncentrifuged urine.
- 4. Immediately remove the urine strip.
- 5. While removing the strip, run the edge against the side of the container.

This removes excess liquid.



#### **CAUTION**

Do not blot the edge of the strip. This could affect results.

6. Place the urine strip onto the supports of the strip loading station, with the reagent pads facing up.

Place the strip to the right of and parallel to the push bar. Ensure that the end of the strip is against the back wall of the platform and that it is not touching the bottom of the strip loading station.



#### **CAUTION**

Improper placement may cause the analyzer to jam or the strip to incorrectly align under the readheads.

Figure 2-1: Placement of Urine Strip



7. Repeat steps 2 to 6 for each specimen.

When the push bar is to the far left of the platform, you can place a new strip on the loading station until the previous strip placed enters the waste bin. When the final strip moves to the waste bin, the run ends, and end of run reports are processed.

See *Printing and Transmitting Results*, page 35 for information on printing and transmitting the results.

## **Using the Specimen ID Without a Loadlist**

You can enter Specimen IDs immediately prior to testing each specimen using the following steps:

**Note** You can use this procedure only if Enter Sample IDs is On. See *Enter Sample IDs*, page 127 for information on this setting.

- 1. At the Ready/Run screen, select ID.
- 2. Enter the ID number for the specimen you are about to test.
  - Select A-Z to enter alphabetic characters.

You can also enter the ID from a computer keyboard, or scan it from a barcoded label using the handheld barcode reader.

- 3. If needed, enter or scan the color and clarity.
- 4. When this information is correctly entered, select **Enter** or scan the **Enter** code from the color or clarity card.

The display changes to allow entry of the next ID number, and the push bar moves to the left so you can place a strip on the loading station.

5. Dip and place a urine strip.

**Note** If another ID is entered without a strip being detected, the analyzer automatically creates a loadlist.

6. Repeat steps 2 to 5 for each specimen.

## **Using Loadlists**

You can enter a loadlist of up to 200 specimen IDs before starting the run. You can enter the IDs from the analyzer display, a computer keyboard, a host computer, or Laboratory or Hospital Information System (LIS/HIS).

**Note** You can use loadlists only if Enter Sample IDs is On. See *Enter Sample IDs*, page 127 for information on this setting.

## Entering a Loadlist from the Display or Computer Keyboard

To report color and clarity, enter initial values at the same time as the ID. You can edit color and clarity while running the specimens, immediately prior to dipping each urine strip using the following steps:

Note Duplicate ID numbers are allowed by the analyzer.

- 1. At the Ready/Run screen, select ID.
- 2. Enter the **ID** for the first specimen.

Select A-Z to enter alphabetic characters.

You can also enter the ID from a computer keyboard, or scan it from a barcoded label using the handheld barcode reader.

**Note** Do not select or scan Enter from the ID entry screen before entering the color and clarity.

- 3. If needed, enter or scan the color and clarity.
- Select Enter or scan the Enter code.
- 5. Repeat steps 2 to 4 for each specimen.

#### **Editing a Loadlist**

Use this procedure to make changes to the loadlist when initial entry is complete:

- 1. Use Move Up and Move Down to select the record to edit.
- 2. Edit the ID number.

**Note** You cannot change or delete the ID number during Run mode. Make any changes while the analyzer is in the Ready mode.

3. Select **Delete** to delete an item from the loadlist.

You can delete only the ID number being displayed or all IDs in memory.

- 4. Edit the color and clarity.
- 5. Select **Enter** to accept the new number, color, and clarity.

# Entering a Loadlist from a Host or Laboratory/Hospital System

You can connect the CLINITEK Advantus analyzer to a host computer or laboratory system. See *Appendix F*, *Computer and Printer Interface*, for more information.

- 1. Before sending a loadlist from a host or laboratory system, ensure that the following conditions are true:
  - The analyzer is at the Ready/Run screen.
  - No IDs from an earlier loadlist are still stored in the analyzer. If a loadlist was sent but is no longer needed, you can overwrite the unused IDs with a new loadlist.
  - The computer port is set to computer port, ethernet port, or both.
  - The computer port options for Baud, Data, and Parity are correct for the computer or LIS/HIS sending the loadlist. See the specifications accompanying the computer or Laboratory/Hospital Information System for information on the required parameters.
  - The output format for the computer port is CCS. See Computer Port Options, page 129 for more information on setting the computer port.

**Note** Loadlist data is only transferred if it is formatted correctly. If a loadlist is not transferred, see Section 6, *Troubleshooting*, for possible causes.

2. Review or delete a loadlisted number and add a color or clarity description.

The loadlist order is indicated by a number to the left of the ID number. The total number of IDs in the loadlist is shown in the lower right corner of the display.

- a. At the Ready/Run screen, select ID.
- b. Use Move Up and Move Down to display the ID number.Use the loadlist order number to locate the proper location.

**Note** You cannot change or delete an ID number transferred from a host computer or Laboratory/Hospital Information System.

- Delete the number from the loadlist by selecting **Delete**.
   You can delete only the ID number being displayed or all IDs in memory.
- d. If needed, enter or scan the color and clarity.
- e. Select **Enter** to accept the new color and clarity.
- 3. Select **Print** to print the ID list.
- 4. Select **Return to Ready/Run** to begin testing specimens.

You can also print the ID list from the Ready/Run screen.

- a. At the Ready/Run screen, select Menu.
- b. Select **Print**.
- c. Select ID list.

**Note** You must make changes to the loadlist before starting testing. To edit remaining IDs in the loadlist, enter a loadlist from the analyzer display or a computer keyboard and then cancel the run. Add new IDs when the run is complete.

5. Test each specimen.

The Ready/Run screen displays each ID number and the color/clarity descriptions in the same order as they were entered into the loadlist.

- a. Check that the ID number, color, and clarity descriptions are correct for the specimen you are about to test.
- b. Edit the color and clarity, if necessary.
- c. Dip and place a urine strip.

When the strip for the last loadlisted specimen is moved to the read area, you are not allowed to place any additional strips on the table. The push bar stays at the right side and the analyzer completes the run.

## **Performing a STAT Test**

Use this procedure to run a STAT test when using a loadlist. After the STAT test the analyzer will continue testing specimens from the loadlist.

- 1. At the Ready/Run screen, select **STAT**.
- 2. Enter an ID for the STAT test.

The SEQ # shown is the next number available after the end of the loadlist.

- 3. Edit the color and clarity, if necessary.
- 4. Select a urine strip.



#### CAUTION

Only use Siemens brand urine strips. Use of other strips may cause erroneous results.

5. Dip and place a urine strip.

The result is printed when the STAT test is complete. The analyzer displays any confirmatory or microscopic flags from the STAT test.

6. Run another STAT test or resume loadlist testing.

The next test is allocated the SEQ # which follows the number used for the STAT test just completed.

## Cancelling a Run

Select **Stop Run** if you need to stop the run before all readings are complete.

You can cancel the entire run or only the last strip placed on the platform.

If the you cancel the entire run, all strips on the platform are moved immediately to the waste bin. No results are reported. No SEQ # is assigned for any strip that was not read at both readheads before Stop Run was selected. You must retest all the specimens for all cancelled strips.

If only the last strip is cancelled, the run continues and you can test a new strip using the same SEQ #.

## **Managing Results**

Results are transmitted to the printer and computer as soon as all reagent areas on the strip are read. If a record is flagged for a confirmatory report and Edit flagged results is On, that record is not transmitted until after the end-of-run reports complete.

#### **End-of-Run Reports**

The analyzer may display up to 3 end-of-run reports when the run, or a STAT test, is completed. These reports display if you have marked any analytes to flag for confirmatory or microscopic tests, and if Mark Positives is On. Use this procedure to request end-of-run reports:

- Specify 1 or more tests for the Confirmatory Reports A and B or Microscopy Report.
- 2. In the Setup routine, select **On** for Edit flagged results.

The Confirmatory and Microscopic Report screens display the **SEQ** # and **ID** of the record, and the abbreviation for each positive analyte marked for flagging.

Up to 5 records may be displayed on 1 screen.

- 3. Use **Move Up** and **Move Down** to view additional records.
  - If both the Confirmatory and Microscopic Reports contain records, the Confirmatory Reports display first.
- 4. Edit these results before exiting the Confirmatory Report. See *Editing Results in the Confirmatory Reports*, page 32.
- 5. Select **Print** to print a report.
- 6. Select Return to Ready/Run to exit the report screen.

If an error is reported for 1 or more analytes, a report displays after the Confirmatory and Microscopic Reports. This report displays last.

7. Retest any specimens listed.

#### **Editing Results in the Confirmatory Reports**

Use this procedure to edit the results of confirmatory testing:

1. During the end of run review, access the Confirmatory Report screens.

- 2. Select a record from the Confirmatory Report A screen.
  - The flagged positive test results display.
- 3. Select the cycle key next to the test name to change the displayed result to the next available reported result.
  - When the cycle key is selected, the result for that test is printed and stored with an exclamation point (!) to indicate that it was edited, even if the result is reset to its original value.
  - If the selected output format is CCS, an E is transmitted with the results.
- 4. Select **Previous Screen** when editing is complete for that record to return to the Confirmatory Report.
- 5. Repeat Steps 2 to 4 above for each record.
- 6. When all editing is complete, select **Return to Ready/Run** to exit Confirmatory Report A.
  - When you leave a Report, you are not able to edit the report any further.
  - Records for Confirmatory Report B display.
- 7. Repeat Steps 2 to 4 above to edit these records.
- 8. When all Confirmatory Report editing is complete, select **Return to Ready/Run** to exit the Confirmatory Reports.

**Note** When you leave the Edit routine, you are not able to edit the run any further.

Records in the Microscopic Report display.

After you exit Confirmatory and Microscopic Report screens, results for the records included in Confirmatory Reports A and B are sent to the printer and computer; all other records are printed and transmitted as soon as they are available.

#### Merging Data from Microscopic Testing

Use this procedure to add the microscopic test results:

This option is available only if you created customized microscopy headings.

- 1. At the Ready/Run screen, select **Menu**.
- 2. Select Enter Microscopics results.
- 3. Search for the correct test results:
  - a. Enter the patient ID.
  - Select Enter to start the search.
     The patient ID results display with the earliest test displayed first.
  - c. Use **Move Up** and **Move Down** to select the correct test results.
  - d. Select Select Result.
- 4. Select the heading where you will add results.
- 5. Enter the microscopic test result for the heading.
- Select Enter to enter the data.
- 7. Repeat this procedure to add all required microscopic test data.
- 8. Select **Print** to print the microscopic result data and the results of the patient test on the analyzer.
- Select Merge to store the microscopic data with the analyzer results.

When the test results are recalled, Microscopics displays on the results display to show that microscopic results are stored with the test results.

## **Recalling Results**

Up to 500 patient records and 200 quality control records are stored in memory. Use the following procedure to recall 1 or more records:

- 1. At the Ready/Run screen, select **Menu**.
- 2. Select **Memory**.
- 3. Recall a group of records.
  - All patient records
  - All QC records

- The last batch of patient results
- Stored results by Patient ID

The number of records in memory displays next to the first 2 options.

The last batch of patient results tests are those tests run between the last pause in testing and the latest test. If the latest test is a QC test, it is not recalled.

- 4. If you selected **Search for stored results**, enter the patient ID.
- Select Enter to start the search.

The earliest record of the selected group displays. The date and time the record was stored displays, along with the Technician ID, SEQ #, and ID for the record. All results are then listed. Positive results are flagged with an asterisk (\*) and edited results with an exclamation point (!).

6. Locate the first record to review using the movement keys shown on the display.

The next lower- or higher-numbered record in memory is recalled when Move Up and Move Down are used. The record 10 higher or lower is recalled when Move Up 10 and Move Down 10 are used.

If microscopic results are merged with the patient test results, **Microscopics** displays on the patient record.

7. Select **Microscopics** to view the merged microscopic results.

### **Printing and Transmitting Results**

#### **Printing Records from Memory**

Use this procedure to print records from memory:

- 1. Recall a group of results. See Recalling Results, page 34.
- 2. Select **Print** to print 1 or more records.

#### 3. Select one of the following options:

То	Select
Print the record displayed	Print only this result The SEQ # and ID of that record continues to display on the print option menu.
Specify the beginning and ending records to print	<ol> <li>Print a group of results</li> <li>Use the movement keys to specify the start record to print.</li> <li>Select Enter to select the end record to print.         This record must have a SEQ # that is higher than or the same as the start record.     </li> <li>Select Enter to begin printing.</li> <li>All records in the sequential group print.</li> <li>Note The results tested using a loadlist may include STAT tests carried out during the loadlist testing.</li> </ol>
Print all records that were recalled	Print all patient (control) results

After printing is complete, the screen returns to the earliest record of the group. If Print a group of results is selected, the display first returns to the screen from which the group was selected.

4. Select **Previous Screen** as needed to return to the first record.

### **Resending Records from Memory**

Use this procedure to resend one or more records to a host computer or LIS:

- 1. Recall a group of results. See Recalling Results, page 34.
- 2. Select Resend.

#### 3. Select one of the following options:

То	Select
Send the record displayed	Send only this result  The SEQ # and ID of that record continues to display on the sent option menu.
Specify the start and end records to resend	<ol> <li>Send a group of results</li> <li>Use the movement keys to specify the start and end records to resend.</li> <li>Select Enter to begin resending.</li> <li>All records in the sequential group are sent.</li> <li>Note The results tested using a loadlist may include STAT tests carried out during the loadlist testing.</li> </ol>
Send all records that were recalled	Send all patient (control) results

After resending is complete, the screen returns to the earliest record of the group. If Send a group of results is selected, the display first returns to the screen from which the group was selected.

4. Select **Previous Screen** as needed to return to the first record.

### **Deleting Results from Memory**

Use this procedure to delete all patient or control results from memory:

- 1. Recall a group of results. See *Recalling Results*, page 34.
- Select **Delete**.
- 3. Confirm the deletion.
- 4. Select **Previous Screen** to return to the previous menu, or select **Return to Ready/Run** to return to the Ready/Run screen.

# **Additional Operating Instructions**

### **Using a Form Printer**

While printing results using a form printer, each set of results is stored in memory until you insert a form into the printer. When the analyzer detects a form, the next set of results is sent to the printer.

Check each form immediately after it is printed to ensure that all results are printed and are clearly readable. If the printed form has a problem, immediately reprint the last report using the following steps:

**Note** If you are using the CLINITEK<sup>®</sup> Form Printer, use **Reprint** on the Form Printer. Do not select **Reprint last result** on the analyzer display.

Select Reprint last result.

As long as the checkmark displays in the selection key, the last set of results are reprinted each time a form is inserted into the printer.

- 2. Insert a new form into the Form Printer.
  - Do not insert the form before selecting **Reprint last result** or the last set of results is lost.
- 3. When the report is printed correctly, select **Reprint last result** again to remove the checkmark.
- 4. Insert a new form to print the next set of results.

### Removing a Jammed Test Strip

See Section 6, *Troubleshooting* for more information on this procedure.

### **Thermal Printing**

Thermal print from the internal printer fades with time, especially when exposed to light. The print also fades if covered with transparent tape or when exposed to extremes in temperature or humidity.

### **Managing the Printer Paper**

The analyzer detects when the internal printer is out of paper and retains the results until the printer paper roll is replaced. The last meter of paper on the roll has a pink edge. Change the roll when the pink edge displays. See *Changing the Paper*, page 58.

### **Emptying the Waste Bin**

Empty the waste bin as it starts to fill. This prevents problems with strips jamming as they leave the read station.

## 3 Calibration

### Overview

Calibration is performed at each readhead immediately before each urine strip is read. The fixed platform contains 2 white calibration bars, positioned directly under each readhead. As a strip comes into position under a readhead, the analyzer reads the calibration bar and calibrates for that scanning cycle. The analyzer then scans the urine strip and stores the data in memory.

# **Confirming a Calibration**

Use the following procedure to print a report of the most recent successful calibration:

- 1. At the Ready/Run screen, select Menu.
- 2. Select Print.
- 3. Select Calibration confirmation.

The date and time of the latest successful calibration prints.

# 4 Quality Control

Run negative and positive controls on a regular basis to check the Siemens urine strip performance and analyzer operation. Quality control (QC) testing provides confidence that the urine strips are reacting and being read correctly. It can also detect errors resulting from user techniques. See your laboratory quality assurance program to ensure quality throughout the entire testing process. Run controls under the following conditions:

- At the start of the day's run
- When using a new bottle of urine strips
- · Whenever test results are in doubt
- When training new operators

The CLINITEK Advantus analyzer can prompt for regular QC testing. You can set the interval between QC tests from 1 hour to 99 days. You can prevent the analyzer from being used for testing when a QC test is due. Select the QC interval and requirement through the Setup routine.

Use Chek-Stix<sup>®</sup> Positive and Negative Control Strips for Urinalysis. The solutions prepared using the control strips provide positive, negative, or defined concentrations when used with traditional Siemens Reagent Strips for Urinalysis. You can also use a urine specimen from a normal, healthy individual as a negative specimen.

**Note** When using Multistix PRO Reagent Strips for Urinalysis, use commercially available controls that include values for each test on the strip. Chek-Stix Control Strips are not suitable for use with this product.

For information about control manufacturers, contact your local technical support provider.

# **Testing Control Specimens**

Use the following procedure to test control specimens:

1. Select a urine strip.



#### CAUTION

Only use Siemens brand urine strips. Use of other strips may cause erroneous results.

- 2. Prepare the appropriate control solution(s) by following the directions found in the package insert or on the bottle label.
- 3. At the Ready/Run screen, select **Menu**.
- 4. Select QC.
  - a. Enter an identification number of up to 13 digits:
  - b. Select QC 0001 to reset the number.
  - c. Select **A-Z** to enter alphabetic characters.
  - d. Select **Enter** to return to the numeric keypad.

You can also enter the QC Lot ID from a computer keyboard, or scan it from a barcoded label using the handheld barcode reader.

- 5. Enter the expiration date of the controls:
  - a. Enter the expiration year in the format YYYY.
  - b. Enter the expiration month in the format MM.
  - c. You can also enter the date from a computer keyboard, or scan it from a barcoded label using the handheld barcode reader.
  - d. Select **Enter** to save the expiration date.
- 6. When you are ready to test the control, select **Enter**.
- 7. Completely immerse all of the reagent pads on a urine strip into the quality control solution.
- 8. Immediately remove the urine strip.

9. While removing the strip, run the edge against the side of the container.

This removes excess liquid.



#### **CAUTION**

Do not blot the edge of the strip. This could affect results.

10. Place the urine strip onto the supports of the strip loading station, with the reagent pads facing up.

Place the strip to the right of and parallel to the push bar. Ensure that the end of the strip is against the back wall of the platform and that it is not touching the bottom of the strip loading station.



#### **CAUTION**

Improper placement may cause the analyzer to jam or the strip to incorrectly align under the readheads.

Figure 4-1: Urine Strip Placement



11. Repeat steps a through 10 for each additional control.

The strip automatically advances along the strip loading station, under the readheads, and into the waste bin.

If the printer is set to On, the results are printed and stored in memory. If the computer port is set to computer port, ethernet port, or both, and CCS is selected as the output format, the control results are also transmitted to the host computer.

12. After all controls are run, select **Return to Ready/Run** to exit the quality control screen.

# **Quality Control Errors**

If the control results fall outside of the values stated in the product's package insert, the following sources of error may have occurred:

Cause	Corrective Action
Improper technique or analyzer setup.	Verify that the urine strip used corresponds to the urine strip name given on the top of the Ready/Run screen.  Carefully repeat the control procedure described above.
Deterioration of the urine strip test areas due to exposure to light, ambient moisture, or heat.	Use a fresh bottle of Siemens Reagent Strips for Urinalysis to repeat the quality control procedure.  If fresh urine strips fail to give results within the expected values, proceed to the next possible cause.
Deterioration of the control solution.	Use a fresh control solution to repeat the quality control procedure.  If fresh solution fails to give results within the expected values, proceed to the next possible cause.
Deterioration of the quality control product.	Prepare control solution using a fresh bottle of control product.  Repeat the quality control procedure.  If the fresh control solution fails to give results within the expected values, proceed to the next possible cause.
CLINITEK Advantus analyzer malfunction.	Perform the procedure in <i>Performing the Initial Analyzer Check</i> , page 103.  If you cannot successfully complete the initial analyzer check or the quality control procedure, an analyzer malfunction or urine strip problem may exist. See Section 6, <i>Troubleshooting</i> for more information, or contact your local technical support provider for assistance.

## 5 Maintenance

### **General Cleaning**

Keep the exterior of the CLINITEK Advantus analyzer free of dust at all times. Clean the exterior using a damp cloth and a mild detergent.



#### **CAUTION**

Do not use any type of solvent, oil, grease, or silicone spray on any part of the analyzer. Harsh chemicals can damage the platform components.

# **Performing the Daily Cleaning**

Clean the following parts at least once each day or after running 300 strips, whichever is more frequent:

- Push bar
- Fixed platform
- Moving table
- Urine strip holddown plate

Clean the display screen once a day if it is used to enter ID, color, or clarity during the run using the following steps:

- 1. Ensure that the run is complete, and the analyzer is at the Ready/Run screen, before removing components.
  - In this analyzer state, the moving table is in its lowest position and you can reinstall the fixed platform.
- 2. Turn analyzer power off.

- 3. Remove the push bar:
  - a. Tilt the bar slightly upwards.
  - b. Pull the bar straight out.

Figure 5-1: Remove the Push Bar



- 4. Remove the waste bin liner.
- 5. Discard the used urine strips into an appropriate container, according to your standard laboratory procedures.

6. Remove the fixed platform by pulling the entire assembly towards you.

Figure 5-2: Remove the Fixed Platform



7. Remove the moving table by pulling the entire assembly towards you.

Figure 5-3: Remove the Moving Table



- 8. Remove the holddown plate from the fixed platform:
  - a. Press upwards on the tab at the back of the plate.
  - b. Pull the other end from its retaining hole.

**Note** You must remove the holddown plate for proper cleaning.

Figure 5-4: Remove the Holddown Plate



1. Tab



#### CAUTION

Do not use any type of solvent to clean the analyzer. Harsh chemicals can damage the platform components.

9. Clean the push bar, the platform, the holddown plate, and the table with warm water and mild detergent.



#### \ CAUTION

When cleaning the platform, avoid wiping across the 2 white calibration bars. Use a cotton-tipped swab, wetted with plain water, to clean the bars. Cleaning solution can damage the calibration bars.

10. If the holddown plate or push bar is extremely dirty, soak it in warm water and mild detergent to loosen the dried residue.

- 11. Rinse each piece thoroughly.
- 12. Dry each piece with a paper towel or soft cloth.Use care when drying around the pins on the moving table.
- 13. Allow the calibration bars on the platform to air dry.
- 14. After cleaning, inspect the calibration bars for scratches, marks, or discoloration.
  - If you cannot clean the bars, discard the current platform and replace it with a new one.
- 15. Disinfect the parts, if required. See *Performing a Decontamination*, page 55.

