

# CLINITEK Microalbumin 2 Reagent Strips



**In-service Training**

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# Training Agenda: CLINITEK® Microalbumin 2 Reagent Strips

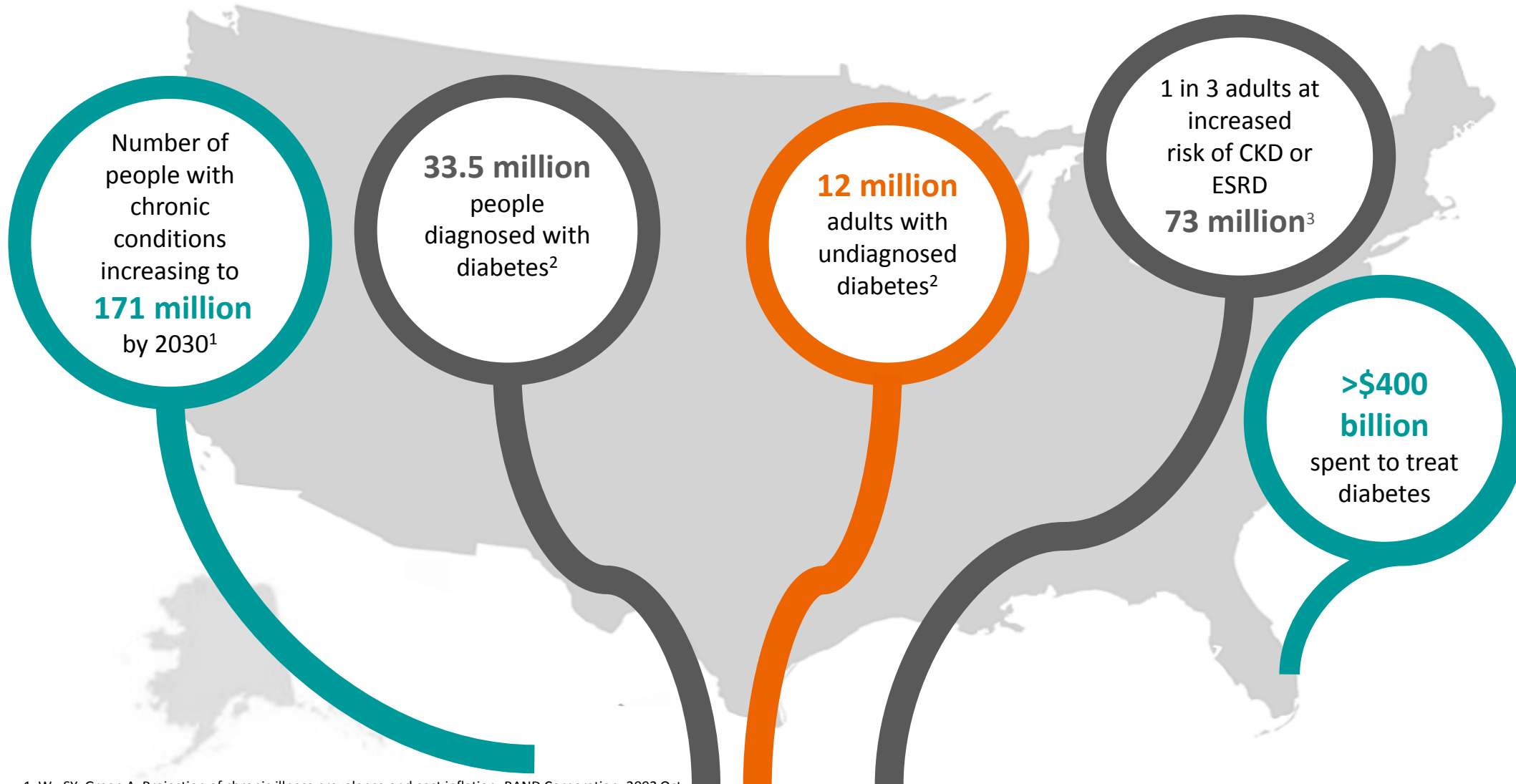
- Diabetes and Kidney Disease Statistics
- Test Overview
- Getting Ready to Test
- Results Interpretation
- Ordering and Reimbursement Information