**Note** Do not disinfect the liner. Discard it into an appropriate container and use a new liner.

- 16. Reinstall the moving table:
  - a. Hold the table with the small rectangular tab facing to the back.
  - b. Align the 2 grooves on the bottom of the table with the edges of the platform on which the table rests.
  - c. Gently push the table in until you hear the tab latch into the hold position.
  - d. Check that the table is secure.

### 17. Reinstall the holddown plate:

- a. Position the holddown plate with the arrow side facing up and the arrow pointing to the back.
- b. Place the pin on the front of the holddown plate into the hole at the front of the fixed platform.
- c. Align the tab at the back of the holddown plate with the slot at the back of the platform.
- d. Snap the holddown plate into place. Listen for a loud click, indicating proper installation.
- e. Ensure that the white calibration bars are visible.

#### 18. Reinstall the fixed platform:

- a. Align the 2 grooves on the bottom of the fixed platform with the arms extending forward from the analyzer.
  - The flanges on the sides of the holddown plate align just outside the read area cover. The top edge of the platform aligns just under the cover.
- b. Gently push the platform in as far as possible.Push past the ridge to correctly position the platform.



#### CAUTION

Do not force the platform. Ensure that the moving table is correctly positioned before you attempt to reinstall the fixed platform. If you force the platform, you may damage the moving table or fixed platform.

#### 19. Reinstall the push bar:

- a. Hold the push bar at the indented end.
- b. With this end slightly upward, insert the peg on the other end of the bar into the hole in the pusher mechanism.
- c. Lower the push bar into place.
- 20. Place a new liner into the waste bin.
- 21. Clean the display screen, with a soft, nonabrasive cloth dampened with a mild glass cleaner.



#### CAUTION

Do not use bleach to clean the display. Do not spray or pour the glass cleaner directly onto the screen. Do not use laboratory wipes, such as Kimwipes, because they may scratch the screen.

22. Turn analyzer power on.

## **Performing a Decontamination**

Use the following procedure to disinfect the push bar, the holddown plate, the fixed platform, the moving table, and the display screen. You can also use this procedure when taking the analyzer out of service.

See the labeling accompanying the disinfection products for complete instructions on their use.

1. Remove, clean, and dry the push bar, the fixed platform, the holddown plate, and the moving table. See *Performing the Daily Cleaning*, page 49.

**Note** Do not disinfect the liner. Discard it into an appropriate container and use a new liner.

- 2. Prepare 1 of the following solutions:
  - Household Bleach (5% sodium hypochlorite) use either full strength or dilute to as much as a 1:20 dilution. To make a 1:20 dilution, add 5 mL of bleach to a container and add 95 mL of water, for a total volume of 100 mL. To make a 1:10 dilution, combine 10 mL of bleach and 90 mL of water.
  - Cidex and Theracide<sup>1</sup> you can use these products, or their equivalents, in general disinfection. Prepare and use the solution according to the directions that come with the product.

**Note** Repeated or prolonged soaks over a long period of time with glutaraldehyde solutions may cause a slight fading or discoloration of the platform and table, and a cloudy appearance to the push bar. These changes do not affect performance.



#### CAUTION

Do not soak analyzer components in solution for more than 10 minutes once a day.

Do not use isopropyl alcohol or any product containing phenol, such as Amphyl. These cause damage to the calibration bars.

3. Completely immerse the pieces in the solution for no longer than 10 minutes.

<sup>1.</sup> These products may not be available in all locations.

- 4. Rinse each piece thoroughly.
- Dry each piece with a paper towel or soft cloth.Use care when drying around the pins on the moving table.
- 6. Allow the calibration bars on the platform to air dry.
- 7. Reinstall the pieces. See Performing the Daily Cleaning, page 49.
- Disinfect the display screen, if needed.
   Use either Cidex or Theracide solution, or their equivalents, only.



### CAUTION

Do not use bleach to clean the display. Do not spray or pour the disinfectant directly onto the screen. Do not use laboratory wipes, such as Kimwipes, because they may scratch the screen.

- a. Wipe the solution on the screen using a soft, nonabrasive cloth.
- b. Allow the solution to remain for 10 minutes.
- c. Rinse using a clean, soft cloth dampened with water, then dry.

# Lubricating the Push Bar Slide and Shaft

Clean and lubricate the push bar shaft:

- When the push bar chatters or moves in a jerky motion
- If you see an increase in skewed strip errors, caused by the vibration of the push bar movement.
- 1. Turn analyzer power off.
- 2. Disconnect the power cord.
- 3. Remove the push bar, the fixed platform, the holddown plate, and the moving table. See *Performing the Daily Cleaning*, page 49.
- 4. Clean the right side of the push bar shaft using ethanol or isopropyl alcohol on a cotton tipped applicator.
- 5. Move the slide arm to the right to access the left side of the shaft.
- 6. Clean the left side of the shaft.

- 7. Using a cotton tipped applicator, apply a thin film of Lubriplate lubricant to both sides of the push bar shaft
  - Do not apply too much or too little lubrication, as this may cause the push bar to move erratically.
  - An initial tube of Lubriplate lubricant is supplied with your analyzer. See *Appendix C, Orderable Supplies*, for information on obtaining additional tubes.
- 8. Move the slide arm several times to spread the lubrication.
- 9. Reinstall the pieces. See Performing the Daily Cleaning, page 49.
- 10. Reconnect the power cord.
- 11. Turn analyzer power on.

# **Changing the Paper**

Use the following procedure to change the printer paper:

- 1. Ensure the analyzer is at the Ready/Run screen.
- 2. Press the tab on the back of the printer cover.
- 3. Lift the cover off.

Figure 5-5: Remove the Printer Cover





#### WARNING

Be careful when touching the printer. It may be hot.



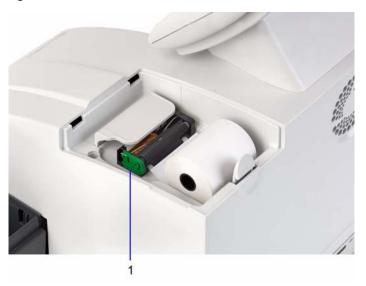
#### **CAUTION**

Do not touch the printer without observing precautions for handling electrostatic sensitive devices. A risk of electrostatic discharge to the analyzer exists when touching the printer.

- 4. Remove the paper roll:
  - a. Lift up the roll.
  - b. Tear the paper between the roll and the printer.
  - c. Remove the core and remaining paper on the roll.

- 5. Remove any paper remaining in the printer:
  - Locate the printer paper release lever.
     This lever is colored green and is located on the right of the printer when looking at the front of the analyzer.
  - b. Push down on the back of the lever to unlock the roller.
  - c. Pinch and lift the front of the lever to raise the paper guide.
  - d. Carefully pull paper through the printer in its normal direction of travel.

Figure 5-6: Printer Release Lever



- 1. Printer release lever
- 6. Obtain a new paper roll.
- 7. Unroll sufficient paper to feed the printer.
- 8. Hold the roll just above the printer, with the paper unrolling from underneath.
- 9. Push the paper gently under the roller at the back of the printer.

  The printer automatically pulls the paper into the printer and behind the paper guide on the top of the printer.

10. Set the roll of paper into position.

Figure 5-7: Feed Paper into the Printer



- 11. If necessary, feed more paper through the printer cover:
  - a. Carefully pull sufficient paper through the printer to enable you to feed it through the printer cover.
  - b. Ensure the edges of the paper are aligned with the edges of the printer.
  - c. Return the printer paper release lever to its locked position by pressing firmly down on the front of the lever.
- 12. Set the paper into position behind the printer.
- 13. Place the front tabs of the cover into their slots.
- 14. Feed the end of the paper through the opening in the cover.
- 15. Snap the cover into place.

## **Replacing the Printer**



#### **WARNING**

Be careful when touching the printer. It may be hot.



### CAUTION

Do not touch the printer without observing precautions for handling electrostatic sensitive devices. A risk of electrostatic discharge to the analyzer exists when touching the printer.

### **Disconnect the Analyzer**

Use the following procedure to disconnect the analyzer:

- 1. Turn analyzer power off.
- 2. Disconnect the power cord.

#### Remove the Cover on the Internal Printer

Use the following procedure to remove the printer cover:

- 1. Ensure the analyzer is at the Ready/Run screen.
- 2. Press the tab on the back of the printer cover.
- 3. Lift the cover off.

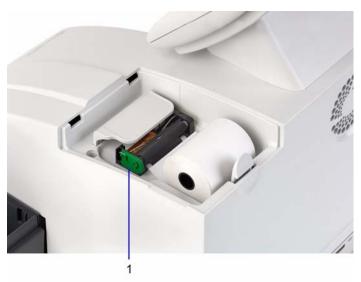
Figure 5-8: Remove the Printer Cover



### Remove the Paper Roll

- 1. Remove the paper roll:
  - a. Lift up the roll.
  - b. Tear the paper between the roll and the printer.
  - c. Remove the core and remaining paper on the roll.
- 2. Remove any paper remaining in the printer:
  - Locate the printer paper release lever.
     This lever is colored green and is located on the right of the printer when looking at the front of the analyzer.
  - b. Push down on the back of the lever to unlock the roller.
  - c. Pinch and lift the front of the lever to raise the paper guide.
  - d. Carefully pull paper through the printer in its normal direction of travel.

Figure 5-9: Printer Release Lever



1. Printer release lever

### Remove the Printer

- 1. Carefully remove the printer shield:
  - a. Press the bottom of the shield on the right-hand side toward the touch screen.
  - b. Lift to release the 2 clips located on either side at the bottom of the shield.

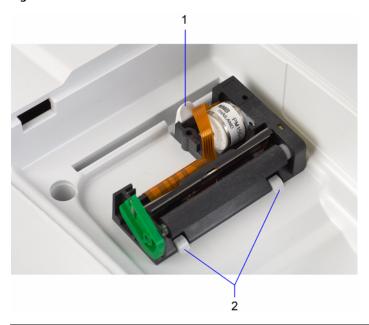
Figure 5-10: Remove the Printer Shield



- 2. Locate the clip at the front of the printer.
- 3. Pull the clip towards the front of the analyzer to release the printer.

  The printer is held in position at the back by 2 hooks.
- 4. Pull the printer forward.
- 5. Raise the printer to release it from the hooks.

Figure 5-11: Remove the Printer



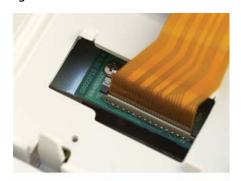
- 1. Clip
- 2. Hooks

The printer is connected to the analyzer through a flat 29-pin interface cable for transfer of data. The cable slides into a connector that snaps down to secure the cable into position.

- 6. Unsnap the connector by lifting up on both sides of the top plate. The plate raises by about 2 mm (1/16 in).
- 7. Gently pull the interface cable from the connector.

  You may need to wiggle the cable slightly to loosen it.

Figure 5-12: Remove the Interface Cable





#### Install the New Printer

Use the following procedure to install the new printer:

- 1. Set the replacement printer partially into position.
- 2. Slide the interface cable into the narrow slot on the top plate of the connector with the silver pins on the cable facing towards the front of the analyzer.
- 3. Press the cable straight down until it stops again.
- 4. Ensure both sides of the cable are fully inserted.
- 5. Press down on both sides of the connector until it snaps shut.
- Gently pull up on the cable to ensure that it is secured in place.If it pulls out easily, unsnap the connector and repeat steps 3 to 5.
- 7. Place the printer fully into position:
  - a. Lower the back of the printer under the 2 clips.
  - b. Lower the front of the printer.
  - c. Press down firmly until it snaps under the clip at the front.
- 8. Replace the printer shield:
  - a. Place the front of the shield into the cavity at the front of the printer.
  - b. Press down firmly until the printer shield snaps into place.
- 9. Reconnect the power cord.
- 10. Turn analyzer power on.
- 11. Replace the roll of paper. See Changing the Paper, page 58.
- 12. Test the new printer.

Print the analyzer setup parameters or perform several urine strip tests.

**Note** If you turned the internal printer off prior to replacement, turn it back on. If Printer Error displays when attempting to print, check for a tight and proper connection of the interface cable.

## **Calibrating the Touch Screen**

Calibrate the touch screen if it does not respond correctly when a key is touched:

- 1. Turn analyzer power off.
- Wait several seconds.
- 3. Turn analyzer power on.
- 4. When the title screen displays, touch the screen anywhere.

  The display prompts Touch the top left corner and an X displays in the corner.
- 5. Touch the screen at the center of the X.
- 6. Repeat when the prompt changes to Touch the bottom right corner.

When the touch screen is calibrated, the display automatically continues in the normal sequence of screens.

# 6 Troubleshooting

### **General Information**

If an operational or analyzer problem occurs, an error number may display on the analyzer screen with an explanation of the problem. This section of the guide lists the various errors and messages, along with probable causes and corrective actions. If the problem persists, record the error number being displayed and contact your local technical service provider for assistance.

If you think Siemens Reagent Strips for Urinalysis are causing the problem, consult the product insert that comes with the urine strips for troubleshooting information.

If you turn the analyzer off, you must retest all samples in process when the error occurs. The normal end-of-run reports for samples processed prior to the error display when the analyzer is turned back on.

With some errors, the analyzer continues to run while the error displays. Select **Return to Ready/Run** to return to the Ready/Run screen before attempting to correct the error. If another error occurs while the previous error is being displayed, the new error displays in its place.

# Removing a Jammed Test Strip

Use this procedure if a strip becomes jammed under the readhead to the extent that movement of the strips is prevented.

- Select Stop Run to stop the run and return to the Ready/Run screen.
- 2. To determine the specimen(s) to retest, record the information provided on the Results Error Report.
- 3. Turn analyzer power off.
- 4. Remove the push bar. See *Performing the Daily Cleaning*, page 49.
- 5. Remove the fixed platform by pulling the entire assembly towards you.

Figure 6-1: Remove the Fixed Platform



- 6. Remove the holddown plate from the fixed platform. See *Performing the Daily Cleaning*, page 49.
- 7. Remove the jammed strip.
- 8. Reinstall the holddown plate. See *Performing the Daily Cleaning*, page 49.
- 9. Reinstall the fixed platform. See *Performing the Daily Cleaning*, page 49.
- 10. Reinstall the push bar. See Performing the Daily Cleaning, page 49.
- 11. Turn analyzer power on.
- 12. Rerun the specimen(s) without results.

# Reinstalling the Fixed Platform

If you turn the analyzer off during a run, or at any screen other than the Ready/Run screen, the moving table may not be in its lowest position. If you then remove the fixed platform, the moving table is pulled out at the same time. You cannot reinstall the fixed platform because the pins of the moving table are in the way.

Use the following procedure to resolve this problem:

1. Turn analyzer power on.

- 2. Let the analyzer initialize.
  - An error displays because the fixed platform is not in place, but the moving table is rotated into the correct position.
- 3. Turn analyzer power off.
- 4. Install the fixed platform. See *Performing the Daily Cleaning*, page 49.
- 5. Turn analyzer power on.

# **Errors and Corrective Actions**

Symptom	Possible Cause	Remedy
Changes made in Setup are not saved	You did not select Return to Ready/Run after making changes.	Always select <b>Return to Ready/Run</b> after making changes in Setup.
Display is blank	No power	<ol> <li>Listen for the fan.</li> <li>If it is not running, turn analyzer power off.</li> <li>Check that the power cord is firmly connected</li> </ol>
		to the analyzer and into a live AC electrical outlet. 4. Turn analyzer power on.
	Defective analyzer electronics	Contact your local technical support provider.
	Improperly inserted memory card when updating software	<ol> <li>Turn analyzer power off.</li> <li>Remove the memory card.</li> </ol>
		<ol> <li>Ensure that the label is facing forward, with the arrows pointing in and up.</li> </ol>
		4. Reinsert it firmly.
		When properly inserted, the edge of the card is flush with the analyzer case.
		5. Turn analyzer power on.

Symptom	Possible Cause	Remedy	
Fixed platform cannot be installed	The moving table is not in the lowest position	<ol> <li>Turn analyzer power on.</li> <li>Let the analyzer initialize.</li> <li>Ignore the error that displays.</li> <li>Turn analyzer power off.</li> <li>Install the fixed platform.</li> <li>Turn analyzer power on.</li> <li>If you are still unable to install the fixed platform, contact your local technical support provider.</li> </ol>	
Printout does not contain all reports	Missing reports are flagged for a Confirmatory Report, and Edit flagged results is On	When the run is complete, review and edit the list of flagged reports. When you exit the End-of-Rur Report screens, the reports are printed.	
Push bar does not move to the right after a strip is placed onto the platform	Other strips are being moved along the platform	Allow up to 7 seconds to elapse prior to movement of the push bar. The time lapse depends upon the timing cycle for movement of the strips across the platform.	
	Strip sensor problem	<ol> <li>Ensure that the run is complete, and the analyzer is at the Ready/Run screen.</li> <li>Turn analyzer power off.</li> <li>Wait several seconds.</li> <li>Turn analyzer power on.</li> <li>If the problem continues, contact your local technical support provider.</li> </ol>	

Symptom	Possible Cause	Remedy
Push bar does not move back to the left after moving a strip	The last strip has been placed in a loadlisted run, or the analyzer is waiting for entry of an ID	The analyzer is functioning properly.  Begin a new loadlisted run after the current run is complete, or enter the ID number being requested.
	A very dark urine is being tested. The strip sensor is unable to verify the presence of the strip until it reaches the first readhead	Presence of the strip is verified at the first readhead, requiring an additional 3 cycles (21 seconds). The push bar moves back to the left. Continue testing in the normal manner.
Push bar moves to the right when a strip has not been placed on the platform	The strip sensor was accidentally triggered by a hand, sleeve, or other foreign object	<ol> <li>The push bar moves back to the left after 3 cycles (21 seconds).</li> <li>Continue testing in the normal manner.</li> <li>Do not place your hand or other objects on the strip loading station.         These can be mistaken for a urine strip.     </li> </ol>

Symptom	Possible Cause	Remedy
	Strip sensor problem	Ensure that the run is complete, and the analyzer is at the Ready/Run screen.
		2. Ensure that the strip loading station is clear of all strips and foreign objects.
		3. Turn analyzer power off.
		4. Wait several seconds.
		5. Turn analyzer power on.
		<ol> <li>If the problem continues, contact your local technical support provider.</li> </ol>
Test results are not being printed by the internal printer.	Internal printer is set to off	Set the internal printer to On through the Setup Routine.
	No paper installed in printer	Install a new roll of paper.
	Paper is misfed, accompanied by an unusual noise	<ol> <li>Open the printer cover and check the paper path.</li> </ol>
		2. Reinstall if necessary.
	The print head is not latched correctly	Latch the printhead.
	Loose electrical connection to the printer	Carefully remove and reinstall the interface cable to the printer.
	Defective printer	<ol> <li>Run the Printer test.</li> <li>Contact your local technical support provider if it does not print correctly.</li> </ol>

Symptom	Possible Cause	Remedy
Touch screen does not respond correctly	Screen needs recalibrating	Recalibrate.
	Defective screen	Contact your local technical support provider.
Loadlist will not transfer from host computer or Laboratory/ Hospital Information System	The loadlist contains other data as well as IDs	Ensure that the loadlist contains only IDs.
	The data for transfer has less than 1 ID or more than 200 IDs	Ensure that the loadlist has at least 1, and no more than 200 IDs.
	The list contains an ID that has more than 13 characters	Ensure that the loadlist contains no IDs with more than 13 characters.
	The data includes characters that cannot be transferred. The characters that can be transferred are those within ASCII code range 0032 to 0126, with the exception of these characters: & \^	Ensure that the loadlist uses only characters that can be transferred.
	A run is in progress or the analyzer is not displaying the Ready/Run screen when the loadlist is downloaded	Allow all tests in the current run to complete and the analyzer to return to the Ready/Run screen.

Symptom	Possible Cause	Remedy	
	A loadlist has already been downloaded and not all tests have been run	Complete all tests on the current loadlist before transferring another loadlist. When the problem that caused the loadlist to fail is removed, send the loadlist to the analyzer.	
Error 01 Error 02 Error 03 Error 04 Error 05	Analyzer optical error	<ol> <li>Turn analyzer power off.</li> <li>Wait several seconds.</li> <li>Turn analyzer power on.</li> </ol>	
Error 06-2	A urine strip detected at the first readhead is not detected at the second readhead	<ol> <li>Select Return to         Ready/Run to cancel the         run and return to the         Ready/Run screen.</li> <li>Turn analyzer power off.</li> <li>Remove the fixed         platform to locate the         strip.</li> </ol>	
		<ol> <li>Check the pins on the moving table to ensure that none are bent or broken.</li> </ol>	
		5. Perform the Performing the Daily Cleaning, page 49.	
		6. Check your printout of results, or the Results Error Report to determine the specimen(s) for which no results exist.	
		7. Retest those specimens.	

Symptom	Possible Cause	Remedy
Error 07-1	A urine strip either is not fully wetted or is upside-down on the platform	1. If the strip is upside- down, remove and clean the push bar, the fixed platform, and the holddown plate.
		<ol> <li>Check your printout of results, or the Results Error Report, to determine the specimen(s) for which no results exist.</li> </ol>
		3. Retest those specimens.  Ensure that the strip is dipped completely into the specimen and is placed onto the platform with the pads facing up.

Symptom	Possible Cause	Rei	medy
Error 08-n Error 09-n	A urine strip has become misaligned	1.	Check the right side of the read station area.
	during processing	2.	Remove any strips that have not fallen into the waste bin.
		3.	Check your printout of results, or the Results Error Report, to determine the specimen(s) for which no results exist.
		4.	Retest those specimens.
		5.	Ensure that the end of the strips are placed against the back wall of the platform, and are not touching the bottom of the strip loading station.
		6.	If the error repeats, remove and clean the moving table, the fixed platform, the push bar, and holddown plate.
		7.	Check the moving table to ensure that no pins are bent or broken.
		8.	Reinstall the parts.
		9.	Ensure that the fixed platform is fully pushed in on both sides.

Symptom	Possible Cause	Rer	medy
Error 10-n	Analyzer optical error	1.	Turn analyzer power off.
		2.	Remove and clean the fixed platform.
			Use care when cleaning the calibration bars.
		3.	Check your printout of results, or the Results Error Report, to determine the specimen(s) for which no results exist.
		4.	Retest those specimens.
Error 20-2	Strip type mismatch The system does not recognize the strip type. Improper dipping technique may generate this error.  Note Extremely dark colored or highly positive samples or controls may also generate this error.	5.	Retest the sample using a strip listed in the Chapter 8, System Configuration. Use proper dipping technique, as described in Testing Routine Specimens, page 25.
Error 21	Internal memory error	1. 2.	Turn analyzer power off. Wait several seconds.
		3.	Turn analyzer power on.

Symptom	Possible Cause	Re	medy
Error 23	Moving table is misaligned	1. 2.	Turn analyzer power off. Remove the push bar, the fixed platform, and the moving table.
			You may have to pull firmly to remove these items.
		3. 4.	Turn analyzer power on. Allow the analyzer to reinitialize and the table mechanism to move to its lowest position. Another error displays.
		5. 6.	Turn analyzer power off. Reinstall the moving
			table.
		7.	Ensure it is pushed in completely.
		8.	Reinstall the fixed platform, and push bar.
		9.	Turn analyzer power on.
	Analyzer mechanical error		ntact your local technical oport provider.
Error 24	Fixed platform is	1.	Turn analyzer power off.
Error 25	misaligned or push bar is misaligned or upside down	2.	Inspect the analyzer for any obvious signs of misalignment or incorrect installation of the push bar, the fixed platform, or the holddown plate.
		3.	Remove and reinstall, if needed.
		4.	Ensure the feet on the push bar are on the bottom, nearest the platform.
		5.	Turn analyzer power on.

Symptom	Possible Cause	Remedy	
	Analyzer mechanical error	Contact your local technical support provider.	
Error 26	Fixed platform is missing or not installed properly	<ol> <li>Install the moving table and the fixed platform, if missing.</li> </ol>	
		<ol> <li>If already installed, carefully push in on the sides of the platform to make sure it is fully engaged.</li> </ol>	
		<ol><li>If the error continues, remove and reinstall the fixed platform.</li></ol>	
Error 27	Holddown plate is improperly installed or	<ol> <li>Remove the fixed platform.</li> </ol>	
	missing, or is dirty	2. Install the holddown plate if missing, or clean it if it appears dirty.	
		3. Reinstall the holddown plate.	
		4. Ensure that it is properly installed.	
		<ol><li>Reinstall the fixed platform.</li></ol>	
		<ol> <li>If the holddown plate appears damaged or discolored, replace with a new holddown plate.</li> </ol>	
		7. Check your printout of results, or the Results Error Report displayed at the end of the run, to determine the specimen(s) for which no results exist.	
		8. Retest those specimens.	

Symptom	Possible Cause	Remedy
Error 28	A urine strip that was detected as being placed on the platform was not detected at the first readhead	If a strip was never placed or was removed after being placed:  1. Check your printout of results, or the Results Error Report displayed at the end of the run, to determine the specimen(s) for which no results exist.
		2. Retest those specimens.
		3. Do not place your hand or other objects on the strip loading station.  These can be mistaken for a urine strip.
		If the error occurs repeatedly:
		<ol> <li>Turn analyzer power off.</li> <li>Wait several seconds</li> <li>Turn analyzer power on.         This will recalibrate the strip sensor.     </li> </ol>
		If a strip was present:
		Remove and clean the moving table, fixed platform, and the holddown plate.
Error 29	Shipping foam is still in place. This occurs the first time the analyzer is powered on. It is accompanied by a loud noise.	<ol> <li>Turn analyzer power off.</li> <li>Remove the foam.</li> <li>Turn analyzer power on.</li> </ol>

	- "I - "		
Symptom	Possible Cause	Rer	nedy
	Calibration bar error	1.	Turn analyzer power off.
		2.	Remove the fixed
			platform.
		3.	Inspect the calibration
			bars for damage or
			misalignment.
		4.	Clean the platform and calibration bars.
		5.	Reinstall the fixed platform.
		6.	Turn analyzer power on.
Error 30	Analyzer mechanical	Cor	ntact your local technical
Error 31	error	support provider.	
Error 34			
Error 36	Both areas of analyzer	1.	Turn analyzer power off.
	memory where factory calibration parameters are stored are corrupt	2.	Wait several seconds.
		3.	Turn analyzer power on.
		4.	If the error repeats, contact your local
			technical support provider.
Error 37	Touch screen calibration error	1.	Follow the instructions on the display to calibrate the touch screen.
		If th	ne error repeats:
		1.	Turn analyzer power off.
		2.	Contact your local
			technical support
			provider.

Symptom	Possible Cause	Remedy
Error 40	The Laboratory Information System (LIS) is attempting to send a load list to the analyzer that does not match the format outlined in the CLINITEK Advantus Interface Specification (CLINITEK Advantus V3.10 and Higher). Causes for this error include:  • The load list contains an invalid character. Use an ASCII code range 0032 to 0126 excepting these characters: &\^  • The load list contains more than 200 records.  • The load list contains less than 1 record. • A Patient ID in the load list contains only space characters. A Patient ID in the load list contains more than 13 characters	<ol> <li>Make sure the load list complies with the format outlined in the CLINITEK Advantus Interface Specification (CLINITEK Advantus V3.10 and Higher).</li> <li>Resend the load list.</li> </ol>

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Symptom	Possible Cause	Remedy
Error 40-2	The strip was exposed to excessive humidity.  Note Extremely dark colored or highly positive samples or controls may also generate this error.	Retest the sample using a new strip. If the issue is not resolved, open a new bottle of strips.
Error 41	The LIS or HIS is attempting to download a load list to the analyzer and the analyzer is not at the Ready/Run screen.	<ol> <li>Return the analyzer to the Ready/Run screen.</li> <li>Resend the load list.</li> </ol>
Error 42 Error 43	The analyzer's print memory is almost full. Error 42 displays when using an internal printer. Error 43 displays when using an external printer.	<ol> <li>For internal printer:</li> <li>Ensure the printer is set to ON</li> <li>Ensure the internal printer has paper</li> <li>Check the printer flex cable connection</li> <li>For external printer:</li> <li>Ensure the printer power is on</li> <li>Ensure the printer has paper</li> <li>Ensure cable connections are secure</li> <li>Replace the printer or connect to a different printer</li> <li>If the issue cannot be resolved, contact your local technical service representative.</li> </ol>

Symptom	Possible Cause	Remedy
Error 44 Error 45	The analyzer's LIS transfer memory is almost full. Error 44 displays when the analyzer is connected to an LIS with a serial port. Error 45 displays the analyzer is connected to an LIS through an Ethernet port.	<ol> <li>Ensure the host PC or LIS/HIS power is on</li> <li>Ensure cable connections are secure</li> </ol>
Error 46 Error 47	The analyzer's print memory is full. Error 46/47 only display after E42/43 errors are reported and not resolved. Testing cannot continue until you print the results. Error 46 displays when using an internal printer. Error 47 displays when using an external printer.	<ol> <li>For internal printer:</li> <li>Ensure the printer is set to ON</li> <li>Ensure the internal printer has paper</li> <li>Check the printer flex cable connection</li> <li>Ensure the printer</li> <li>Ensure the printer power is on</li> <li>Ensure the printer has paper</li> <li>Ensure cable connections are secure</li> <li>Replace the printer or connect to a different printer</li> <li>If the issue can not be resolved, contact your local technical service representative.</li> </ol>

Symptom	Possible Cause	Remedy
Error 48 Error 49	The analyzer's LIS transfer memory is almost full. These errors will only be displayed after E44/45 errors are reported and not resolved. With Errors 48/49, patient testing cannot continue until you download the results. Error 48 displays when the analyzer uses a serial port.  Error 49 displays when using an Ethernet port	1. Ensure the host PC or LIS/HIS power is on 2. Ensure cable connections are secure  If the issue can not be resolved, contact your local technical service representative
Error 50	Printer Error	<ol> <li>Ensure that the external printer is turned on and is online.</li> <li>Verify that both ends of the interface cable are securely connected.</li> <li>Check that the printer has paper.</li> </ol>
Error 50-2	The strip being tested may not be a Siemens brand strip. Improper dipping technique may generate this error.  Note Extremely dark colored or highly positive samples or controls may also generate this error.	<ol> <li>Retest the sample using a Siemens brand urine strip listed in Chapter 8, System Configuration.</li> <li>Use proper dipping technique, as described in Testing Routine Specimens, page 25.</li> </ol>

Symptom	Possible Cause	Remedy
Error 51 Error 52	Quality control results memory (51) or sample results memory (52) is almost full	Nearly 200 quality control result sets or nearly 500 patient result sets are stored in memory and have not been transferred to a computer.  1. Ensure that the computer is turned on.  2. Ensure that the interface cable is securely connected at both ends  3. Ensure that the setup parameters for the computer interface are correct.  4. Transfer at least some of the records.  5. If unable to transfer records, contact your local technical support provider.
Error 53 Error 54	The analyzer's memory has reached the maximum storage of 200 quality control results or 500 patient results, and the LIS or printer is not available. Testing cannot continue until you transfer or delete the results.  Error 53 displays when the analyzer's quality control memory is full.  Error 54 displays when the analyzer's patient memory is full.	<ol> <li>Ensure the host PC or LIS/HIS power is on</li> <li>Ensure cable connections are secure</li> <li>If the issue can not be resolved, contact your local technical service representative.</li> </ol>

Symptom	Possible Cause	Re	medy
Error 55	Both areas of analyzer memory where the Setup parameters are	1.	Print a Setup report to view the default parameters.
	stored are corrupt. The manufacturer's defaults were restored.	2.	If you previously printed and saved a copy of the Setup report of your customized selections, compare the 2 reports.
		3.	Reselect the options that need to change.
Error 56-n	Analyzer error	1.	Turn analyzer power off.
		2.	Wait several seconds.
		3.	Turn analyzer power on.
		4.	If the error repeats, contact your local technical support provider.

# 7 File Management

The analyzer stores the operating parameters, including those selected by the user, and up to 500 patient results and 200 quality control results. The analyzer automatically overwrites the oldest results when it exceeds capacity.

If you connect the analyzer to a computer, it automatically transfers results at the end of a run. See Section 8, *System Configuration* for information on connecting to a computer.

If your analyzer is connected to a computer, or if you accidentally set Computer port to Computer port, Ethernet port, or Both, the computer expects an acknowledgement after it attempts to send results. If it does not receive the acknowledgement, it continues to hold results in memory instead of overwriting them. The analyzer generates an error when the memory nears capacity. See Section 6, *Troubleshooting* for error message details, and suggested corrective actions.

# 8 System Configuration

## Installation

### Overview

This section provides detailed installation instructions for the CLINITEK Advantus analyzer. You must follow the installation steps correctly to ensure proper installation, operation, and service.



### **CAUTION**

Do not drop the analyzer or handle it roughly. This can disturb internal calibrated optics and electronics or cause other damage. Always handle the analyzer with care. The CLINITEK Advantus analyzer is a precision instrument and must be handled accordingly.

Place the analyzer where it will not be subjected to extreme temperature variations. Avoid proximity to open windows, direct sunlight, ovens, hot plates, open burners, radiators, and dry ice baths.

Do not place it on the same bench as a source of vibration, such as a centrifuge.

The CLINITEK Advantus analyzer should not be used in an explosive atmosphere.

The bench space should be large enough to allow free air circulation around the analyzer (7.6 cm/3 inches on all sides).

## **Unpacking the Analyzer**

Your CLINITEK Advantus analyzer is delivered in one shipping carton:

- 1. Carefully remove the contents of the shipping carton.
- 2. Inspect the carton and analyzer for visible signs of damage.
- 3. If damage to the analyzer exists, immediately file a complaint with the carrier.
- 4. Make sure all items are included with your analyzer, and keep them for future use.
  - Fixed platform and holddown plate

- 2 Push bars
- Moving table
- Quality Package of printed documents
- Box of 5 waste bin liners
- Roll of printer paper
- 2 Power cords
- Operator's Guide CD

Figure 8-1: Instrument Parts



- 1. Fixed platform and holddown plate
- 2. Push bar
- 3. Moving table
- 5. Retain the CLINITEK Advantus shipping carton and packing for several weeks.

If you need to ship the analyzer, the shipping carton affords the best protection against damage.

- 6. Place the analyzer on a firm, level work surface in the designated work area.
- 7. Ensure that the analyzer is level, and that the back and sides of the analyzer are at least 7.6 cm (3 in) from any adjacent wall or analyzer.
- 8. Locate the piece of foam packing that is under the read area cover.

  The foam has a red tag attached.
- 9. Remove the foam by gently pulling the red tag down and forward.

Figure 8-2: Remove the Foam



## Installing the Analyzer

## **Record the Warranty Information**

1. Locate the serial number.

The serial number is found inside the analyzer near the front left corner.

Figure 8-3: Locate the Serial Number.



#### 1. Serial number

- 2. Print the *Pre-service Checklist*, page 143, and the *Warranty Information*, page 141.
- 3. Write the installation date and serial number in the spaces provided in the *Pre-service Checklist*, page 143, and on the *Warranty Information*, page 141.
- 4. Contact your Siemens representative for your warranty information if this page is not included in your guide.

## **Install the Moving Table**

- 1. Hold the table with the small rectangular tab facing to the back.
- 2. Align the 2 grooves on the bottom of the table with the edges of the platform on which the table rests.
- 3. Gently push the table in until you hear the tab latch into the hold position.
- 4. Check that the table is secure.

Figure 8-4: Install the Moving Table



### Install the Holddown Plate

- 1. Position the holddown plate with the arrow side facing up and the arrow pointing to the back.
- 2. Place the pin on the front of the holddown plate into the hole at the front of the fixed platform.
- 3. Align the tab at the back of the holddown plate with the slot at the back of the platform.
- 4. Snap the holddown plate into place. Listen for a loud click, indicating proper installation.
- 5. Ensure that the white calibration bars are visible.

Figure 8-5: Install the Holddown Plate



#### 1. Tab

#### Install the Fixed Platform

1. Align the 2 grooves on the bottom of the fixed platform with the arms extending forward from the analyzer.

The flanges on the sides of the holddown plate align just outside the read area cover. The top edge of the platform aligns just under the cover.

2. Gently push the platform in as far as possible.

Push past the ridge to correctly position the platform.



### CAUTION

Do not force the platform. Ensure that the moving table is correctly positioned before you attempt to reinstall the fixed platform. If you force the platform, you may damage the moving table or fixed platform.

During the initial installation, you may need to use firm pressure to push the platform the final 1.3 cm (0.5 in). The platform must be seated, and not even slightly crooked or the strips may jam as they are pushed along the platform.

Figure 8-6: Install the Fixed Platform



### Install the Push Bar

- 1. Hold the push bar at the indented end.
- 2. With this end slightly upward, insert the peg on the other end of the bar into the hole in the pusher mechanism.
- 3. Lower the push bar into place.

Figure 8-7: Install the Push Bar



### Install the Waste Bin Liner

- 1. Take a waste bin liner from the pack delivered with the analyzer.
- 2. Place the liner into the waste bin.

Figure 8-8: Install the Waste Bin Liner



## **Installing Connections**

Figure 8-9: Analyzer Connections



- 1. Keyboard and barcode reader interface connector
- 2. Printer interface connector
- 3. Serial interface connector

- 4. Ethernet interface connector
- 5. Line cord receptacle

### **Connect the Analyzer Power**

- 1. Ensure that the analyzer power switch is in the off position.
- 2. Select the correct power cord for your use.
  - Two power cords are packed with the analyzer.
- 3. Connect the power cord to the analyzer and to an appropriate, grounded AC electrical outlet.
- 4. Dispose of the other power cord.

#### Connect to a Printer

You can use most 80-column, continuous feed printers or the CLINITEK Form Printer with the CLINITEK Advantus analyzer.

Some printers include an interface cable that can connect to the printer port on the back of the analyzer. If not, you need to obtain the cable separately. See *Appendix F*, *Computer and Printer Interface*, for the pin specifications for the male connector. The requirements for the other end of the cable depend on the printer. Appropriate cables are available at most retail computer stores.

- 1. Connect the appropriate end of the interface cable to the 25-pin printer port on the CLINITEK Advantus analyzer.
- 2. Connect the other end to the printer.
- 3. Carefully read the operator's guide that accompanies the printer and become familiar with its operation before using.

## Connect to a Computer

You can connect the CLINITEK Advantus analyzer to a host computer or LIS (Laboratory Information System) via the serial port and a null modem cable, or via an ethernet cable. See *Appendix F, Computer and Printer Interface* for cable requirements for interfacing to a computer.

## **Connecting Through the Serial Port**

1. Connect the appropriate end of the interface cable to the 9-pin computer port on the back of the CLINITEK Advantus analyzer.

2. Connect the other end of the cable to the appropriate port on the computer, following the instructions given with the computer.

### **Connecting Through the Ethernet Port**

- 1. Connect the appropriate end of the interface cable to the ethernet port on the back of the CLINITEK Advantus analyzer.
- 2. Connect the other end of the cable to the appropriate port on the computer, following the instructions given with the computer.

### Connect to a Computer Keyboard

You can use any US QWERTY keyboard with a PS2 connection with the CLINITEK Advantus analyzer. Connect the appropriate end of the keyboard cable to the keyboard port.

#### Connect to a Barcode Reader

A handheld barcode reader is available for use with the CLINITEK Advantus Urinalysis analyzer. Connect it through the PS2 barcode reader port on the back of the analyzer. See *Appendix E*, *Barcode Reader*.

## Installing the Barcode Reader Bracket

A barcode reader bracket is supplied with the barcode reader. See *Appendix E, Barcode Reader*, for instructions on fixing the bracket to the analyzer.

## **Installing a Roll of Printer Paper**

Install a roll of printer paper and re-install the printer cover. See *Changing the Paper*, page 58.

## **Performing the Initial Analyzer Check**

After the CLINITEK Advantus analyzer is properly installed, perform the following initial analyzer check. If problems occur during this procedure or if an error message displays, see Section 6, *Troubleshooting*.

1. Turn analyzer power on.

The push bar moves and the display shows the analyzer name and a series of dots while the analyzer initializes. The title screen then displays, showing the software version numbers, along with the analyzer name and copyright information. The analyzer then performs some internal checks and procedures. Each check and its status displays while the testing is in progress.

2. Verify that the fan is on by checking for airflow from the analyzer.

The fan is located at the top left at the back of the analyzer.

**Note** If an error occurs, a message displays that instructs you to turn the power off and back on after several seconds, or to contact Siemens Customer Support.

The display changes to the Ready/Run screen.

The screen displays the default setting for the primary urine strip for use on the analyzer.

3. If you want to enter strip lot information, check that the primary and alternate Siemens Reagent Strips for Urinalysis displayed corresponds to the strip types you are using. If the strip types do not agree, change the selected strip type.

See *Strip*, page 111, for instructions on changing the strip type used on your analyzer.



### **CAUTION**

Only use Siemens brand urine strips. Use of other strips may cause erroneous results.

4. Completely immerse all of the reagent pads on a Siemens Reagent Strip for Urinalysis in negative control solution, such as Chek-Stix Negative Control solution.

- 5. Immediately remove the urine strip.
- 6. While removing the strip, run the edge against the side of the container.

This removes excess liquid.



### **CAUTION**

Do not blot the edge of the strip. This could affect results.

7. Place the urine strip onto the supports of the strip loading station, with the reagent pads facing up.

Place the strip to the right of and parallel to the push bar. Ensure that the end of the strip is against the back wall of the platform and that it is not touching the bottom of the strip loading station.



### CAUTION

Improper placement may cause the analyzer to jam or the strip to incorrectly align under the readheads.

The push bar moves almost immediately, pushing the strip into the read area. Most of the keys on the display become inactive.

Figure 8-10: Placement of Urine Strip



After the strip is read, the internal printer prints the test results. The analyzer produces a result for each reagent pad that is within the limits given in the package insert for the control solution.

8. If the analyzer does not perform as expected, or if the printed results do not agree with the expected values, see Section 6, *Troubleshooting*.

With satisfactory completion of the initial analyzer check, the CLINITEK Advantus analyzer is ready for routine testing.

- 9. At the Ready/Run screen, select Menu.
- 10. Select **Setup**.
- 11. Use the information in *Setup Information* to customize the software for your laboratory.

# **Setup Information**

Use Set Options to customize the analyzer for use in your laboratory.

- 1. At the Ready/Run screen, select Menu.
- 2. Select **Setup** to display the first setup options menu.

Memory may be erased if a change is made to any of several Setup options. All results and loadlisted ID numbers stored in memory are deleted when the change is made. A warning screen displays first, and you are given the option of not making the change to the Setup option, saving the stored results and numbers.

Ensure all patient and QC results are printed or transferred and that a loadlist is not stored in memory before making the changes.

## Setup Menu 1

Use the first Setup menu to change the date and time, turn the computer port on or off, set printer options, and adjust the display contrast.

Menu Options	Default
Date	N/A (current)
Time	N/A (current)
Computer port	Off
Printer	Internal: On, 2 blank lines between patient results
	External: Off
Display contrast	N/A

Select the key symbol that displays next to the option to change the option. Each option is described below.

#### Date

Use this option to set the current date.

You can change the Date Format and Separator using Setup Menu 3.

### Select Date.

The display changes to show the current date and the numeric keypad.

2. Enter the date.

Select the **Move Left** and **Move Right** keys to move the cursor to the digit to change and enter the correct number.

The message changes as you move from 1 part of the date to the next, showing the prompts **Enter day**, **Enter month**, or **Enter year**. Enter the date in the order shown on the prompts. Enter the leading 0 where needed.

3. Select Enter.

#### Time

Use this option to set the current time.

You can change the Time Format and Separator using Setup Menu 3.

1. Select **Time**.

The display changes to show the current time and the numeric keypad.

2. Enter the time.

Select the **Move Left** and **Move Right** keys to move the cursor to the digit to change and enter the correct number.

The message changes as you move from 1 part of the time to the next, showing the prompts **Enter hour** and **Enter minutes**. Enter the leading 0 where needed.

3. If the time format is 12 Hour, select the **AM/PM** cycle key to set the time to AM or PM.

The AM/PM cycle key is only active if the time format is 12 Hour.

4. Select Enter.

### **Computer Port**

Use the **Computer port** cycle key to set the computer port.

То	Select
use no computer	Off
transfer selected results to a	Computer port
computer	Ethernet port
	Both

The specifications for the computer port are selected using Setup Menu 8.

#### Printer

Select **Printer** to set several printer options.

### Internal

The internal printer is used to print patient results.

Use the **Internal** cycle key to set the internal printer.

То	Select
stop the internal printer	Off
turn the printer on	On, 2 blank lines between patient result sets
	On, 6 blank lines between patient result sets
	On, 12 blank lines between patient result sets

**Note** QC result sets are always separated by 2 blank lines.

#### **Custom Header**

Use this procedure to set the custom report header.

If you select 12 blank lines between patient result sets for the internal printer, it prints a header at the end of each printed report. The default header is MICROSCOPICS. You can customize the header or set it to contain all blanks if you do not want a header.

- Select Custom header.
- Enter up to 24 letters and spaces.
   Use Move Left to erase any existing text.
- 3. Select Enter.

#### **External**

You can attach and configure an external printer. This printer can be a form or 80-column, continuous-page printer.

Use the **External** cycle key to set an external printer.

To Use	Select
No external printer	Off
80-column printer	On, 80 column
Printer Products Form Printer,	On, Form printer 1
80-column printer printing single record on each page	
CLINITEK Form Printer <sup>a</sup>	On, Form printer 2
Star Form Printer	On, Form printer 3

a. If you are using the CLINITEK Form Printer, set the Mode Switches on the printer to Computer (both DS1-1 and DS1-2 switches down).

If necessary, use this procedure to determine which form printer to select.

- 1. Print a record using each option.
- 2. Select the 1 that provides the best placement of the printed results on the form and that works appropriately with your form printer.
  - See *Appendix F*, *Computer and Printer Interface*, for additional information on the 3 formats.
- 3. Select Enter.