**Statistics**

# Kidney Disease

# Diabetes Is a Leading Chronic Disease, and Its Burden Continues to Grow<sup>2</sup>



1. Wu SY, Green A. Projection of chronic illness prevalence and cost inflation. RAND Corporation. 2002 Oct.

2. IDF Diabetes Atlas. 8th Edition. 2017.

3. The American Kidney Association. The facts about CKD. 2013. Available at: [www.kidney.org](http://www.kidney.org)

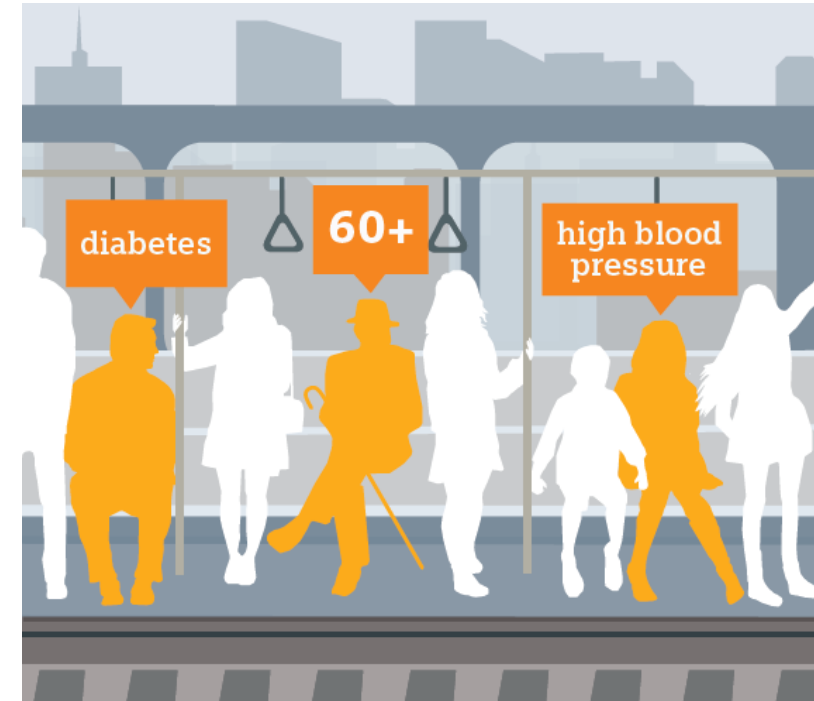
# Common Risk Factors May Impact Family and Friends

National Kidney Foundation (NKF) updated the risk factors to include persons with:

- Diabetes
- High blood pressure (hypertension)
- Age 60 or older
- Family history of kidney failure requiring dialysis or transplantation

Annual screening test recommended by NKF:

- Urinary albumin-to-creatinine test
- Blood tests for kidney function
- Glomerular filtration rate (GFR)



- Recommendations for annual check with a urinary albumin test.
- Supports urinary albumin-to-creatinine ratio in a random spot urine collection.
- Measurement of a spot urine sample for albumin alone (whether by immunoassay or by using a sensitive dipstick test specific for albuminuria) without simultaneously measuring urine creatinine (Cr) is susceptible to false-negative and false-positive results.
- Two to three specimens collected in 3 to 6 months to confirm albuminuria with UACR.



[http://care.diabetesjournals.org/content/suppl/2017/12/08/41.Supplement\\_1.DC1](http://care.diabetesjournals.org/content/suppl/2017/12/08/41.Supplement_1.DC1)

## Overview

# CLINITEK® Microalbumin 2 Urine Test

# What is the CLINITEK Microalbumin 2 Urine Test?

- Semiquantitative urine test that provide results in minutes.
- Provides results for albumin, creatinine, and albumin-to-creatinine (A:C) ratio.
- For screening samples for microalbuminuria; positive results should be confirmed with quantitative methods for albumin.
- For patients with diabetes and hypertension and at risk of developing kidney disease and preeclampsia.
- Test results may aid clinicians in the detection of patients at risk of developing kidney damage.