## **Display Contrast**

Use this procedure to adjust the contrast of the analyzer display.

1. Select **Display contrast**.

- 2. Use the + and keys to increase or decrease the contrast.
- 3. Select **Previous Screen** to confirm the setting and return to the first Setup menu.

## Setup Menu 2

Use the second Setup menu to select the Language, Result Units, and Test Strips.

- 1. At the first Setup menu, select **Next Screen** to access the second Setup menu.
- 2. If password protection is set, enter the password.
- Select Enter.

Menu Option	Default
Language	English
Result units	Conventional
Plus system	Off
Strip	MULTISTIX 10 SG
Alternate strip	None

## Language

Use the **Language** cycle key to select the language for the user interface. All screens display in the language selected.

Key	Options
Language	English
	Français
	Deutsch
	Italiano
	Kanji (Japanese)
	Español
	Português
	Chinese
	Svenska

The default selection for several other options may change, depending upon the language selected. For example, the date and time formats, strip and alternate strip names, and reporting of color.

#### **Result Units**

Several of the languages have options for the units in which results display. See *Tables of Results*, page 151 for the results that display and print for each option. As with Language, the default selection for several other options may change, depending upon the result units selected.

Use the **Result units** cycle key to set the Result Units.

Key	Options
Result units	Conventional
	S.I. <sup>a</sup>
	Nordic <sup>b</sup>
	JCCLS <sup>c</sup>

- a. Not available in Japanese
- b. English and Swedish only
- c. Japanese only

## Plus System

Use the **Plus system** cycle key to display and print results in the Plus system, which uses **+** symbols, rather than in clinical units, such as mg/dL.

Key	Options
Plus system	Off
	On

## Strip

Siemens urine strips have identification (ID) bands, which can be white or colored. When using these strips, this procedure is not required unless you want to identify strip lot information.

Many configurations of Siemens Reagent Strips for Urinalysis are available for the CLINITEK Advantus analyzer. However, not all configurations are available in every country.

Use the **Strip** cycle key to select the primary test strip.

If you are entering strip lot information, ensure the urine strip selected agrees with the name of the Siemens Reagent Strip for Urinalysis used as the primary urine strip on the analyzer.

Key	Options
Strip <sup>a</sup>	MULTISTIX 10 SG (default) <sup>b</sup>
	MULTISTIX 9 SG
	MULTISTIX 8 SG <sup>b</sup>
	MULTISTIX SG
	MULTISTIX SG L
	MULTISTIX
	NEPHROSTIX L
	URO-HEMA-COMBISTIX SG L
	URO-LABSTIX SG L
	MULTISTIX 9
	URO-HEMA-COMBISTIX
	HEMA-COMBISTIX-LONG
	URO-LABSTIX
	LIFESTIX
	MULTISTIX PRO 11 <sup>b</sup>
	MULTISTIX PRO 10LS <sup>b</sup>
	N-MULTISTIX SG L
	CLINITEK MICROALBUMIN 9 <sup>b</sup>

- a. Not all urine strips are available in all countries.
- b. Alternate strip option available only when one of these strip configurations is selected as a Primary strip.

**Note** In some geographies, the Multistix GP urine strip is also available for use on the CLINITEK Advantus system. This strip is auto-detected by the instrument, and strip lot information is not entered for this strip.

**Note** The Japanese version of the CLINITEK Advantus software includes an Auto ID setting. Alternate strip selection is not available when primary strip selection is set to Auto ID, and no strip lot information is printed or sent to the LIS.

#### **Alternate Strip**

When testing patient samples, you can select the alternate urine strip type without re-accessing the Setup menu.

Use the **Alternate strip** cycle key to select the alternate urine strip. This feature is available only with select Primary strip configurations.

Choose different primary and alternate urine strips to enable switching between tests. When Alternate strip is selected, only a single Alternate strip can be tested. To test additional Alternate strips, you must select Alternate strip for each one.

Siemens urine strips have identification (ID) bands, which can be white or colored. When using these strips, this procedure is not required unless you want to identify strip lot information.

Ensure the urine strip selected agrees with the name of the Siemens Reagent Strip for Urinalysis used as the alternate urine strip.

Key	Options
Alternate strip <sup>a</sup>	None
	MULTISTIX 10 SG
	MULTISTIX 8 SG
	MULTISTIX PRO 11
	MULTISTIX PRO 10LS
	CLINITEK MICROALBUMIN 9

a. Not all urine strips are available in all countries.

# Setup Menu 3

Use the third Setup menu to select the separator and format for the date and time.

At the second Setup menu, select **Next Screen** to access the third Setup menu.

Menu Option	Default
Date format	Month/Day/Year
Date separator	-
Time format	12 Hour
Time separator	:

Use the cycle keys next to each item to select an option.

Key	Options
Date format	Month/Day/Year
	Day/Month/Year
	Year/Month/Day
Date separator	- (default)
	•
	I
Time format	12 Hour
	24 Hour
Time separator	: (default)
	,
	•

## Setup Menu 4

Use the fourth setup menu to select tests to report and their order, mark positives, set positive levels for tests, and set normal ranges for SG, pH, and CRE.

The primary urine strip you selected determines the options available. The analyzer uses the same settings for the alternate urine strip, if they are relevant to the urine strip selected.

At the third Setup menu, select **Next Screen** to access the fourth Setup menu.

Menu Option	Default
Tests to report and their order	N/A
Mark positives	On
Positive levels for tests	N/A
Normal range for SG/pH	N/A
Normal range for CRE	N/A

## **Tests to Report and Order**

The Tests to Report and their Order screen allows you to select any parameter to report. The analyzer reports the results associated with the strip used.

Use this procedure to select the order in which analytes and physical parameters are reported. You can choose not to report a test.

These selections apply only to testing with the primary urine strip. They do not apply when testing with the alternate urine strip. Alternate reagent results are always reported in the default order.

1. Select **Tests to report and their order** to display a series of cycle keys, labeled 1 to 14.

То	Then
retain the existing tests and their order	select <b>Previous Screen</b> .
select tests to report, their order, and the position of color and clarity	<ol> <li>At the first position you want to change, use the cycle key to select a test, color or clarity.</li> <li>Any tests not already listed display first. Then a blank displays and all tests from that position are erased and must be re-entered.</li> <li>As each test is selected, the next test in the list is the first test displayed for the following position.</li> <li>Select a test for each of the remaining positions.</li> <li>When finished, select Previous Screen.</li> </ol>
remove a test from the reporting order	Note If English is the selected language and S.I. is the selected Results units, color is automatically included as the last test. You can also add it manually to the end of the list. You can also choose to include visually determined clarity as a reported result.  Select the tests to report and leave a blank description in the final position.

#### Mark Positives

The analyzer can mark all positive results with an asterisk (\*) in the displayed and printed report, and in the data transferred to a computer.

Use the Mark Positives cycle key to set this option.

То	Select
mark positives	On
leave positives unmarked	Off

**Note** If Mark Positives is Off, you are unable to set several other options.

#### **Positive Levels for Tests**

You can only select this option if Mark Positives is On.

Use this procedure to set the lowest positive result for each chemistry test. The analyzer also uses these levels to determine which specimens meet the criteria for the confirmatory and microscopic reports.

If Mark Positives is On, the analyzer marks positive results with an asterisk (\*) in the displayed and printed report and in the data transferred to a host computer.

#### Select Positive levels for tests.

The display shows the lowest level considered positive for the tests selected in Tests to report.

If Protein is selected as a reported test, the first screen displays different options for Protein:

 Option 1 is for traditional Siemens Reagent Strips for Urinalysis. Option 2 is for all selectable Multistix PRO strips.

The reported results for protein vary slightly, depending upon which group of urine strips is used.

Select the first positive level for each group to change your test strip without changing the first positive level of the protein test.

Glucose and Ketone also have 2 options, for Microalbumin 9 urine strips and for most other strips.

Nitrite is not listed, because it has only one positive level. Also, the PC ratios not listed, because these results already include a description of Normal or Abnormal.

- 2. Use the cycle key to set the level for each test.
- If necessary, select Next Screen to display an additional screen of tests.
- 4. When finished, select **Previous Screen**.

#### Normal Range for SG and pH

You can select this option only if Mark Positives is On, and and either SG or pH is selected on the Tests to report and their order screen.

Use this procedure to set the lower and upper limits of the normal range for SG and pH. Set each limit separately. The upper limit must be higher than or equal to the lower limit.

- 1. Select **Normal range for SG/pH**.
- 2. Select the + or keys next to each limit to raise or lower the limit.

The limit changes by 1 reporting level until it is equal to the opposite limit or is at the highest or lowest reporting level.

Select Previous Screen.

## Normal Range for CRE

You can select this option only if CRE is selected on the Tests to report and their order screen and Mark Positives is On.

Use this procedure to select the lower and upper limits of the normal range for creatinine. The upper limit must be equal to or higher than the lower limit.

- 1. Select Normal range for CRE.
- 2. Select the + or keys next to each limit to raise or lower the limit.

  The number changes by one reporting level until it is equal to the opposite limit or is at the highest or lowest reporting level.
- 3. Select Previous Screen.

## Setup Menu 5

At the fourth Setup menu, select **Next Screen** to access the fifth Setup menu.

Menu Option	Default
Color	Determined by analyzer
Color choices	Yellow, Orange, Red, Green, Blue, Brown, Other
Clarity choices	Clear, SL Cloudy, Cloudy, Turbid, Other
Use default COL/CLA during run	On

#### Color

Use the **Color** cycle key to have the analyzer determine color, or allow visual determination.

То	Select
have the analyzer determine color automatically	Determined by analyzer
enter the color as part of a manually entered loadlist or just before testing each specimen	Entered by tech

**Note** The analyzer can only determine color if the Siemens Reagent Strip for Urinalysis used contains the leukocyte test. Results reported by the analyzer may be different from the color seen visually. This is because of the inherent differences between the human eye and the optical system of the analyzer.

#### **Color Choices**

If the color option is Entered by tech, you can specify up to 7 specimen colors. Use this procedure to customize descriptions and remove defaults from the reporting list.

You can select this option only if COL is selected on the Tests to report and their order screen

- Select Color choices.
- 2. Edit the first 4 default colors.
- 3. Select **Next Screen** to display and edit the last 3 default colors.

The default colors are Yellow, Orange, Red, Green, Blue, Brown, and Other.

4. Remove default options from the reporting list.

The colors included on the list are designated by a check mark.

a. Select the check mark to remove it, and delete the option from the list.

The first option is always selected and cannot be made inactive.

- 5. Change the color description:
  - Select the word describing the color to change the color.
     An alphabetic keypad displays.
  - b. Use the **Move Left** key to erase the existing name.
  - c. Enter the new name.You can use up to 15 letters and spaces.
  - d. Select Enter.
- Select Previous Screen.

## **Clarity Choices**

Clarity is only determined visually. You can specify up to 5 clarity descriptions. Use this procedure to customize descriptions and remove defaults from the reporting list.

You can select this option only if COL is selected on the Tests to report and their order screen.

## 1. Select Clarity choices.

The default clarity descriptions are Clear, SL Cloudy, Cloudy, Turbid, and Other.

2. Remove default options from the reporting list:

The clarity descriptions included on the list are designated by a check mark.

a. Select the check mark to remove it, and delete the option from the list

The first option is always selected and cannot be made inactive.

## 3. Change the clarity description:

a. Select the word describing the clarity to change the description.

An alphabetic keypad displays.

- b. Use the **Move Left** key to erase the existing name.
- c. Enter the new name.

You can use up to 15 letters and spaces.

- d. Select Enter.
- 4. Select Previous Screen.

## Use Default COL/CLA During Run

This option is only available if Color is reported and is Entered by tech, or Clarity is reported.

Use the **Use default COL/CLA during run** cycle key to use a default color and clarity.

То	Select
display no default value	Off
set the first listed value for color and clarity as the default	On

**Note** The reported value can be changed prior to testing the specimen.

## Setup Menu 6

At the fifth Setup menu, select **Next Screen** to access the sixth Setup menu.

Menu Option	Default
Positive levels for COL/CLA	N/A
Flags for confirmatory test A	N/A
Flags for confirmatory test B	N/A
Flags for microscopics	N/A
Set QC options	N/A

#### Positive Levels for COL/CLA

Use this procedure to set the lowest positive result for color and clarity.

The analyzer uses these levels to determine which specimens meet the criteria for the confirmatory and microscopic reports.

If Mark Positives is On, positive results are marked with an asterisk (\*) in the displayed and printed report and in the data transferred to a host computer.

You can select this option only if COL or CLA is selected on the Tests to report and their order screen

#### 1. Select Positive levels for COL/CLA.

The lowest level considered positive for color and clarity displays. The available choices are those set earlier.

- 2. For each setting, use the cycle key to set the first level marked as positive.
  - COL must be selected to change the COL setting
  - CLA must be selected to change the CLA setting

All results later in the list are also marked positive.

3. Select Previous Screen.

#### Flags for Confirmatory Test A

The confirmatory reports list those specimens that may require confirmatory testing. Mark Positives must be On to obtain the reports.

Use this procedure to select up to 5 tests for confirmatory report A.

- 1. Select **Flags for confirmatory test A** to display a list of reported tests.
- 2. Select the box next to the tests to include in the confirmatory report.

A check mark displays in the box.

Select the box again to remove the check mark.

3. Select Previous Screen.

## Flags for Confirmatory Test B

Use this procedure to select up to 5 tests for confirmatory report B. Mark Positives must be On to obtain the reports.

- 1. Select **Flags for confirmatory test B** to display the reported tests not selected for confirmatory report A.
- 2. Select the box next to the tests to include in the confirmatory report.

A check mark displays in the box.

Select the box again to remove the check mark.

3. Select Previous Screen.

## Flags for Microscopics

The microscopic report lists those specimens that may require a microscopic examination. Mark Positives must be On to obtain the report.

Use this procedure to select up to 5 tests for the microscopics report.

- 1. Select **Flags for microscopics** to display a list of reported tests.
- 2. Select the box next to the tests to include in the microscopics report.

A check mark displays in the box.

Select the box again to remove the check mark.

Select Previous Screen.

## **Set QC Options**

You can set the entry of QC expiration information and the QC interval.

1. Select Set QC Options.

#### **Set QC Expiration**

You can enter QC Lot and Expiration information from a computer keyboard, or scan it from a barcoded label using the handheld barcode reader.

**Note** The analyzer requires entry of QC lot information.

Use the **QC expiration date** cycle key to set this option.

То	Select	
disable entry of QC expiration information	Off	
force entry of QC expiration information	On	

#### Set QC Interval

Use this procedure to set prompting for regular QC testing. You can set the interval between QC tests from 1 hour to 99 days.

The QC Reminder displays at the end of the selected QC interval when a test is completed or loadlist testing is complete. You can prevent testing when a QC test is due.

1. Use the cycle key to select a QC option.

То	Select
not set a QC interval	No regular QC test
prompt when a QC test is due	Prompted regular QC test
prevent testing of patient samples when a QC test is due	Compulsory regular QC test

- 2. For Prompted regular QC test or Compulsory regular QC test, enter the interval:
  - Select Set QC interval.
  - b. Use the cycle key to select **Hours** or **Days**.
  - c. Enter the QC interval.
  - d. Select Enter.

## Setup Menu 7

At the sixth Setup menu, select **Next Screen** to access the seventh Setup menu.

Menu Option	Default
Strip lot information	Off
Microscopics setup	N/A
Edit flagged results	Off
Enter sample IDs	Off
Tech ID	Off

## **Enter Strip Lot and Expiration Information**

You can enable or disable entry of Strip Lot and expiration information. The default setting is Disabled.

Lot and expiration information can only be entered for the primary and alternate strip types selected for your analyzer.

Use the **Strip lot information** cycle key to set this option.

То	Select	
disable entry of strip lot and expiration information	Off	
force entry of strip lot and expiration information	On	

## **Microscopics Setup**

Enable entry of microscopics results.

1. Select Microscopics setup.

The display shows where to select 5 headings and their associated units. The sixth selection enables you to enter custom data and units.

2. Use the first 5 cycle keys to select headings and associated units for microscopic results.

Key	Options	
Cycle keys 1 to 5	RBC /μL	PATH CASTS /HPF
	RBC /HPF	PATH CASTS /LPF
	RBC /LPF	CRYSTALS
	WBC /µL	CRYSTALS /HPF
	WBC /HPF	CRYSTALS /LPF
	WBC /LPF	YEAST
	EC /μL	YEAST /HPF
	EC /HPF	YEAST /LPF
	EC /LPF	SPERM
	BACT /µL	SRC
	BACT /HPF	OTHER
	BACT /LPF	TOTAL COUNT
	CASTS /µL	NONE
	CASTS /HPF	
	CASTS /LPF	
	PATH CASTS	

- 3. Select the sixth key on the screen to set custom data and units:
  - a. Enter a custom heading.
  - b. Use the cycle key to set units:

Key	Options
Cycle key 6	/µL
	/HPF
	/LPF
	mS/cm
	NONE

- c. Select Enter.
- 4. When finished, select Previous Screen.

## **Edit Flagged Results**

Use the **Edit flagged results** cycle key to set editing of results that are flagged as positive and selected for confirmatory reports. You can select this option only if Mark Positives is On, and confirmatory flags are set.

То	Select
disable editing	Off
allow editing of confirmatory reports	On

## **Enter Sample IDs**

You can enter specimen identification numbers either as part of a manually entered load list or immediately prior to testing the specimen.

Use the **Enter sample IDs** cycle key to set entry of specimen identification numbers.

То	Select	
disable entry of specimen identification numbers	Off	
force entry of specimen identification numbers	On	

#### Tech ID

Identify the technician performing the tests. The Tech ID displays on the Ready/Run screen, and on QC results only, or on both patient and OC results.

Use the **Tech ID** cycle key to set display of the Tech ID.

То	Select
disable display of the Tech ID	Off
display the Tech ID on QC results	On, control results only
display the Tech ID on QC and patient results	On, both patient and control results

## Setup Menu 8

At the seventh Setup menu, select **Next Screen** to access the eighth Setup menu.

Menu Option	Default
Password for setup	Off
Set or reset password	N/A
Computer port options	N/A
Network settings	N/A
Bar code reader options	N/A

## **Password for Setup**

Use the **Password for setup** cycle key to only allow access to the first Setup menu. The remaining menus are not accessible unless the correct password is entered.

То	Select
allow unrestricted access to all setup menus	Off
require a password to access most setup menus	On

#### Set or Reset Password

Use this procedure to set a personal password or reset an existing password. The analyzer has a default password of 84437, which is always active.

- 1. Select **Set or reset password**.
- 2. Enter up to 6 digits.
- 3. Select Enter.
- 4. When prompted, re-enter the password.

## **Computer Port Options**

Use this procedure to specify the interface parameters used when sending results to a host computer or Laboratory Information System (LIS).

1. Select Computer port options.

## 2. Use the cycle keys to set the first 3 options.

Key	Options
Port	Off
	Computer Port
	Ethernet Port
	Both
Baud	1200
	2400
	4800
	9600
	19200
Data, Parity	8/None
	7/Even
	7/Odd
	7/None

The port must be set to either computer port, ethernet port, or both, to transfer results to a computer.

You can also set the computer port through the first Setup menu. If the port selection changes in 1 menu, it automatically changes in the other menu.

See the specifications accompanying the computer for information on the required parameters for Baud, Data, and Parity.

## 3. Select Output format.

4. Use the cycle keys to set the result format.

Key	Options
Output format	CCS
	CT200+
	CT200
Checksum <sup>a</sup>	On
	Off
Handshake <sup>a</sup>	On
	Off

a. Not available in CCS format.

The CT200+ and CT200 formats transmit 2 stop bits. The CCS format transmits 1 stop bit.

5. Select **CCS** to transmit results in the CLINITEK Advantus format.

The parameters for this format are available from your local technical support provider.

**Note** You must set the computer port to CSS to download loadlists from a computer or LIS.

6. Select **CT200+** or **CT200** to transmit results in the same format as a CLINITEK 200+ or CLINITEK 200 Urine Chemistry Analyzer.

Results are not printed in the selected format.

If you are using a CLINITEK 200+ or CLINITEK 200 analyzer in your laboratory, you must:

- Set identical parameters for CLINITEK Advantus analyzer and the CLINITEK 200 analyzer or CLINITEK 200+ analyzer. This helps ensure that the data is transferred in the same format by all analyzers.
- Use checksum and handshake. See your computer specification for the requirements.

The CT200 format does not support the following strip types:

- Multistix PRO 10 LS
- Multistix PRO 11

Multistix GP

The CT200 format does not support the following strip types:

- Multistix GP
- 7. Select Previous Screen when finished.

## **Network Settings**

Specify network settings to send results to a local computer network.

- 1. Select **Network settings.**
- 2. Use the **IP configuration** cycle key to set the configuration.

То	Select	
use dynamically assigned IP addresses	DHCP	
use a static IP address	Static	

- 3. If you selected Static, enter a static IP address:
  - a. Select IP address.
  - b. Enter the IP address.

The header displays the numbers entered and adds the stop characters in the correct positions.

- c. Select **Enter**.
- 4. If you selected DHCP, specify a DHCP name:
  - a. Select DHCP name.
  - b. Enter a DHCP name of up to 16 letters.
  - c. Select **Enter**.
- 5. To move to the next Network settings menu, select **Next Screen**.

6. If you select IP configuration as **Static**, use the **Subnet mask** cycle key to set the subnet mask number.

Key	Options
Subnet mask	255.255.255.000
	255.255.000.000
	255.000.000.000

7. Use the **Gateway** cycle key to activate a Gateway address.

То	Select
not use a gateway address	No
make the gateway address active	Yes

- 8. If you selected Yes, select Gateway address:
  - a. Enter the gateway address.
     The header displays the numbers entered and adds the stop characters in the correct positions.
  - b. Select Enter.

The correct Mac address displays on the screen.

- To return to the first Network settings menu, select **Previous**Screen.
- 10. Select Previous Screen.

## **Barcode Reader Options**

If you are using the optional handheld barcode reader, use this procedure to set parameters based on the barcoded labels being used.

- Select Bar Code reader options.
- 2. Ensure that the barcode label is readable:
  - Select Test bar code.

The message **Scan bar code label** displays.

- b. Scan a label that is representative of the quality and size being used and for which you know the expected results.
- c. Verify that the information on the screen is correct.

- d. Compare the displayed result with the known value of the label and determine if any characters need to be ignored. The handheld barcode reader can read a barcode that contains up to 30 characters, however, a maximum of 13 characters displayed, stored, and transmitted by the analyzer. All characters in excess of 13 must be ignored, up to a maximum of 18. You can have the analyzer ignore characters at the beginning or end of the barcode, or a combination of both.
- e. Select Previous Screen.

**Note** You may want to test more than 1 label, especially if they are printed from different sources. If you use more than 1 format, test at least 1 label from each format. See *Appendix E, Barcode Reader*.

- 3. Use the **Leading char. to ignore** cycle key to ignore between 0 and 9 characters at the beginning of the barcode.
- 4. Use the **Trailing char. to ignore** cycle key to ignore between 0 and 9 characters at the end of the barcode.
- Select Previous Screen.

## Setup Menu 9

At the eighth Setup menu, select **Next Screen** to access the ninth Setup menu. This is the final setup menu.

Menu Option	Default
Reset all features to defaults	N/A
Perform hardware tests	N/A

#### **Reset All Features to Defaults**

1. To return all options in Setup to the manufacturer's default setting, select **Reset all features to defaults.** 

If you reset the options, all stored results and loadlisted ID numbers are deleted.

То	Select
to reset to the defaults	Yes, return to original settings (This will delete all results and all IDs.)
retain your custom settings	No, do not change settings

#### **Perform Hardware Tests**

To perform any of 6 different hardware test, select **Perform hardware tests**. Your local technical support representative may ask you to perform one or more of these tests to assist in troubleshooting a problem.

**Note** The Select Hardware Test screen also displays the total number of strips that the analyzer has read.

#### **Strip Sensor**

Use this test to determine if the strip sensor is functioning properly:

- 1. Select Strip sensor.
- When prompted, place a test strip.
   If the strip sensor detects the presence of a strip placed on the table, the message Strip detected displays.
- 3. Select Previous Screen.

#### **Serial Port**

Use this test to determine if the serial port is functioning properly.

The test sends data from the serial port, through a connector, and back into the same port. The data sent and received should be identical.

- 1. Obtain a loopback connector, either by making your own or by ordering from your local technical support provider.
  - The connector is a serial 9-pin male connector on which pins 2 and 3 are connected and pins 4 and 6 are connected.
- 2. Select **Serial port** to display the test screen.
- 3. Connect the loopback connector into the serial port on the back of the analyzer.
- To begin the test, select the Loopback key.
   The test continues until you exit the screen.
- 5. When finished, select Previous Screen.

#### Touch Screen

Use this test to determine if the touch screen is functioning properly:

- Select Touch screen.
  - A screen displays that is filled with small boxes.
- 2. Select the center of each box.
  - As each box is selected, a check mark should display. It disappears when the same box is selected again.
- 3. Select **Previous Screen** key when finished.

#### **Barcode Reader**

This test is identical to the Test barcode option described in Setup Menu 8.

If your handheld barcode reader is not reading your labels, you must determine whether the problem is with the labels you are using or with the reader.

The package containing your barcode reader includes 2 sheets of barcoded labels that are printed to the minimum specifications of the barcode reader. If these labels cannot be read, the problem is probably with your reader. If they read properly, the labels you are using may not be acceptable.

#### Display

Use this test to ensure that all the lighted elements on the display are lit and turned off properly:

1. Select Display.

The entire screen is lit for several seconds, then becomes blank.

This series is repeated twice more before returning to the previous menu.

2. If numerous faulty pixels exist, or if they are located in critical areas, call your local technical support provider to replace the display.

#### Printer

Use this test to ensure that the internal or 80-column external printer prints all characters correctly:

- 1. If you are using an external printer, ensure that it is turned on.
- Select Printer.
- 3. Follow the directions on the screen.
- Examine the printout for its readability.
   The display automatically returns to the previous menu.

## **Completing Setup**

1. When you have finished selecting the setup parameters, select Return to Ready/Run.

The setup parameters are stored in the CLINITEK Advantus analyzer.

**Note** Your changes are only saved when you select **Return to Ready/Run**.

- 2. Print a copy of the setup report to verify your selections and retain in your files:
  - a. At the Ready/Run screen, select **Menu**.
  - b. Select **Print**.
  - c. Select **Setup report**.

If printing from the internal printer, make a photocopy of the report, because the thermal print may fade over time. If you have a new analyzer, you can use the printout to select the parameters on the new analyzer.

# Appendix A: Safety Information

# **Protecting Yourself from Biohazards**

This information summarizes the established guidelines for handling laboratory biohazards. This summary is based on the guidelines developed by the Centers for Disease Control, the Clinical and Laboratory Standards Institute, and the Occupational Safety and Health Administration.

Use this summary for general information only. It is not intended to replace or supplement your laboratory or hospital biohazard control procedures.

By definition, a biohazardous condition is a situation involving infectious agents biological in nature, such as the hepatitis B virus, the human immunodeficiency virus, and the tuberculosis bacterium. These infectious agents may be present in human blood and blood products and in other body fluids.

The following are the major sources of contamination when handling potentially infectious agents:

- Needlesticks
- Hand-to-mouth contact
- Hand-to-eye contact
- Direct contact with superficial cuts, open wounds, and other skin conditions that may permit absorption into subcutaneous skin layers
- Splashes or aerosol contact with skin and eyes

To prevent accidental contamination in a clinical laboratory, strictly adhere to the following procedures:

- Wear gloves while servicing parts of the system that have contact with body fluids such as serum, plasma, urine, or whole blood.
- Wash your hands before going from a contaminated area to a noncontaminated area, or when you remove or change gloves.
- Perform procedures carefully to minimize aerosol formation.

- Wear facial protection when splatter or aerosol formation are possible.
- Wear personal protective equipment such as safety glasses, gloves, lab coats or aprons when working with possible biohazard contaminants.
- Keep your hands away from your face.
- Cover all superficial cuts and wounds before starting any work.
- Dispose of contaminated materials according to your laboratory's biohazard control procedures.
- Keep your work area disinfected.
- Disinfect tools and other items that have been near any part of the system sample path or waste area with 10% v/v bleach.
- Do not eat, drink, smoke, or apply cosmetics or contact lenses while in the laboratory.
- Do not mouth pipet any liquid, including water.
- Do not place tools or any other items in your mouth.
- Do not use the biohazard sink for personal cleaning such as rinsing coffee cups or washing hands.

Do not recap, purposely bend, cut, break, remove from disposable syringes, or otherwise manipulate needles by hand. Needlestick injuries may result.

#### References

- Centers for Disease Control. Update: Universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus and other bloodborne pathogens in healthcare settings. 1988. MMWR, 37:377–382, 387, 388.
- Clinical and Laboratory Standards Institute (formerly NCCLS). Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline - Third Edition. Wayne, PA: Clinical and Laboratory Standards Institute; 2005. CLSI Document M29-A3. [ISBN 1-56238-567-4].
- 3. Federal Occupational Safety and Health Administration. Bloodborne Pathogens Standard. 29 CFR 1910. 1030.

# Appendix B: Warranty and Support Information

# **Legal Information**

To contact the legal representative for Siemens within the European community, contact the Siemens Authorized Representative. For service, contact your local technical support provider.

# **Warranty Information**

## **Installation Details**

Please record the following information and keep this sheet in the your laboratory for future reference.

Date of Installation:	
Serial Number:	

# Manufacturer's Warranty for U.S. Customers Only

Siemens warrants to the original purchaser that this instrument will be free from defects in materials and workmanship for a period of one year from the later of the date of original purchase or installation, except as noted below. During the stated one-year period, Siemens shall replace with a reconditioned unit or, at its option, repair at no charge a unit that is found to be defective.

This warranty is subject to the following exceptions and limitations:

- 1. A 90-day warranty only will be extended for consumable parts and/or accessories.
- This warranty is limited to repair or replacement due to defects in parts or workmanship. Replacement of nondefective parts shall be at additional cost.
- 3. This warranty shall not cover repairs or replacement of parts necessitated by abuse, accidents, alteration, misuse, neglect, maintenance by other than Siemens, failure to operate the instrument in accordance with instructions, or the use of reagents other than reagents manufactured or recommended by Siemens.

4. Siemens reserves the right to make changes in design of this instrument without obligation to incorporate such changes into previously manufactured instruments.

## **Disclaimer of Warranties**

This warranty is expressly made in lieu of any and all other warranties express or implied (either in fact or by operation of law) including the warranties of merchantability and fitness for use which are expressly excluded, and is the only warranty given by Siemens.

# **Limitations of Liability**

In no event shall Siemens be liable for indirect, special or consequential damages, even if Siemens has been advised of the possibility of such damages.

For warranty service, contact the local Siemens office for assistance and/ or instructions for obtaining repair/ replacement of this instrument.

# **Support Information**

Call for assistance:

- If the error message continues to be displayed after performing the steps described on the screen and in the Troubleshooting Chart
- If additional assistance is required concerning an analyzer problem
- If the problem is beyond the scope of this guide
- If the problem cannot be solved and an analyzer failure is apparent

Our local technical support providers are available to help you. Before calling, please complete the *Pre-service Checklist*, page 143. Make a photocopy of the checklist first. This information helps your local technical support provider to identify the probable cause of the problem.

# **Pre-service Checklist**

Please record the following information and keep this sheet in the your laboratory for future reference.

Date	of Installation:	
Serial	Number:	
	After recording the information, make photocopies of this period before calling your local technical support provider.	age
1.	Does the fan come on when the analyzer is turned on?	
	If NO: Is the analyzer firmly connected to a live AC electrical outlet?	
2.	Is the touch screen operating properly?	
	If NO:	
	Have you performed the Touch Screen test using the procedure in <i>Perform Hardware Tests</i> , page 135?	
	Have you calibrated the touch screen using the procedure in <i>Calibrating the Touch Screen</i> , page 67?	
3.	Does the analyzer proceed properly while analyzing urine strips?	
4.	Is the printer functioning properly? Are the appropriate messages and patient results being printed?	
	If NO:	
	Is the internal or an external printer turned on using the procedure in <i>Printer</i> , page 108?	
	Is there paper in the printer?	
	Have you performed the printer test using the procedure in <i>Perform Hardware Tests</i> , page 135?	
5.	Are reasonable results being displayed and printed for the QC and patient samples?	
	If NO:	
ı		

	Are the Siemens Reagent Strips for Urinalysis within their expiration dating?	
	Is the bottle of Control Strips within its expiration dating and is the QC solution within its use life?	
	Is the analyzer in the proper operating environment and location as described in <i>Appendix D, Specifications</i> ?	
	Is the fixed platform clean? See Section 5, <i>Maintenance</i> for cleaning instructions.	
6.	What is the revision level of the analyzer software? To find this information:	
	1. Turn analyzer power off.	
	2. Wait approximately 15 seconds.	
	3. Turn analyzer power on.	
	The software version displays after the initialization screen.	
7.	Are any error messages or warnings being displayed?	
	If so, what are they? List the error description and any numbers that display.	
8.	Have you performed the appropriate steps suggested on the display for the error being displayed?	
If an external device is being used:		
9.	Is the printer or host computer/LIS connected and turned on?	
10.	Have the correct parameters for transmission been selected through the Setup menus?	
11.	Is the external printer properly printing the test results?	
12.	Is the computer receiving the proper data? This can be checked by comparing the results on the computer display with the results on the analyzer display.	

# Appendix C: Orderable Supplies

### **List of Supplies and Optional Equipment**

The supplies and optional equipment available for the CLINITEK Advantus analyzer are listed below.

Catalog Number	Description
*	Siemens Reagent Strips for Urinalysis
1364	Chek-Stix Combo Pak Control Strips for Urinalysis
1360	Chek-Stix Positive Control Strips for Urinalysis
1421	CLINITEK Advantus Handheld Barcode Reader
5773	Thermal Printer Paper (5 rolls)
6472	CLINITEK Advantus Waste Bin Liners (5 liners)
RC200P	STAR Form Printer Ribbon Cassette
5256	CLINITEK Form Printer Ribbon Cartridge
5163A	CLINITEK 3-Copy Forms (10 x 100)
50336008	Lubriplate Lubricant

### **Siemens Reagent Strips for Urinalysis**

You can use many different configurations of Siemens Reagent Strips for Urinalysis on the CLINITEK Advantus analyzer. Contact your local technical support provider for the configurations available in your country.

### Chek-Stix Positive and Negative Control Strips for Urinalysis

Combo Pak (PN 1364)

Positive Control Strips (PN 1360)

Chek-Stix Positive and Negative Control Strips for Urinalysis provide a performance check for the CLINITEK Advantus analyzer/urine strip system. Chek-Stix Control Strips provide confidence that the urine strips are reacting and being read properly. The control strips can also detect errors resulting from user technique.

Reconstitute Chek-Stix Control Strips in deionized water to make up a Chek-Stix control solution. Instructions are included in the package insert and on the bottle label, and test results that should be obtained are listed in the package insert.

**Note** Chek-Stix Control Strips are not suitable for use with Multistix PRO Reagent Strips for Urinalysis.

The Control Strips are available as a Combo Pak, which contains 1 bottle each of the Positive Control Strips and Negative Control Strips (25 strips/bottle). The Positive Control Strips are also available as a separate product (1 bottle of 25 strips).

#### **CLINITEK Handheld Barcode Reader**

You can connect the CLINITEK Handheld Barcode Reader to the barcode reader port on the CLINITEK Advantus analyzer. The reader can be used to enter the identification numbers from barcoded labels, rather than manually entering each number before the specimen is tested. Color and clarity can also be scanned from special barcodes that are included with the barcode reader.

#### Installing a Barcode Reader Bracket

A barcode reader bracket is supplied with the barcode reader. See *Appendix E, Barcode Reader*, for instructions on installing the bracket.

#### **CLINITEK Advantus Waste Bin Liners**

The CLINITEK Advantus Waste Bin Liners, are plastic liners that fit into the waste bin of the CLINITEK Advantus analyzer. They provide a safe, convenient method for removal of used urine strips. Each package contains 5 liners.

### **List of Replacement Parts**

This is a list of the replacement parts available for your CLINITEK Advantus analyzer. Contact your local technical support representative to order.

- AC power cord
- CLINITEK Advantus Operator's Guide
- CLINITEK Advantus Operator's Guide CD
- Color/Clarity Card (for use with the handheld barcode reader)
- Fixed Platform and Holddown Plate
- Holddown Plate
- Loopback Connector
- Moving Table
- Printer
- Printer Cover
- Push Bar

# Appendix D: Specifications

# **System Specifications**

This section summarizes the design specifications for the CLINITEK Advantus analyzer.

#### **Safety Certifications**

See the DECLARATION OF CONFORMITY shipped with the CLINITEK Advantus analyzer.

#### **Electromagnetic Compatibility (EMC)**

See the DECLARATION OF CONFORMITY shipped with the CLINITEK Advantus analyzer.

### **Analyzer Dimensions**

Dimension	Value
Depth	35 cm (13.75 in)
Height	32 cm (12.75 in)
Width	39 cm (15.75 in)
Weight	7.2 kg (16 lbs)

## **Environmental Specifications**

Specification	Value
Ambient Operating Temperature	18° to 30°C (64° to 86°F). At temperatures under 22°C (72°F), urobilinogen and leukocyte results may be decreased, and at temperatures above 26°C (79°F), increased.
Optimum Operating Temperature	22° to 26°C (72° to 79°F).
Relative Humidity	20 to 80%, non-condensing, actively controlled
Optimum Relative Humidity	35 to 55%
Indoor Use Only	

Specification	Value
Altitude	up to 2000 meters
Ventilation	1709 BTU
IEC 1010-1 Installation	Category II
IEC 1010-1 Equipment	Classification Class I
IEC 1010-1 Pollution D	egree 2

# **Electrical Requirements**

Requirement	Value
Electrical Rating	100 to 240 VAC ± 10%
Power Requirements	50 to 60 Hz
Maximum Power Input	72 VA
Fuse Rating	2 A, 250 V, 2 AG, SB(T)
Line Leakage Current	< 0.5 mA in normal condition < 3.5 mA in single fault condition

## **Tables of Results**

Table D-1: English and Chinese, Units—Conventional

Test	Printed	Units		Reported Re	esults	
			Normal System		PLUS System	
Glucose	GLU	mg/dL	NEGATIVE	500	NEGATIVE	2+
			100	>=1000	TRACE	3+
			250		1+	
Bilirubin	BIL		NEGATIVE	MODERATE	NEGATIVE	2+
			SMALL	LARGE	1+	3+
Ketone	KET	mg/dL	NEGATIVE	40	NEGATIVE	2+
			TRACE	>=80	TRACE	3+
			15		1+	
Specific Gravity	SG		<=1.005	1.020	No Difference	
			1.010	1.025		
			1.015	>=1.030		
Occult Blood	BLO		NEGATIVE	SMALL	NEGATIVE	1+
			TRACE-LYSED	MODERATE	TRACE-LYSED	2+
			TRACE-INTACT	LARGE	TRACE-INTACT	3+

Test	Printed	Units		Reported Re	esults	•
			Normal System		PLUS System	
рН	рН		5.0	7.5	No Difference	
			5.5	8.0		
			6.0	8.5		
			6.5	>=9.0		
			7.0			
Urobilinogen	URO	E.U./dL	0.2	4.0	No Difference	
			1.0	>=8.0		
			2.0			
Nitrite	NIT		NEGATIVE	POSITIVE	No Difference	
Leukocytes	LEU		NEGATIVE	MODERATE	NEGATIVE	2+
			TRACE	LARGE	TRACE	3+
			SMALL		1+	
Protein	PRO	mg/dL	NEGATIVE	100	NEGATIVE	2+
			TRACE (15 <sup>a</sup> )	>=300 (300 <sup>a</sup> )	TRACE (LOW <sup>a</sup> )	3+
			30		1+	

Test	Printed	Units		Reported	Results
			Normal System		PLUS System
Creatinine <sup>a</sup>	CRE	mg/dL	10	200	No Difference
			50	300	
			100		
Protein-to-	P:C	mg/g	NORMAL DILUTE <sup>b</sup>		No Difference
Creatinine Ratio <sup>a</sup>			NORMAL		
			150 ABNORMAL		
			300 ABNORMAL		
			>500 ABNORMAL		
Color <sup>c</sup>	COL		YELLOW	GREEN	No Difference
			ORANGE	BLUE	
			RED	BROWN	
Clarity <sup>d</sup>	CLA		CLEAR	TURBID	No Difference
			SL CLOUDY	OTHER	
			CLOUDY		

a. These tests and results are only available when using Multistix PRO Reagent Strips for Urinalysis.

b. Specimen is too dilute to accurately determine ratio result. Repeat test on new specimen.

c. Color may be preceded with LT or DK when determined by the analyzer. If determined visually, default descriptions can be changed by the user. Other can also be reported.

d. Determined visually. Reported results are default descriptions that can be changed by the user.

Table D-2: English and Chinese, Units—International (SI)

Test	Printed	Units	Reported Values			
			Standard System		PLUS System	
Glucose	GLU	mmol/L	NEGATIVE	28	NEGATIVE	2+
			5.5	>=55	TRACE	3+
			14		1+	
Bilirubin	BIL		NEGATIVE	MODERATE	NEGATIVE	2+
			SMALL	LARGE	1+	3+
Ketone	KET	mmol/L	NEGATIVE	3.9	NEGATIVE	2+
			TRACE	>=7.8	TRACE	3+
			1.5		1+	
Specific Gravity	SG		<=1.005	1.020	No Difference	
			1.010	1.025		
			1.015	>=1.030		
Occult Blood	BLD	Ery/μL	NEGATIVE	Ca 25	NEGATIVE	1+
			TRACE-LYSED	Ca 80	TRACE-LYSED	2+
			TRACE-INTACT	Ca 200	TRACE-INTACT	3+

Test	Printed	Units	Reported Values			
			Standard System		PLUS System	
рН	рН		5.0	7.5	No Difference	
			5.5	8.0		
			6.0	8.5		
			6.5	>=9.0		
			7.0			
Urobilinogen	UBG	µmol/L	3.2	66	No Difference	
			16	>=131		
			33			
Nitrite	NIT		NEGATIVE	POSITIVE	No Difference	
Leukocytes	LEU	Leu/µL	NEGATIVE	Ca 125	NEGATIVE	2+
			Ca 15	Ca 500	TRACE	3+
			Ca 70		1+	
Protein	PRO	g/L	NEGATIVE	1.0	NEGATIVE	2+
			TRACE (0.15 <sup>a</sup> )	$>=3.0 (3.0^{a})$	TRACE (LOW <sup>a</sup> )	3+
			0.3		1+	

Test	Printed	Units		Reported Valu	es
			Standard System		PLUS System
Creatinine <sup>a</sup>	CRE	mmol/L	0.9	17.7	No Difference
			4.4	26.5	
			8.8		
Protein-to-Creatinine	P:C	mg/mmol	NORMAL DILUTE <sup>b</sup>		No Difference
Ratio <sup>a</sup>			NORMAL		
			17.0 ABNORMAL		
			33.9 ABNORMAL		
			> 56.6 ABNORMAL		
Color <sup>c</sup>	COL		YELLOW	GREEN	No Difference
			ORANGE	BLUE	
			RED	BROWN	
Clarity <sup>d</sup>	CLA		CLEAR	TURBID	No Difference
			SL CLOUDY	OTHER	
			CLOUDY		

a. These tests and results are only available when using Multistix PRO Reagent Strips for Urinalysis.

b. Specimen is too dilute to accurately determine ratio result. Repeat test on new specimen.

c. Color may be preceded with LT or DK when determined by the analyzer. If determined visually, default descriptions can be changed by the user. Other can also be reported.

d. Determined visually. Reported results are default descriptions that can be changed by the user.

Table D-3: English Nordic, Units—Nordic Plus System

Test	Printed	Units		Reported I	Results	
			Normal System		PLUS System	
Glucose	GLU		NEGATIVE	3+	NEGATIVE	2+
			1+	4+	TRACE	3+
			2+		1+	
Bilirubin	BIL		NEGATIVE	2+	No Difference	
			1+	3+		
Ketone	KET		NEGATIVE	3+	NEGATIVE	2+
			1+	4+	TRACE	3+
			2+		1+	
Specific Gravity	SG		<=1.005	1.020	No Difference	
			1.010	1.025		
			1.015	>=1.030		
Occult Blood	BLD		NEGATIVE	1+	No Difference	
			+/-	2+		
			+/- INTACT	3+		

Test	Printed	Units		Reported	Results	
			Normal System	1	<b>PLUS System</b>	
рН	рН		5.0	7.5	No Difference	
			5.5	8.0		
			6.0	8.5		
			6.5	>=9.0		
			7.0			
Urobilinogen	UBG	μmol/L	3.2	66	No Difference	
			16	>=131		
			33			
Nitrite	NIT		NEGATIVE	POSITIVE	No Difference	
Leukocytes	LEU		NEGATIVE	3+	NEGATIVE	2+
			1+	4+	TRACE	3+
			2+		1+	
Protein	PRO		NEGATIVE	2+	NEGATIVE	2+
			+/- (LOW <sup>a</sup> )	3+	TRACE (LOW <sup>a</sup> )	3+
			1+		1+	

Test	Printed	Units		Reported	Results
			<b>Normal System</b>		PLUS System
Creatinine <sup>a</sup>	CRE	mmol/L	0.9	17.7	No Difference
			4.4	26.5	
			8.8		
Protein-to-	P:C	mg/mmol	NORMAL DILUTE <sup>b</sup>		No Difference
Creatinine Ratio <sup>a</sup>			NORMAL		
			17.0 ABNORMAL		
			33.9 ABNORMAL		
			> 56.6 ABNORMAL		
Color <sup>c</sup>	COL		YELLOW	GREEN	No Difference
			ORANGE	BLUE	
			RED	BROWN	
Clarity <sup>d</sup>	CLA		CLEAR	TURBID	No Difference
			SL CLOUDY	OTHER	
			CLOUDY		

a. These tests and results are only available when using Multistix PRO Reagent Strips for Urinalysis.

b. Specimen is too dilute to accurately determine ratio result. Repeat test on new specimen.

c. Color may be preceded with LT or DK when determined by the analyzer. If determined visually, default descriptions can be changed by the user. Other can also be reported.

d. Determined visually. Reported results are default descriptions that can be changed by the user.