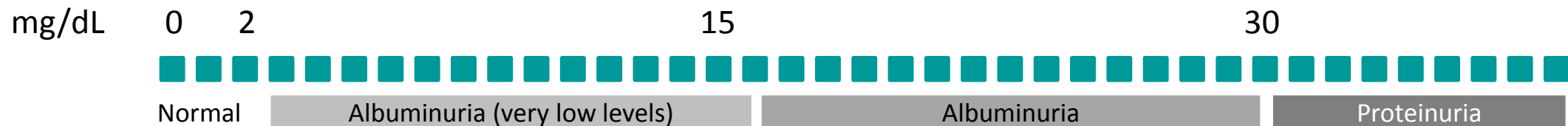
# What Is the Value of the CLINITEK Microalbumin 2 Urine Test?



1. A tool that measures albuminuria as low as 10 mg/dL.
2. A more robust test strip for albumin assessment, since it measures creatinine and provides an albumin-to-creatinine ratio.
3. Offers clinical, operational, and financial benefits:
  - ✓ May reduce false-positive and false-negative results versus measuring albumin alone.
  - ✓ Identifies elevated, clinically significant albumin samples.
  - ✓ Affordable frontline test for early detection of kidney disease in at-risk patients.

# What is Albuminuria?

- Albumin is a type of protein found in blood.
- Helps build muscle, repair tissue, and fight infection.
- Protein from damaged kidneys may leak into urine.
- Albumin is smaller in molecular weight than any of the other proteins.
- Low levels of albumin in the urine of patients with diabetes is clinically significant.
- Urine concentration can impact the albumin measurement.