Table D-4: German, Units—Conventional

Test	Abkürzung	Einheiten		Angegebe	ne Werte	
			Normales Sys	stem	Plus System	
Glucose	GLU	mg/dL	NEGATIV	500	NEGATIV	2+
			100	>=1000	SPUR	3+
			250		1+	
Bilirubin	BIL		NEGATIV	MAESSIG	NEGATIV	2+
			SCHWACH	STARK	1+	3+
Keton	KET	mg/dL	NEGATIV	40	NEGATIV	2+
			SPUR	>=80	SPUR	3+
			15		1+	
Spezifisches	SG		<=1.005	1.020	gleich	
Gewicht			1.010	1.025		
			1.015	>=1.030		
Blut	OBL	Ery/μL	0	Ca 80	NEGATIV	1+
			Ca 10	Ca 200	SPUR-LYSE	2+
			Ca 25		SPUR-ZELLEN	3+

Test	Abkürzung	Einheiten		Angegebene	e Werte	
			Normales Sys	tem	Plus System	
рН	рН		5.0	7.5	gleich	
			5.5	8.0		
			6.0	8.5		
			6.5	>=9.0		
			7.0			
Urobilinogen	UBG	mg/dL	0.2	4.0	gleich	
			1.0	>=8.0		
			2.0			
Nitrit	NIT		NEGATIV	POSITIV	gleich	
Leukozyten	LEU	Leu/µL	0	Ca 125	NEGATIV	2+
			Ca 15	Ca 500	SPUR	3+
			Ca 70		1+	
Protein	PRO	mg/dL	NEGATIV	100	NEGATIV	2+
			SPUR (15 <sup>a</sup> )	>=300 (300 <sup>a</sup> )	SPUR (WENIG <sup>a</sup> )	3+
			30		1+	

Test	Abkürzung	Einheiten	Angegebene Werte		
			Normales Sys	tem	Plus System
Kreatinin <sup>a</sup>	KRE	mg/dL	10	200	gleich
			50	300	
			100		
Protein-Kreatinin-	P:K	mg/g	P OK / K GERIN	G <sup>b</sup>	gleich
Verhältnis <sup>a</sup>			NORMAL		
			150 ABNORMA	<b>AL</b>	
			300 ABNORMA	<b>AL</b>	
			>500 ABNORM	1AL	
Farbe <sup>c</sup>	COL		GELB	GRUEN	gleich
			ORANGE	BLAU	
			ROT	BRAUN	
Klarheit <sup>d</sup>	CLA		KLAR	TRUEB	gleich
			FLOCKIG	ANDERS	
			S. FLOCKIG		

a. Diese Tests und Ergebnisse stehen nur bei Verwendung von Multistix Pro Teststreifen zur Verfügung.

b. Probe ist zu stark verdünnt, um den Quotienten genau zu bestimmen. Test an neuer Probe wiederholen.

c. Vor der Farbe kann HELL oder DUNK stehen, wenn die Auswertung durch das System erfolgt. Bei visueller Bestimmung können die vom System vorgegebenen Farben vom Bediener verändert werden. "ANDERS" kann auch angegeben werden.

d. Wird visuell bestimmt. Die angegebenen Ergebnisse sind Standardbeschreibungen, die vom Benutzer geändert werden können.

Table D-5: German, Units—International (SI)

Test	Abkürzung	Einheiten		Angegebene	e Werte	
			Normales Sys	tem	Plus System	
Glucose	GLU	mmol/L	NEGATIV	28	NEGATIV	2+
			5.5	>=55	SPUR	3+
			14		1+	
Bilirubin	BIL		NEGATIV	MAESSIG	NEGATIV	2+
			SCHWACH	STARK	1+	3+
Keton	KET	mmol/L	NEGATIV	3.9	NEGATIV	2+
			SPUR	>=7.8	SPUR	3+
			1.5		1+	
Spezifisches Gewicht	SG		<=1.005 1.010 1.015	1.020 1.025 >=1.030	gleich	
Blut	OBL	Ery/μL	0	Ca 80	NEGATIV	1+
			Ca 10	Ca 200	SPUR-LYSE	2+
			Ca 25		SPUR-ZELLEN	3+

Test	Abkürzung	Einheiten	Angegebene Werte			
			Normales Sys	tem	Plus System	
рН	рН		5.0	7.5	gleich	
			5.5	8.0		
			6.0	8.5		
			6.5	>=9.0		
			7.0			
Urobilinogen	UBG	μmol/L	3.2	66	gleich	
			16	>=131		
			33			
Nitrit	NIT		NEGATIV	POSITIV	gleich	
Leukozyten	LEU	Leu/µL	0	Ca 125	NEGATIV	2+
			Ca 15	Ca 500	SPUR	3+
			Ca 70		1+	
Protein	PRO	g/L	NEGATIV	1.0	NEGATIV	2+
			SPUR (0.15 <sup>a</sup> )	$>=3.0(3.0^{a})$	SPUR (WENIG <sup>a</sup> )	3+
			0.3		1+	

Test	Abkürzung	Einheiten		Angegebe	ene Werte
			Normales S	ystem	Plus System
Kreatinin <sup>a</sup>	KRE	mmol/L	0.9	17.7	gleich
			4.4	26.5	
			8.8		
Protein-Kreatinin-	P:K	mg/mmol	P OK / K GER	RING <sup>b</sup>	gleich
Quotient <sup>a</sup>			NORMAL		
			17.0 ABNORMAL		
			33.9 ABNOR	MAL	
			>56.6 ABNO	RMAL	
Farbe <sup>c</sup>	COL		GELB	GRUEN	gleich
			ORANGE	BLAU	
			ROT	BRAUN	
Klarheit <sup>d</sup>	CLA		KLAR	TRUEB	gleich
			FLOCKIG	ANDERS	
			S. FLOCKIG		

a. Diese Tests und Ergebnisse stehen nur bei Verwendung von Multistix PRO Teststreifen zur Verfügung.

b. Probe ist zu stark verdünnt, um den Quotienten genau zu bestimmen. Test an neuer Probe wiederholen.

c. Vor der Farbe kann HELL oder DUNK stehen, wenn die Auswertung durch das System erfolgt. Bei visueller Bestimmung können die vom System vorgegebenen Farben vom Bediener verändert werden. "ANDERS" kann auch angegeben werden.

d. Wird visuell bestimmt. Die angegebenen Ergebnisse sind Standardbeschreibungen, die vom Benutzer geändert werden können.

Table D-6: French, Units—Conventional

Test	Abréviation	Unités		Valeurs indic	ļuées	
			Système usuel		Système croix	
Glucose	GLU	g/dL	NEGATIF	5,0	NEGATIF	2+
			TRACES	>=10,0	TRACES	3+
			2,5		1+	
Bilirubine	BIL		NEGATIF	MOYEN	NEGATIF	2+
			FAIBLE	FORT	1+	3+
Corps cétoniques	CET	g/dL	NEGATIF	0,4	NEGATIF	2+
			TRACES	>=0,8	TRACES	3+
			0,15		1+	
Densité	DEN		<=1,005	1,020	Identique	
			1,010	1,025		
			1,015	>=1,030		
Sang	SNG	GR/μL	NEGATIF	env. 25	NEGATIF	1+
			TRACES-LYSE	env. 80	TRACES-LYSE	2+
			TRACES-INTACT	env. 200	TRACES-INTACT	3+

Test	Abréviation	Unités		Valeurs indiq	uées	
			Système usuel		Système croix	
рН	рН		5,0	7,5	Identique	
			5,5	8,0		
			6,0	8,5		
			6,5	>=9,0		
			7,0			
Urobilinogène	URO	mg/dL	0,2	4,0	Identique	
			1,0	>=8,0		
			2,0			
Nitrites	NIT		NEGATIF	POSITIF	Identique	
Leucocytes	LEU	GΒ/μL	NEGATIF	env. 125	NEGATIF	2+
			env. 15	env. 500	TRACES	3+
			env. 70		1+	
Protéines	PRO	g/L	NEGATIF	1,0	NEGATIF	2+
			TRACES (0,15 <sup>a</sup> )	>=3,0 (3,0 <sup>a</sup> )	TRACES (FAIBLE <sup>a</sup> )	3+
			0,3		1+	

Test	Abréviation	Unités		Valeurs indiqu	ées
			Système usuel		Système croix
Créatinine <sup>a</sup>	CRE	mg/dL	10	200	Identique
			50	300	
			100		
Ratio protéines-	P:C	mg/g	NORMAL, DILUEE <sup>b</sup>		Identique
créatinine <sup>a</sup>			NORMAL	300 ANORMAL	
			150 ANORMAL	>500 ANORMAL	
Couleur <sup>c</sup>	COL		JAUNE	VERT	Identique
			ORANGE	BLEU	
			ROUGE	MARRON	
Aspect <sup>d</sup>	ASP		LIMPIDE	OPAQUE	Identique
			LEG TROUBLE	AUTRE	
			TROUBLE		

- a. Ces analyses et résultats sont disponibles uniquement lors de l'utilisation de bandelettes réactives Multistix PRO.
- b. L'échantillon est trop dilué pour permettre de déterminer avec précision le résultat du rapport. L'analyse doit être effectuée sur un nouvel échantillon.
- c. La couleur peut être précédée de la mention CLR. ou FONC. en cas de définition par l'analyseur. En cas de détermination visuelle, les descriptions par défaut peuvent être modifiées par l'utilisateur. La mention Autre peut également être indiquée.
- d. Détermination visuelle. Les résultats rapportés sont des descriptions par défaut qui peuvent être modifiées par l'utilisateur.

Table D-7: French, Units—International (SI)

Test	Abréviation	Unités		Valeurs indiqu	ıées	
			Système usuel		Système croix	
Glucose	GLU	mmol/L	NEGATIF	28	NEGATIF	2+
			5,5	>=55	TRACES	3+
			14		1+	
Bilirubine	BIL		NEGATIF	MOYEN	NEGATIF	2+
			FAIBLE	FORT	1+	3+
Corps	CET	mmol/L	NEGATIF	3,9	NEGATIF	2+
cétoniques			TRACES	>=7,8	TRACES	3+
			1,5		1+	
Densité	DEN		<=1,005	1,020	Identique	
			1,010	1,025		
			1,015	>=1,030		
Sang	SNG		NEGATIF	FAIBLE	NEGATIF	1+
			TRACES-LYSE	MOYEN	TRACES-LYSE	2+
			TRACES-INTACT	FORT	TRACES-INTACT	3+

Test	Abréviation	Unités		Valeurs indic	<sub>l</sub> uées	
			Système usuel		Système croix	
рН	рН		5,0	7,5	Identique	
			5,5	8,0		
			6,0	8,5		
			6,5	>=9,0		
			7,0			
Urobilinogène	URO	µmol/L	3,2	66	Identique	
			16	>=131		
			33			
Nitrites	NIT		NEGATIF	POSITIF	Identique	
Leucocytes	LEU		NEGATIF	MOYEN	NEGATIF	2+
			TRACES	FORT	TRACES	3+
			FAIBLE		1+	
Protéines	PRO	g/L	NEGATIF	1,0	NEGATIF	2+
			TRACES (0,15 <sup>a</sup> )	$>=3,0 (3,0^a)$	TRACES (FAIBLE <sup>a</sup> )	3+
			0,3		1+	

Test	Abréviation	Unités	Valeurs indiqu		ıées
			Système usuel		Système croix
Créatinine <sup>a</sup>	CRE	mmol/L	0,9	17,7	Identique
			4,4	26,5	
			8,8		
Ratio protéines-	P:C	mg/mmol	NORMAL, DILUEE <sup>b</sup>		Identique
créatinine <sup>a</sup>			NORMAL	33,9 ANORMAL	
			17,0 ANORMAL	>56,6 ANORMAL	
Couleur <sup>c</sup>	COL		JAUNE	VERT	Identique
			ORANGE	BLEU	
			ROUGE	MARRON	
Aspect <sup>d</sup>	ASP		LIMPIDE	OPAQUE	Identique
			LEG TROUBLE	AUTRE	
			TROUBLE		

- a. Ces analyses et résultats sont disponibles uniquement lors de l'utilisation de bandelettes réactives Multistix Pro.
- b. L'échantillon est trop dilué pour permettre de déterminer avec précision le résultat du rapport. L'analyse doit être effectuée sur un nouvel échantillon.
- c. La couleur peut être précédée de la mention CLR. ou FONC. en cas de définition par l'analyseur. En cas de détermination visuelle, les descriptions par défaut peuvent être modifiées par l'utilisateur. La mention Autre peut également être indiquée.
- d. Détermination visuelle. Les résultats rapportés sont des descriptions par défaut qui peuvent être modifiées par l'utilisateur.

Table D-8: Italian, Units—Conventional

Analisi	Stampato	Unità		Risultati	refertati	
			Sistema norma	ıle	Plus System	
Glucosio	GLU	g/L	NEGATIVO	5,0	NEGATIVO	2+
			1,0	>=10,0	TRACCE	3+
			2,5		1+	
Bilirubina	BIL		NEGATIVO	MEDIO	NEGATIVO	2+
			LEGGERO	FORTE	1+	3+
Chetoni	KET	mg/dL	NEGATIVO	40	NEGATIVO	2+
			TRACCE	>=80	TRACCE	3+
			15		1+	
Peso Specifico	PS		<=1,005	1,020	Uguale	
			1,010	1,025		
			1,015	>=1,030		
Sangue occulto	SAN		NEGATIVO	LEGGERO	NEGATIVO	1+
			TRACCE(LIS.)	MEDIO	TRACCE(LIS.)	2+
			TRACCE(INT.)	FORTE	TRACCE(INT.)	3+

Analisi	Stampato	Unità		Risultati re	efertati	
			Sistema norma	le	Plus System	
рН	рН		5,0	7,0	Uguale	
			5,5	7,5		
			6,0	8,0		
			6,5	8,5		
				>=9,0		
Urobilinogeno	URO	E.U./dL	0,2	4,0	Uguale	
			1,0	>=8,0		
			2,0			
Nitriti	NIT		NEGATIVO	POSITIVO	Uguale	
Leucociti	LEU	Cel/µL	NEGATIVO	Ca 125	NEGATIVO	2+
			Ca 15	Ca 500	TRACCE	3+
			Ca 70		1+	
Proteina	PRO	mg/dL	NEGATIVO	100	NEGATIVO	2+
			TRACCE(15 <sup>a</sup> )	>=300(300 <sup>a</sup> )	TRACCE(BASSO <sup>a</sup> )	3+
			30		1+	

Analisi	Stampato	Unità		efertati	
			Sistema norma	le	Plus System
Creatinina <sup>a</sup>	CRE	mg/dL	10	200	Uguale
			50	300	
			100		
Rapporto	P:C	mg/g	DILUITO NORMA	ALE <sup>b</sup>	Uguale
creatinina/proteine <sup>a</sup>			NORMALE		
			150 ANORMALE		
			300 ANORMALE		
			>500 ANORMAL	_E	
Colore <sup>c</sup>	COL		GIALLO	VERDE	Uguale
			ARANCIONE	AZZURO	
			ROSSO	MARRONE	
Aspetto <sup>d</sup>	ASP		LIMPIDA	MOL. TORB.	Uguale
			LEGG. TORBIDA	ALTRO	
			TORBIDA		

- a. Queste analisi e risultati sono disponibili solo quando si utilizzano le strisce reattive Multistix Pro.
- b. Il campione è troppo diluito per determinare con precisione un risultato accurato. Ripetere l'analisi con un nuovo campione.
- c. Il colore può essere accompagnato da "LT" (Chiaro) o "DK" (Scuro) quando è determinato dallo strumento. Se si determina visivamente, le descrizioni di default possono essere cambiate dall'utente; i risultati possono refertare anche "ALTRO".
- d. Determinato a vista. I risultati riportati sono le descrizioni predefinite modificabili dall'utente.

Table D-9: Italian, Units—International (SI)

Analisi	Stampato	Unità		Risultat	i refertati	
			Sistema norma	ale	Plus System	
Glucosio	GLU	mmol/L	NEGATIVO	28	NEGATIVO	2+
			5,5	>=55	TRACCE	3+
			14		1+	
Bilirubina	BIL		NEGATIVO	MEDIO	NEGATIVO	2+
			LEGGERO	FORTE	1+	3+
Chetoni	KET	mmol/L	NEGATIVO	3,9	NEGATIVO	2+
			TRACCE	>=7,8	TRACCE	3+
			1,5		1+	
Peso Specifico	PS		<=1,005	1,020	Uguale	
			1,010	1,025		
			1,015	>=1,030		
Sangue occulto	SAN	eri/μL	0	Ca 80	NEGATIVO	1+
			Ca 10	Ca 200	TRACCE(LIS.)	2+
			Ca 25		TRACCE(INT.)	3+

Analisi	Stampato	Unità		Risultati r	refertati	
			Sistema normale	•	Plus System	
рН	рН		5,0	7,5	Uguale	
			5,5	8,0		
			6,0	8,5		
			6,5	>=9,0		
			7,0			
Urobilinogeno	URO	μmol/L	3,2	66	Uguale	
			16	>=131		
			33			
Nitriti	NIT		NEGATIVO	POSITIVO	Uguale	
Leucociti	LEU	Cel/µL	0	Ca 125	NEGATIVO	2+
			Ca 15	Ca 500	TRACCE	3+
			Ca 70		1+	
Proteina	PRO	g/L	NEGATIVO	1,0	NEGATIVO	2+
			TRACCE (0,15 <sup>a</sup> ) 0,3	>=3,0(3,0 <sup>a</sup> )	TRACCE (BASSO <sup>a</sup> ) 1+	3+

Analisi	Stampato	Unità	Risultati re		efertati
			Sistema normale	е	Plus System
Creatinina <sup>a</sup>	CRE	mmol/L	0,9	17,7	Uguale
			4,4	26,5	
			8,8		
Rapporto	P:C	mg/mmol	DILUITO NORMAI	_E <sup>b</sup>	Uguale
creatinina/proteine <sup>a</sup>			NORMALE		
			17,0 ANORMALE		
			33,9 ANORMALE		
			>56,6 ANORMAL	E	
Colore <sup>c</sup>	COL		GIALLO	VERDE	Uguale
			ARANCIONE	AZZURO	
			ROSSO	MARRONE	
Aspetto <sup>d</sup>	ASP		LIMPIDA	MOL. TORB.	Uguale
			LEGG. TORBIDA	ALTRO	
			TORBIDA		

a. Queste analisi e risultati sono disponibili solo quando si utilizzano le strisce reattive Multistix Pro.

b. Il campione è troppo diluito per determinare con precisione un risultato accurato. Ripetere l'analisi con un nuovo campione..

c. Il colore può essere accompagnato da "LT" (Chiaro) o "DK" (Scuro) quando è determinato dallo strumento. Se si determina visivamente, le descrizioni di default possono essere cambiate dall'utente; i risultati possono refertare anche "ALTRO".

d. Determinato a vista. I risultati riportati sono le descrizioni predefinite modificabili dall'utente.

Table D-10: Spanish, Units—Conventional

Análisis	Abre-	Unidades		Valores Repo	rtados	
	viatura		Sistema Normal		Sistema de Cruces	
Glucosa	GLU	mg/dL	NEGATIVO	500	NEGATIVO	2+
			100	>=1000	INDICIOS	3+
			250		1+	
Bilirrubina	BIL		NEGATIVO	MODERADO	NEGATIVO	2+
			BAJO	ALTO	1+	3+
Cetona	CET	mg/dL	NEGATIVO	40	NEGATIVO	2+
			INDICIOS	>=80	INDICIOS	3+
			15		1+	
Densidad	DEN		<=1.005	1.020	Ninguna Diferencia	
(Gravedad			1.010	1.025		
específica)			1.015	>=1.030		
Sangre oculta	SAN	Hem/µL	NEGATIVO	Apr 25	NEGATIVO	1+
			IND. HEMOLIZ.	Apr 80	IND. HEMOLIZ.	2+
			IND. INTACTOS	Apr 200	IND. INTACTOS	3+

Análisis	Abre-	Unidades		Valores Repo	ortados	
viatura			Sistema Normal	Sistema Normal		
рН	рН		5.0	7.5	Ninguna Diferencia	
			5.5	8.0		
			6.0	8.5		
			6.5	>=9.0		
			7.0			
Urobilinógeno	URO	E.U./dL	0.2	4.0	Ninguna Diferencia	
			1.0	>=8.0		
			2.0			
Nitrito	NIT		NEGATIVO	POSITIVO	Ninguna Diferencia	
Leucocitos	LEU	Leu/µL	NEGATIVO	Apr 125	NEGATIVO	2+
			Apr 15	Apr 500	INDICIOS	3+
			Apr 70		1+	
Proteínas	PRO	mg/dL	NEGATIVO	100	NEGATIVO	2+
			INDICIOS (15 <sup>a</sup> )	$>=300(300^{a})$	INDICIOS (BAJO <sup>a</sup> )	3+
			30		1+	

Análisis	Abre-	Unidades		Valores Repo	ortados
	viatura		Sistema Normal		Sistema de Cruces
Creatinina <sup>a</sup>	CRE	mg/dL	10	200	Ninguna Diferencia
			50	300	
			100		
Cociente de	P:C	mg/g	DILUIDO NORMAL <sup>b</sup>		Ninguna Diferencia
proteínas/ creatinina <sup>a</sup>			NORMAL		
Creatifilla			150 ANORMAL		
			300 ANORMAL		
			>500 ANORMAL		
Color <sup>c</sup>	COL		AMARILLO	VERDE	Ninguna Diferencia
			NARANJA	AZUL	
			ROJO	MARRON	
Aspecto <sup>d</sup>	ASP		CLARO	MUY TURBIO	Ninguna Diferencia
			LIG. TURBIO	OTROS	
			TURBIO		

a. Estas pruebas y resultados sólo estarán disponibles si se utilizan tiras reactivas MULTISTIX PRO.

b. La muestra está demasiado diluida para determinar de forma exacta el resultado del cociente. Repetir la prueba con una muestra nueva.

c. El color puede ir precedido de CL. u OSC. cuando es determinado por el analizador. Si se determina visualmente, el usuario puede modificar las descripciones predeterminadas. El resultado también puede ser "Otros".

d. Determinado visualmente. Los resultados comunicados son descripciones predeterminadas que el usuario puede modificar.

Table D-11: Spanish, Units—International (SI)

Análisis	Abre-	Unidades		Valores Repo	rtados	
	viatura		Sistema Normal		Sistema de Cruces	
Glucosa	GLU	mmol/L	NEGATIVO	28	NEGATIVO	2+
			5.5	>=55	INDICIOS	3+
			14		1+	
Bilirrubina	BIL		NEGATIVO	MODERADO	NEGATIVO	2+
			BAJO	ALTO	1+	3+
Cetona	CET	mmol/L	NEGATIVO	3.9	NEGATIVO	2+
			INDICIOS	>=7.8	INDICIOS	3+
			1.5		1+	
Densidad	DEN		<=1.005	1.020	Ninguna Diferencia	
(Gravedad			1.010	1.025		
específica)			1.015	>=1.030		
Sangre oculta	SAN	Eri/µL	0	Apr 80	NEGATIVO	1+
			Apr 10	Apr 200	IND.HEMOLIZ.	2+
			Apr 25		IND.INTACTOS	3+

Análisis	Abre-	Unidades		Valores Rep	ortados	
	viatura		Sistema Normal		Sistema de Cruces	
pH <sup>a</sup>	рН		5.0	7.5	Ninguna Diferencia	
			5.5	8.0		
			6.0	8.5		
			6.5	>=9.0		
			7.0			
Urobilinógeno	URO	μmol/L	3.2	66	Ninguna Diferencia	
			16	>=131		
			33			
Nitrito	NIT		NEGATIVO	POSITIVO	Ninguna Diferencia	
Leucocitos	LEU	Leu/µL	NEGATIVO	Apr 125	NEGATIVO	2+
			Apr 15	Apr 500	INDICIOS	3+
			Apr 70		1+	
Proteínas	PRO	g/L	NEGATIVO	1.0	NEGATIVO	2+
			INDICIOS (0.15 <sup>a</sup> )	$>=3.0(3.0^{a})$	INDICIOS (BAJO <sup>a</sup> )	3+
			0.3		1+	

Análisis	Abre-	Unidades		Valores Repo	ortados
	viatura		Sistema Normal		Sistema de Cruces
Creatinina <sup>a</sup>	CRE	mmol/L	0.9	17.7	Ninguna Diferencia
			4.4	26.5	
			8.8		
Cociente de	P:C	mg/mmol	DILUIDO NORMAL <sup>b</sup>		Ninguna Diferencia
proteínas/ creatinina <sup>a</sup>			NORMAL		
Creatifilia			17.0 ANORMAL		
			33.9 ANORMAL		
			>56.6 ANORMAL		
Color <sup>c</sup>	COL		AMARILLO	VERDE	Ninguna Diferencia
			NARANJA	AZUL	
			ROJO	MARRON	
Aspecto <sup>d</sup>	ASP		CLARO	MUY TURBIO	Ninguna Diferencia
			LIG. TURBIO	OTROS	
			TURBIO		

a. Estas pruebas y resultados sólo estarán disponibles si se utilizan tiras reactivas MULTISTIX PRO.

b. La muestra está demasiado diluida para determinar de forma exacta el resultado del cociente. Repetir la prueba con una muestra nueva.

c. El color puede ir precedido de CL. u OSC. cuando es determinado por el analizador. Si se determina visualmente, el usuario puede modificar las descripciones predeterminadas. El resultado también puede ser "Otros".

d. Determinado visualmente. Los resultados comunicados son descripciones predeterminadas que el usuario puede modificar.

Table D-12: Portuguese, Units—Conventional

Exame	Impresso	Unidades		Valores re	latados	
			Sistema padrão		Sistema PLUS	
Glicose	GLI	mg/dL	NEGATIVO	500	NEGATIVO	2+
			100	>=1000	INDICIO	3+
			250		1+	
Bilirrubina	BIL		NEGATIVO	MODERADO	NEGATIVO	2+
			PEQUENO	GRANDE	1+	3+
Acetona	CET	mg/dL	NEGATIVO	40	NEGATIVO	2+
			INDICIO	>=80	INDICIO	3+
			15		1+	
Densidade	DEN		<=1,005	1,020	Sem diferenças	
			1,010	1,025		
			1,015	>=1,030		
Sangue oculto	SAN		NEGATIVO	PEQUENO	NEGATIVO	1+
			INDICIO-LISADO	MODERADO	INDICIO-LISADO	2+
			INDICIO- INTACTO	GRANDE	INDICIO-INTACTO	3+

Exame	Impresso	Unidades		Valores rel	atados	
			Sistema padrão	)	Sistema PLUS	
рН	рН		5,0	7,5	Sem diferenças	
			5,5	8,0		
			6,0	8,5		
			6,5	>=9,0		
			7,0			
Urobilinogênio	URO	mg/dL	0,2	4,0	Sem diferenças	
			1,0	>=8,0		
			2,0			
Nitrito	NIT		NEGATIVO	POSITIVO	Sem diferenças	
Leucócitos	LEU		NEGATIVO	MODERADO	NEGATIVO	2+
			INDICIO	GRANDE	INDICIO	3+
			PEQUENO		1+	
Proteína	PRO	mg/dL	NEGATIVO	100	NEGATIVO	2+
			INDICIO (15ª )	$>=300 (300^{a})$	INDICIO (BAIXO <sup>a</sup> )	3+
			30		1+	

Exame	Impresso	Unidades		Valores rela	atados
			Sistema padrão		Sistema PLUS
Creatinina <sup>a</sup>	CRE	mg/dL	10	200	Sem diferenças
			50	300	
			100		
Relação proteína-	P:C	mg/g	DILUIDO NORMA	۲ <sub>p</sub>	Sem diferenças
creatinina <sup>a</sup>			NORMAL	300 ANORMAL	
			150 ANORMAL	>500 ANORMAL	
Cor <sup>c</sup>	COR		AMARELO	VERDE	Sem diferenças
			LARANJA	AZUL	
			VERMELHO	MARROM	
Aspecto <sup>d</sup>	ASP		CLARO	TURVO	Sem diferenças
			POUCO NEBULOSO	OUTROS	
			NEBULOSO		

- a. Esses testes e resultados estão disponíveis apenas usando as tiras reagentes Multistix Pro.
- b. A amostra está muito diluída para determinar um resultado de relação com precisão. Repita o teste em uma nova amostra.
- c. A coloração pode ser precedida por CL. ou ES. quando determinada pelo analisador. Se forem determinadas visualmente, as descrições padrão poderão ser mudadas pelo usuário. Outras descrições também podem ser informadas.
- d. Determinado visualmente. Os resultados informados são descrições padrão que podem ser mudadas pelo usuário.

Table D-13: Portuguese, Units—International (SI)

Exame	Impresso	Unidades		Valores rel	atados	
			Sistema padrão		Sistema PLUS	
Glicose	GLI	mmol/L	NEGATIVO	28	NEGATIVO	2+
			5,5	>=55	INDICIO	3+
			14		1+	
Bilirrubina	BIL		NEGATIVO	MODERADO	NEGATIVO	2+
			PEQUENO	GRANDE	1+	3+
Acetona	CET	mmol/L	NEGATIVO	3,9	NEGATIVO	2+
			INDICIO	>=7,8	INDICIO	3+
			1,5		1+	
Densidade	DEN		<=1,005	1,020	Sem diferenças	
			1,010	1,025		
			1,015	>=1,030		
Sangue oculto	SAN		NEGATIVO	PEQUENO	NEGATIVO	1+
			INDICIO-LISADO	MODERADO	INDICIO-LISADO	2+
			INDICIO- INTACTO	GRANDE	INDICIO-INTACTO	3+

Exame	Impresso	Unidades		Valores rel	atados	
			Sistema padrão		Sistema PLUS	
рН	рН		5,0	7,5	Sem diferenças	
			5,5	8,0		
			6,0	8,5		
			6,5	>=9,0		
			7,0			
Urobilinogênio	URO	μmol/L	3,2	66	Sem diferenças	
			16	>=131		
			33			
Nitrito	NIT		NEGATIVO	POSITIVO	Sem diferenças	
Leucócitos	LEU		NEGATIVO	MODERADO	NEGATIVO	2+
			INDICIO	GRANDE	INDICIO	3+
			PEQUENO		1+	
Proteína	PRO	g/L	NEGATIVO	1,0	NEGATIVO	2+
			INDICIO (0,15 <sup>a</sup> )	$>=3,0 (3,0^a)$	INDICIO (BAIXO <sup>a</sup> )	3+
			0,3		1+	

Exame	Impresso	Unidades		Valores relat	ados
			Sistema padrão		Sistema PLUS
Creatinina <sup>a</sup>	CRE	mmol/L	0,9	17,7	Sem diferenças
			4,4	26,5	
			8,8		
Relação	P:C	mg/mmol	DILUIDO NORMAL	b -	Sem diferenças
proteína- creatinina <sup>a</sup>			NORMAL	33,9 ANORMAL	
Creatifilia			17,0 ANORMAL	>56,6 ANORMAL	
Cor <sup>c</sup>	COR		AMARELO	VERDE	Sem diferenças
			LARANJA	AZUL	
			VERMELHO	MARROM	
Aspecto <sup>d</sup>	ASP		CLARO	TURVO	Sem diferenças
			POUCO NEBULOSO	OUTROS	
			NEBULOSO		

a. Esses testes e resultados estão disponíveis apenas usando as tiras reagentes Multistix Pro.

b. A amostra está muito diluída para determinar um resultado de relação com precisão. Repita o teste em uma nova amostra.

c. A coloração pode ser precedida por CL. ou ES. quando determinada pelo analisador. Se forem determinadas visualmente, as descrições padrão poderão ser mudadas pelo usuário. Outras descrições também podem ser informadas.

d. Determinado visualmente. Os resultados informados são descrições padrão que podem ser mudadas pelo usuário.

Table D-14: Swedish, Units—Conventional

Test	Förkortning	Enheter		Rapporterade r	esultat	
			Normalt system		Plussystem	
Glukos	GLU	mmol/L	NEGATIV	500	NEGATIV	2+
			100	>=1000	SPAAR	3+
			250		1+	
Bilirubin	BIL		NEGATIV	LAGOM	NEGATIV	2+
			LITEN	STOR	1+	3+
Keton	KET	mg/dL	NEGATIV	40	NEGATIV	2+
			SPAAR	>=80	SPAAR	3+
			15		1+	
Specifik vikt	SG		<=1,005	1,020	Ingen skillnad	
			1,010	1,025		
			1,015	>=1,030		
Ockult blod	BLD		NEGATIV	LITEN	NEGATIV	1+
			SPAAR-LYSERAD	LAGOM	SPAAR-LYSERAD	2+
			SPAAR-INTAKT	STOR	SPAAR-INTAKT	3+

Test	Förkortning	Enheter	Rapporterade resultat				
			Normalt system		Plussystem		
рН	рН		5,0	7,5	Ingen skillnad		
			5,5	8,0			
			6,0	8,5			
			6,5	>=9,0			
			7,0				
Urobilinogen	UBG	E.U./dL	0,2	4,0	Ingen skillnad		
			1,0	>=8,0			
			2,0				
Nitrit	NIT		NEGATIV	POSITIV	Ingen skillnad		
Leukocyter	LEU		NEGATIV	LAGOM	NEGATIV	2+	
			SPAAR	STOR	SPAAR	3+	
			LITEN		1+		
Protein	PRO	mg/dL	NEGATIV	100	NEGATIV	2+	
			SPAAR (15 <sup>a</sup> )	$>=300 (300^{a})$	SPAAR (LAAG <sup>a</sup> )	3+	
			30		1+		

Test	Förkortning	Enheter		Rapporterade re	esultat
			Normalt system		Plussystem
Kreatinin <sup>a</sup>	CRE	mg/dL	10	200	Ingen skillnad
			50	300	
			100		
Protein-	P:C	mg/g	NORMAL SPAEDNING	b	Ingen skillnad
kreatinin-kvot <sup>a</sup>			NORMAL		
			150 ONORMAL		
			300 ONORMAL		
			>500 ONORMAL		
Färg <sup>c</sup>	COL		GUL	GROEN	Ingen skillnad
			ORANGE	BLAA	
			ROED	BRUN	
Klarhet <sup>d</sup>	CLA		KLAR	GRUMLIG	Ingen skillnad
			ANINGEN OKLAR	ANNAT	
			OKLAR		

- a. De här testerna och resultaten finns endast om du använder Multistix-Pro reagensstickor.
- b. Det går inte att bestämma rätt kvotresultat eftersom proverna är för utspädda. Upprepa testet med ett nytt prov.
- c. Färg kan föregås av CL eller DK när den bestäms med analysinstrumentet. Om färgen bestäms med ögat kan standardbeskrivningar ändras av användaren. Även annat kan rapporteras.
- d. Bestämd med ögat. Rapporterade resultat är standardbeskrivningar som kan ändras av användaren.

Table D-15: Swedish, Units—International (SI)

Test-	Utskrivna	Enheter		Rapporterade	värden	
			Standardsystem		PLUS-system	
Glukos	GLU	mmol/L	NEGATIV	28	NEGATIV	2+
			5,5	>=55	SPAAR	3+
			14		1+	
Bilirubin	BIL		NEGATIV	LAGOM	NEGATIV	2+
			LITEN	STOR	1+	3+
Keton	KET	mmol/L	NEGATIV	3,9	NEGATIV	2+
			SPAAR	>=7,8	SPAAR	3+
			1,5		1+	
Specifik	DEN		<=1,005	1,020	Ingen skillnad	
gravitet			1,010	1,025		
			1,015	>=1,030		
Ockult blod	BLD	Ery/μL	NEGATIV	Ca 25	NEGATIV	1+
			SPAAR-LYSERAD	Ca 80	SPAAR-LYSERAD	2+
			SPAAR-INTAKT	Ca 200	SPAAR-INTAKT	3+

Test- Utskrivn		Enheter		Rapporterad	e värden	värden			
			Standardsystem		PLUS-system				
рН	рН		5,0	7,5	Ingen skillnad				
			5,5	8,0					
			6,0	8,5					
			6,5	>=9,0					
			7,0						
Urobilinogen	UBG	μmol/L	3,2	66	Ingen skillnad				
			16	>=131					
			33						
Nitrit	NIT		NEGATIV	POSITIV	Ingen skillnad				
Leukocyter	LEU	Leu/µL	NEGATIV	Ca 125	NEGATIV	2+			
			Ca 15	Ca 500	SPAAR	3+			
			Ca 70		1+				
Protein	PRO	g/L	NEGATIV	1,0	NEGATIV	2+			
			SPAAR (0,15 <sup>a</sup> )	$>=3,0 (3,0^a)$	SPAAR (LAAG <sup>a</sup> )	3+			
			0,3		1+				

Test-	Utskrivna	Enheter		Rapporterade	värden
			Standardsystem		PLUS-system
Kreatinin <sup>a</sup>	CRE	mmol/L	0,9	17,7	Ingen skillnad
			4,4	26,5	
			8,8		
Protein-	P:C	mg/mmol	NORMAL SPAEDNII	νG <sup>b</sup>	Ingen skillnad
kreatinin-kvot <sup>a</sup>			NORMAL		
			17,0 ONORMAL		
			33,9 ONORMAL		
			>56,6 ONORMAL		
Faerg <sup>c</sup>	COL		GUL	GROEN	Ingen skillnad
			ORANGE	BLAA	
			ROED	BRUN	
Klarhet <sup>d</sup>	CLA		KLAR	GRUMLIG	Ingen skillnad
			ANINGEN OKLAR	ANNAT	
			OKLAR		

a. De här testerna och resultaten finns endast om du använder Multistix-Pro reagensstickor.

b. Det går inte att bestämma rätt kvotresultat eftersom proverna är för utspädda. Upprepa testet med ett nytt prov.

c. Färg kan föregås av CL eller DK när den bestäms med analysinstrumentet. Om färgen bestäms med ögat kan standardbeskrivningar ändras av användaren. Även annat kan rapporteras.

d. Bestämd med ögat. Rapporterade resultat är standardbeskrivningar som kan ändras av användaren.

Table D-16: Swedish, Units—Nordic Plus System

Test-	Utskrivna	Enheter		Rapporterade	resultat	
			Normal-system		PLUS-system	
Glukos	GLU		NEGATIV	3+	NEGATIV	2+
			1+	4+	SPAAR	3+
			2+		1+	
Bilirubin	BIL		NEGATIV	2+	Ingen skillnad	
			1+	3+		
Keton	KET		NEGATIV	3+	NEGATIV	2+
			1+	4+	SPAAR	3+
			2+		1+	
Specifik gravitet	DEN		<=1,005	1,020	Ingen skillnad	
			1,010	1,025		
			1,015	>=1,030		
Ockult blod	BLD		NEGATIV	1+	Ingen skillnad	
			+/-	2+		
			+/- INTAKT	3+		

Test-	Utskrivna	Utskrivna Enheter		Rapporter	ade resultat	resultat			
			Normal-syster	n	PLUS-system				
рН	рН		5,0	7,5	Ingen skillnad				
			5,5	8,0					
			6,0	8,5					
			6,5	>=9,0					
			7,0						
Urobilinogen	URO	μmol/L	3,2	66	Ingen skillnad				
			16	>=131					
			33						
Nitrit	NIT		NEGATIV	POSITIV	Ingen skillnad				
Leukocyter	LEU		NEGATIV	3+	NEGATIV	2+			
			1+	4+	SPAAR	3+			
			2+		1+				
Protein	PRO		NEGATIV	2+	NEGATIV	2+			
			+/- (LAAG <sup>a</sup> )	3+	SPAAR (LAAG <sup>a</sup> )	3+			
			1+		1+				

Test-	Utskrivna	Enheter	Rapporterade resultat		
			Normal-system		PLUS-system
Kreatinin <sup>a</sup>	KRE	mmol/L	0,9	17,7	Ingen skillnad
			4,4	26,5	
			8,8		
Protein- kreatinin-kvot <sup>a</sup>	P:K	mg/mmol	NORMAL SPAEDNING <sup>b</sup>		Ingen skillnad
			NORMAL	33,9 ONORMAL	
			17,0 ONORMAL	>56,6 ONORMAL	
Faerg <sup>c</sup>	COL		GUL	GROEN	Ingen skillnad
			ORANGE	BLAA	
			ROED	BRUN	
Klarhet <sup>d</sup>	CLA		KLAR	GRUMLIG	Ingen skillnad
			ANINGEN OKLAR	ANNAT	
			OKLAR		

- a. De här testerna och resultaten finns endast om du använder Multistix-Pro reagensstickor.
- b. Det går inte att bestämma rätt kvotresultat eftersom proverna är för utspädda. Upprepa testet med ett nytt prov.
- c. Färg kan föregås av CL eller DK när den bestäms med analysinstrumentet. Om färgen bestäms med ögat kan standardbeskrivningar ändras av användaren. Även annat kan rapporteras.
- d. Bestämd med ögat. Rapporterade resultat är standardbeskrivningar som kan ändras av användaren.

Table D-17: Japanese, Units—Conventional

検査	印刷	単位	報告された結果			
			標準システム		プラスシステ	۲-
Glucose	GLU	g/dL	-	0.5	-	2+
(ブドウ糖)			0.1	>=1.0	+/-	3+
			0.25		1+	
Bilirubin	BIL		-	2+	同左	
(ビリルビン)			1+	3+		
Ketone	KET		-	2+	同左	
(ケトン体)			+/-	3+		
			1+			
Specific Gravity	SG		<=1.005	1.020	同左	
(比重) (屈折率 - 0.005 選択単位)			1.010	1.025		
(畑州平 - 0.003 医扒羊瓜)			1.015	>=1.030		
Occult Blood	OB		-	1+	同左	
(潜血)			+/- LYSED	2+		
			+/- INTACT	3+		

検査	印刷	単位		報告された約	·····································	
		標準システム	4	プラスシス	テム	
рН	рН		5.0	7.5	同左	
			5.5	8.0		
			6.0	8.5		
			6.5	>=9.0		
			7.0			
Protein	PRO	mg/dL	-	100	-	2+
(蛋白質)			+/- (15 <sup>a</sup> )	>=300 (300 <sup>a</sup> )	+/-(LOW <sup>a</sup> )	3+
			30		1+	
Urobilinogen	URO	E.U./dL	0.1	4.0	同左	
(ウロビリノーゲン)			1.0	>=8.0		
			2.0			
Nitrite (亜硝酸塩)	NIT		-	+	同左	
Leukocytes	WBC		-	2+	同左	
(白血球)			+/-	3+		
			1+			

検査	印刷 単位		報告された結果		
			標準システム		プラスシステム
Creatinine	CRE	mg/dL	10	200	同左
(クレアチニン) <sup>a</sup>			50	300	
			100		
Protein-to-Creatinine Ratio	P:C	mg/g	NORMAL DILUTEb		同左
(蛋白 / クレアチニン比) <sup>a</sup>			NORMAL	300 ABNORMAL	
			150 ABNORMAL	>500 ABNORMAL	
Color	COL		YELLOW	GREEN	同左
(色調) <sup>c</sup>			ORANGE	BLUE	
			RED	BROWN	
Clarity	CLA		-	2+	同左
(混濁) d			+/-	OTHER	
			1+		

a. MULTISTIX PRO 試験紙を使用した場合のみ、これらの検査を実施して結果を得ることができます。

b. 尿検体が希薄すぎます。正確な結果を得ることができません。新たに採取した検体 (早朝第一尿が望ましい)で再検査してください。

c. 色調を尿分析器で測定する場合、"LT." (Light) または "DK." (Dark) を表示することがあります。 見た目で判断する場合、ユーザーが初期設定の説明を変更することができます。"OTHER" もレポートできます。

d. 目視判定します。目視判定する場合、ユーザーが初期設定の表示値を変更することができます。

Table D-18: Japanese, Units—JCCLS

検査	印刷	単位	報告された結果		果	
			標準システム		プラスシス	テム
Glucose	GLU	mg/dL	-	500	-	3+
(ブドウ糖)			100	>=1000	1+	4+
			250		2+	
Bilirubin	BIL		-	2+	同左	
(ビリルビン)			1+	3+		
Ketone	KET		-	2+	同左	
(ケトン体)			+/-	3+		
			1+			
Specific Gravity	SG		<=1.005	1.020	同左	
(比重) (屈折率 - 0.005 選択単位)			1.010	1.025		
(周列举 - 0.003 選扒单位)			1.015	>=1.030		
Occult Blood (潜血)	ОВ		-	1+	同左	
			+/- LYSED	2+		
			+/- INTACT	3+		

検査	印刷	印刷 単位		報告された	結果	
			標準システム	<u>ل</u>	プラスシス	テム
рН	рН		5.0	7.5	同左	
			5.5	8.0		
			6.0	8.5		
			6.5	>=9.0		
			7.0			
Protein	PRO	mg/dL	-	100	-	2+
(蛋白質)			+/- (15 <sup>a</sup> )	>=300(300 <sup>a</sup> )	+/-(LOW <sup>a</sup> )	3+
			30		1+	
Urobilinogen	URO	E.U./dL	0.1	4.0	同左	
(ウロビリノーゲン)			1.0	>=8.0		
			2.0			
Nitrite (亜硝酸塩)	NIT		-	+	同左	
Leukocytes	WBC		-	2+	同左	
(白血球)			+/-	3+		
			1+			

検査	印刷	単位		報告された結	i果
			標準システム		プラスシステム
Creatinine	CRE	mg/dL	10	200	同左
(クレアチニン) <sup>a</sup>			50	300	
			100		
Protein-to-Creatinine Ratio	P:C	mg/g	NORMAL DILUTEb		同左
(蛋白 / クレアチニン比) <sup>a</sup>			NORMAL		
			150 ABNORMAL		
			300 ABNORMAL		
			>500 ABNORMAL		
Color	COL		YELLOW	GREEN	同左
(色調) <sup>c</sup>			ORANGE	BLUE	
			RED	BROWN	
Clarity	CLA		-	2+	同左
(混濁) <sup>d</sup>			+/-	OTHER	
			1+		

- a. MULTISTIX PRO 試験紙を使用した場合のみ、これらの検査を実施して結果を得ることができます。
- b. 尿検体が希薄すぎます。正確な結果を得ることができません。新たに採取した検体 (早朝第一尿が望ましい)で再検査してください。
- c. 色調を尿分析器で測定する場合、"LT." (Light) または "DK." (Dark) を表示することがあります。
  - 見た目で判断する場合、ユーザーが初期設定の説明を変更することができます。"OTHER"もレポートできます。
- d. 目視判定します。目視判定する場合、ユーザーが初期設定の表示値を変更することができます。

#### Table D-19:

Table D-20: German Conventional UnitsGerman S.I. UnitsFrench
Conventional UnitsFrench S.I. UnitsItalian Conventional
UnitsItalian S.I. UnitsSpanish Conventional UnitsSpanish S.I.
UnitsPortuguese Conventional UnitsPortuguese S.I.
UnitsSwedish Conventional UnitsSwedish S.I. UnitsSwedish
Nordic UnitsKatakana (JAPANESE) Conventional
UnitsKatakana (JAPANESE) JCCLS Units

# Appendix E: Barcode Reader

### **General Information**

You can use the optional CLINITEK Advantus handheld barcode reader to:

- scan barcoded labels that are adhered to the specimen tubes,
- scan the color and clarity barcodes from the special card that is included with the reader
- enter lot and expiration information
- enter patient and operator IDs.

The software in the barcode reader automatically distinguishes between barcode formats.

Note You must configure the barcode prior to use.

### Installing the Handheld Barcode Reader

Use the following procedure to install the hand held barcode reader:

- 1. Turn analyzer power off.
- 2. Connect the interface cable to the opening at the bottom of the handheld barcode reader.
- 3. Connect the other end of the cable to the barcode reader port at the back of the analyzer.
- 4. Press in firmly until the connection is secure and you hear a slight click.
- 5. Turn analyzer power on.
  - The handheld barcode reader should beep.
- 6. Scan the configuration barcodes provided on the barcode card.
  - Scan all barcodes in the order listed on the card. Scan each barcode only one time.
  - The reader automatically processes the codes, without user intervention.

**Note** Do not scan any of the barcodes provided by the manufacturer for setting up the reader. These may change the parameters required by the analyzer.

- 7. Test your barcode reader, and select the correct parameters for the labels used in your laboratory. See *Barcode Reader Options*, page 133, in this guide for more information.
- 8. Attach the backing included with the reader bracket to the bracket.
- 9. Set the bracket near the analyzer.

## Testing the Barcode Reader

Ensure that your barcode reader has been correctly installed using the procedure in *Installing the Handheld Barcode Reader*. Ensure that the barcoded labels used in your laboratory comply with the specifications given later in this section.

Use the following procedure to test the hand held barcode reader:

- 1. Obtain a label for which you know the barcode value.
- 2. Attach the label to a specimen tube or cup.
- 3. At the Ready/Run screen, select **Menu**.
- 4. Select **Setup**.
- 5. Select **Next Screen** eight times to access the ninth Setup screen.
- 6. Select **Perform hardware tests**.
- 7. Select Bar code reader.
- 8. Aim the reader toward the barcode.
- 9. Press and hold the trigger.
- 10. Move the reader until the red line crosses the entire width of the barcode.

The reader beeps, and the number displays on the analyzer screen.

- 11. If the result is not correct, or if the barcode cannot be read, repeat the test using a new label.
- 12. If the result is still not correct, see Troubleshooting, below.

## **Troubleshooting**

It is important that the labels be printed to the required specifications. Reading errors may occur if any of the following conditions exist:

- The narrow bar width is too small
- The barcode length too great
- The height too small
- The reader is held too far from the label
- The background reflection too high or low

The test labels included with the barcode reader can be used to verify the operation of the reader. Two sheets of labels are provided. Each sheet contains 2 labels in each of the 6 symbology and check digit combinations. These test labels are of a known quality, printed within the barcode reader specifications.

If the reader is not able to consistently read your labels, apply a test label of the format being used to a new specimen tube and perform the Barcode Test. If the reader is able to read the test label, the quality of your labels may be suspect. If the test label cannot be read, the reader itself is suspect.

If you have problems that cannot be resolved, contact your local technical support provider for assistance.

### **Specifications**

#### **Barcode Formats**

The CLINITEK Advantus barcode reader meets the requirements of ASTM E1466-92, "Standard Specification for Use of Bar Codes on Specimen Tubes in the Clinical Laboratory" (available from ASTM, 100 Barr Harbor Dr., West Conshohocken, PA 19428).

#### **Barcode Symbols and Labels**

The barcode symbols, and the labels themselves, must meet certain specifications, detailed below:

**Number of Characters:** 1 to 30 data characters. A maximum of 13 characters can be displayed, stored and transmitted by the CLINITEK Advantus analyzer. Excess characters must be removed as leading or trailing characters.

**Narrow Bar Width:** 0.15 to 0.51 mm (0.006 to 0.02 in). It is better to be closer to the upper limit (0.51 mm/0.02 inch), as long as the entire barcode can be contained within the maximum length.

This measurement effects both the symbol length and how far away from the label you can hold the handheld barcode reader. If the narrow bar width is at the minimum, the symbol length can be no greater than 90 mm (3.5 in), including quiet zones, and the reader can be held no more than 75 mm (3 in) away.

**Narrow to Wide Ratio:** Must be within the specifications for the format being used. This is generally 2.0 to 3.0.

**Symbol Length:** Variable. See *Narrow Bar Width* for more information.

**Quiet Zone:** Minimum of ten times the narrow bar width at each end of the symbol.

Symbol Height: Minimum of 10 mm (0.40 in).

**Total Size of Label:** May be greater than the size of the symbol to allow for printing of human readable information. Printing of the specimen ID number in alphanumeric digits is strongly recommended.

**Symbol grade:** Minimum grade of "C" as defined by ANSI X3.182-1990 (available from American National Standards Institute, 1430 Broadway, New York, NY 10018).

Wavelength of Light: 630 nm (visible red LED).

#### Maintenance



#### CAUTION

Do not submerge the reader in water. The reader's housing is not water-tight.

Do not use laboratory wipes, such as Kimwipes, because they may scratch the window.

Do not use any type of solvent to clean the reader. Harsh chemicals can damage the finish or the window.

Clean the barcode reader window whenever it appears dirty or smeared:

- 1. Wipe the reader window with a soft cloth or facial tissue dampened with water, or a mild detergent-water solution.
- 2. If a detergent solution is used, rinse with a soft cloth or facial tissue dampened with water only.
- 3. Clean the plastic case in the same manner.

## Appendix F: Computer and Printer Interface

#### **General Information**

You can connect the CLINITEK Advantus analyzer to a host computer or Laboratory Information System (LIS). You can also connect an 80-column or form printer. This appendix contains the specifications needed for the interface cables required. Contact your local technical support provider for additional information on programs to interface the analyzer to a computer or LIS.

### Cable and Pin Specifications - Computer

You can use a null modem serial cable, or ethernet cable, to interface with the CLINITEK Advantus analyzer.

The null modem cable crosses pins 2 and 3, 4 and 6, and 7 and 8. Pin 5 is straight through.

Serial cable pin assignments and hardware handshaking are described below.

To connect from the ethernet port to a network, use a standard straight-through CAT 5 cable. To connect directly to a PC, use a crossover CAT 5 cable.

## Pin Assignments for Interface Cable – Serial Port

Pin Number	Signal Name	Function	Туре	Signal Source
2	RXD	Receive Data	Data	Computer
3	TXD	Transmit Data	Data	CLINITEK Advantus
4	DTR	Data Terminal Ready	Control	CLINITEK Advantus
5	SG GND	Signal Ground	Ground	N/A
6	DSR	Data Set Ready	Control	Computer
7	RTS	Request To Send	Control	CLINITEK Advantus
8	CTS	Clear to Send	Control	Computer

All other pins are unused.

### **Hardware Handshaking**

Signal Name	Function	Description
TXD	Transmit Data	This output sends test data, control characters, and analyzer information.
RXD	Receive Data	This input receives control characters for software handshaking and data for IDs.
RTS	Request to Send	This output line, when high, indicates to the computer that it may send data.
CTS	Clear to Send	This input is checked before sending each character, and, if high, the next character is sent. If it is not supplied by the computer, jumper pin 7 to pin 8.
DSR	Data Set Ready	The computer must raise this line whenever it is ready to receive data. If it is not supplied by the computer, jumper pin 4 to pin 6.
DTR	Data Terminal Ready	This signal is on whenever the analyzer IO is configured for a computer and the computer is on.

The following signal line is not implemented.

Signal Name	Function	Description
DCD	Data Carrier Detect	Pin 1
RNG	Ring Indicator	Pin 9

## **Cable and Pin Specifications – Printer**

The parallel data printer port is a Centronics style with a DB-25 connector.

You can use any standard 80-column printer with a Centronics style interface.

- Set the External Printer option to **On, 80-column**. See *Printer*, page 108 for more information.
- Ensure that the interface cable contains a DB-25 male connector. This is the standard IBM configuration.

The analyzer also generates data suitable for use with the following 3 types of form printers.

Printer Products Form Printer – Set the external printer option to **On**, **Form Printer 1**. This format adds 9 spaces to the beginning of each line, so that the results are in the proper location on the CLINITEK Report Form.

CLINITEK Form Printer – Set the external printer option to **On, Form Printer 2**. This format does not add additional spaces to the front of the line.

Star Form Printer or another simple form printer – Set the external printer option to **On, Form Printer 3.** This format does not add additional spaces to the front of the line. This format also includes commands to the printer preventing it from printing a record until a form is in place, and ejecting the form when printing is complete.

If any of the form printer formats are used, the display includes a Reprint key that you can use if a record needs reprinting.

To determine the best format, print a record using each of the Form Printer options.

# Pin Assignments for Interface Cable – DB-25 Male Connector

Pin Number	Signal Name	Function	Note	Signal Source
1	STROBE-L	Data Strobe	1	CLINITEK Advantus
2	Data 1	Parallel Data Line		CLINITEK Advantus
3	Data 2	Parallel Data Line		CLINITEK Advantus
4	Data 3	Parallel Data Line		CLINITEK Advantus
5	Data 4	Parallel Data Line		CLINITEK Advantus
6	Data 5	Parallel Data Line		CLINITEK Advantus
7	Data 6	Parallel Data Line		CLINITEK Advantus
8	Data 7	Parallel Data Line		CLINITEK Advantus
9	Data 8	Parallel Data Line		CLINITEK Advantus
11	BUSY	Busy Line		Printer
12	PRINTER OUT	Printer Out Line		Printer
18	SIG GND	Signal Ground	2	N/A

#### **Notes**

	Signal Name	Function	Description
1	STROBE-L	Data Strobe	-L indicates active low signal
2	SIG GND	Signal Ground	Pins 19 through 25 are also connected to the signal ground.

## Appendix G: Symbols

## **System and Packaging**

This section describes the symbols that can display in the analyzer documentation, the exterior of the CLINITEK Advantus analyzer, or on the analyzer packaging. The symbols on the analyzer provide you with the location of certain components and with warnings for proper operation. The symbols on the analyzer packaging provide you with other important information. For information on the symbols that can display on the CLINITEK Advantus reagent packaging and labeling, see the related assay instruction for use.

# Symbol Description This symbol is used for both Warnings and Cautions. A Warning indicates the risk of personal injury or loss of life if operating procedures and practices are not correctly followed. A Caution indicates the possibility of loss of data or damage to or destruction of equipment if operating procedures and practices are not strictly observed. This symbol alerts you to a biohazard. This symbol indicates that the input electricity is alternating current. This symbol identifies the location of a power connector (power cord). This symbol identifies the location of a printer port. These symbols identify the location of a barcode reader or keyboard port. This symbol identifies the location of a serial port.

Symbol	Description
11	This symbol identifies the location of an ethernet port.
	This symbol indicates that the main power supply is on.
$\bigcirc$	This symbol indicates that the main power supply is off.
5°C - 1 40°C	This symbol indicates that the product has a temperature limitation. You need to store the product between $5-40^{\circ}$ C.
IVD	This symbol indicates an <i>in vitro</i> diagnostic device or an <i>in vitro</i> diagnostic medical device.
<u>Ti</u>	This symbol indicates that you should consult instructions for use.
Ī	This symbol indicates that the product is fragile and you need to handle it with care.
<b>†</b>	This symbol indicates that you should keep the product dry.
誉	This symbol indicates that you should keep the product away from sunlight and heat.
<b>(P)</b>	This symbol indicates that the product is heavy, and should only be lifted by two or more persons.
<u></u>	This symbol indicates a temperature hazard. In this instance, the hazard is from a printer component.

Symbol	Description
	This symbol cautions you to observe precautions for handling electrostatic sensitive devices, to avoid causing a hazard to the product.
$\dot{\uparrow}$	This symbol indicates that the instrument is type B equipment, which provides a particular degree of protection against electric shock.
X	This symbol indicates to follow the appropriate procedures for disposal of electrical and electronic equipment.
REF	This symbol indicates the number used for ordering a part or product.
SN	This symbol indicates the serial number of a part or product.
Rev.	This symbol indicates the revision letter of a part or product.
	This symbol indicates the name and location of the product manufacturer.
M	This symbol indicates the date of manufacture of the product.
EC REP	This symbol indicates the manufacturer's authorized representative within the European community.
	This symbol indicates that the product or container should be oriented in the direction of the arrows.
<b>⊕</b>	This symbol indicates that the product or container contains recycled material.
REZY	This symbol is intended to facilitate recycling of corrugated materials. The number is licensed in Germany and printed on corrugated shippers.

This symbol indicates that the product complies with the applicable directives of the European Union.

( (

Symbol	Description
$\Rightarrow$	This symbol indicates information about the fuse.
c (UL) us Listed 5N48 Laboratory Equipment	This symbol indicates that the product is CSA approved for safety (United States and Canada).

## **User Interface**

This section describes the symbols that display on the analyzer user interface.

Key	Name	Description
	Action Key	Many options are next to an Action key. Select this key to select the option. The display always changes to another screen, where you can either start the selected routine or define how the selected option will work.
Ω	Cycle Key	Some options are next to a Cycle key. Use the cycle key when several options are available. Each time you select the key, a different option displays for the selection. When the option you want displays, the selection is complete.
<b>✓</b>	Selection Key	Use Selection keys to select or reject the use of an option. If a check mark displays in the key symbol, the option is selected. If the key symbol is empty, the option is not selected.
偷	Return to Ready/Run	Select this key to return to the Ready/Run screen.
		You must select this key when you exit the Setup Routine to save your changes. At any screen where you enter data, you must select Enter before selecting this key to save your data.

Key	Name	Description
	Stop Run	Select this key to cancel the run or the last strip.  If the run is cancelled, all strips on the platform are immediately moved to the waste bin and no results are reported for them.  This key displays on the Ready/Run screen and becomes active as soon as the first strip in a run is detected.
?	Help	Select this key to display a Help screen with information about the screen.  Select Previous Screen from the Help screen to return to the previous screen.  Help is not available on all screens.
<b>→</b>	Next Screen	Select this key to display the next screen in a series. This key displays only if additional screens exist.
+	Previous Screen	Select this key to change the display back to the previous screen in a series. This key displays only if previous screens exist.
4	Enter	Select this key to accept data you enter, such as ID and sequence numbers, date, and time. If you exit the screen without selecting Enter, the analyzer does not save the newly entered data and retains any data in memory.
<b>→</b>	Move Right	Select this key to move the cursor one space to the right.  If the cursor is at its right-most position, selecting this key has no effect. Moving the cursor does not erase any characters and new characters can be entered directly over the incorrect characters.

Key	Name	Description
←	Move Left	Select this key to move the cursor one space to the left.
		If the cursor is at its left-most position, the cursor does not move. The character at the current position is usually erased before the cursor is moved to the left. If this key displays in conjunction with the Move Right key, the existing characters are not erased as the cursor is moved.
lacktriangle	Move Up	Select this key to display the previous stored result or entry in descending order (lower sequence number).
<b>1</b> 10	Move Up 10	Select this key to display the record stored ten positions lower than the currently displayed record. If fewer than ten lowernumbered results exist, the oldest stored result or entry displays.
<b>1</b>	Move Down	Select this key to display the next stored result or entry in ascending order (higher sequence number).
<b>↓10</b>	Move Down 10	Select this key to display the record stored ten positions higher than the currently displayed record. If fewer than 10 higher-numbered results exist, the most recently stored result or entry displays.
+	Plus	Select this key to increase the displayed number by 1.
	Minus	Select this key to decrease the displayed number by 1.
A-Z	Alphabet	Select this key to enter alphabetic characters.
$\boxtimes$	Delete	Select this key to delete one or more records.

Key	Name	Description
	Print	Select this key to print one or more records.
	Cancel Print	Select this key to cancel printing.
$\bigcirc$	Resend	Select this key to resend one or more records to a computer.
É	Microscopics	Select this key to display the merged microscopy results.
<b>@</b>	Run QC Sample	Select this key to display the Run Controls screen and test a QC sample.
<b>( &gt;</b>	Loopback	Select this key to start the serial port loopback test.

## **Appendix H: Performance Results**

The CLINITEK Advantus analyzer was evaluated against the CLINITEK 500 analyzer.

The evaluation was conducted at three clinical laboratory sites.

Two (2) reagent strip types (Multistix 10 SG and Multistix PRO 10LS), and 2 lots of each type, were used at each site. Both strip types provide glucose, protein, ketone, SG, pH, occult blood, nitrite, and leukocyte. In addition, the Multistix 10 SG strip provides bilirubin and urobilinogen, while the Multistix PRO 10 LS provides creatinine (and the protein-to-creatinine ratio, P:C, when the strip is used on an analyzer).

Each site tested between 390–400 urine specimens, using protocol guidelines to assure collecting a sufficient number of specimens at each clinical level.

The study results are summarized in *Table H-21* and *Table H-22* below.

Table H-21 shows the example results for sensitivity and specificity, assuming that the comparative method was 100% sensitive and specific. For example, for bilirubin with the comparative method CLINITEK 500 analyzer, this table can be read as follows:

- Sensitivity: For bilirubin, the CLINITEK 500 analyzer reported 204 (N) results as positive. Of these 204 positive results on the CLINITEK 500 analyzer, the CLINITEK Advantus analyzer showed a positive result 86.8% of the time (the observed rate of agreement). The one-sided 95% upper confidence bound (UCB) for this agreement rate is 90.5%.
- Specificity: For bilirubin the CLINITEK 500 analyzer reported 2140
   (N) results as negative. Of these 2140 negative results on the CLINITEK 500 analyzer, the CLINITEK Advantus analyzer showed a negative result 97.3% of the time (the observed rate of agreement). The one-sided 95% upper confidence bound (UCB) for this agreement rate is 97.9%.

For the CLINITEK Advantus analyzer, sensitivity and specificity rates were  $\geq$  85% for all tests; and in most cases, sensitivity and specificity were well over 90%. See *Table H-21*.

Table H-22 presents the example results for the percent of CLINITEK Advantus urine specimen results that had exact agreement and within-one-level agreement with the CLINITEK 500 analyzer.

For example, for bilirubin with the comparative method CLINITEK 500 analyzer, this table can be read as follows:

Over all 2344 (N) bilirubin results on the CLINITEK 500 analyzer, the CLINITEK Advantus analyzer reported exact agreement 95.7% of the time, and within-one-level agreement 99.9 % of the time. These are the observed rates of agreement.

Exact agreement means that the CLINITEK Advantus analyzer reported the same category as the comparative method (or the next closest category if the same category does not exist on the CLINITEK Advantus analyzer). Within-one-level agreement means that the CLINITEK Advantus analyzer reported the same category as or one category lower or higher than the comparative method.

CLINITEK Advantus within-one-level agreement rates were 90%, for all tests, with most cases 99%. See *Table H-22*.

Table H-21: Sensitivity (Positive) and Specificity (Negative), CLINITEK Advantus Analyzer versus CLINITEK 500 Analyzer Using Clinical Laboratory Urine Specimens

Test	Product	N	% Agreement	One Sided 95% Upper Confidence Bound Sensitivity (%)	N	% Agreement	One sided 95% Upper Confidence Bound Specificity (%)
Bilirubin	Multistix 10 SG	204	86.8	90.5	2140	97.3	97.9
Blood	Both <sup>a</sup>	2281	98.6	98.9	2411	94.0	94.8
Glucose	Both	1245	96.1	97.0	3447	98.2	98.6
Ketone	Both	1213	93.9	95.0	3479	97.0	97.4
Leukocyte	Both	1580	91.8	92.9	3112	93.9	94.6
Nitrite	Both	1088	85.7	87.4	3604	96.1	96.6
Protein	10SG	1024	96.7	97.5	1320	95.8	96.7
	Multistix PRO 10 LS	865	99.1	99.5	1483	96.0	96.8
P:C	Multistix PRO 10 LS	1062	92.4	93.7	1162	98.9	99.3
Urobilinogen	Multistix 10 SG	376	96.5	97.9	1968	98.9	99.3

a. Multistix 10 SG and Multistix PRO 10 LS

Table H-22: Exact and Within-One-Level Agreement, CLINITEK Advantus Analyzer versus CLINITEK 500 Analyzer, Clinical Laboratory Urine Specimens

Test	Product	N	Percent Exact Agreement	Percent Within One Level Agreement
Bilirubin	Multistix 10 SG	2344	95.7	99.9
Blood	Both <sup>a</sup>	4692	86.3	99.9
Creatinine	Multistix PRO 10 LS	2348	83.1	100.0
Glucose	Both	4692	94.0	99.8
Ketone	Both	4692	93.8	100.0
Leukocyte	Both	4692	87.5	99.9
Nitrite	Both	4692	93.7	100.0
рН	Both	4692	73.7	97.0
Protein	Multistix 10 SG	2344	91.8	100.0
	Multistix PRO 10 LS	2348	93.1	99.6
P:C	Multistix PRO 10 LS	2224	89.8	97.0
SG	Both	4692	80.9	99.7
Urobilinogen	Multistix 10 SG	2344	93.2	100.0

a. Multistix 10 SG and Multistix PRO 10 LS

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