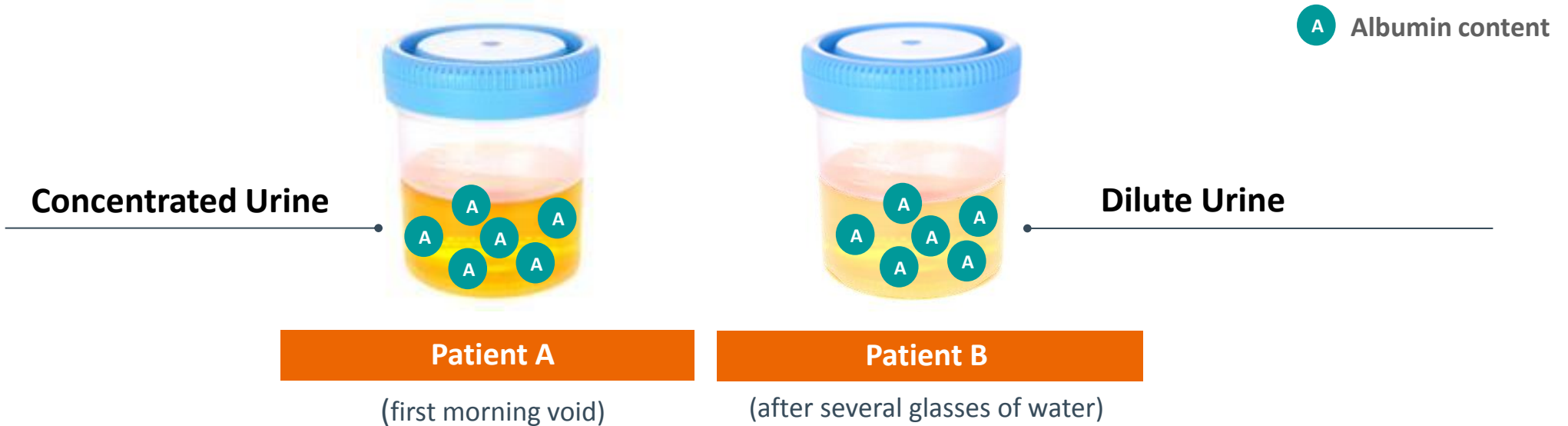


# What Do Frontline Urine Dipstick Tests Measure?

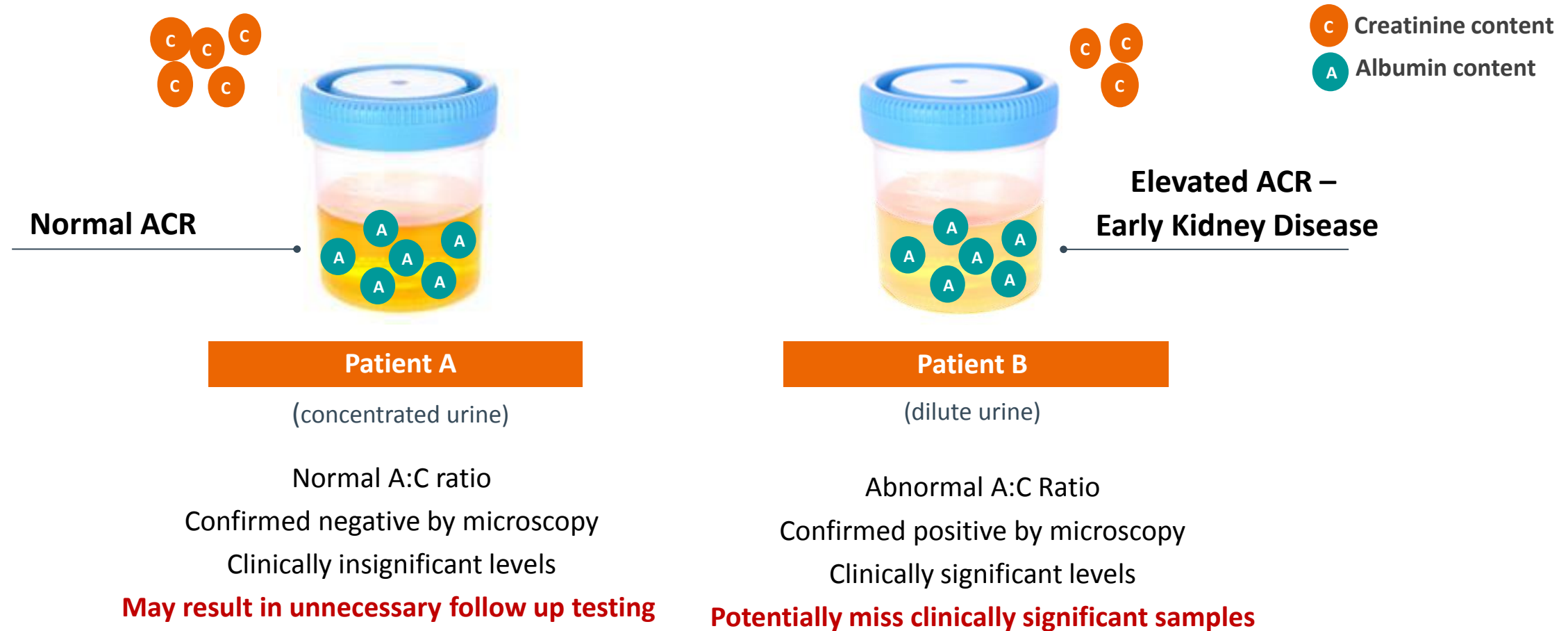
Substance	Description	Semiquantitative Units	
Albumin	Albumin is a type of protein and is one of the smallest by molecular weight	10–150 mg/L	Often indicates early kidney damage
Creatinine	Normal waste product from dehydration of skeletal muscle	10–300 mg/dL	Excreted at a continuous rate into the urine
Albumin-to-creatinine ratio (ACR)	Comparison of albumin and creatinine results obtained from individual urine tests	<30 mg/g (Normal) 30-300 mg/g (Abnormal) >300 mg/g (High Abnormal)	Comparative test that allows a clinician to correct for varying urine concentration in patient samples

# Why is Creatinine Adjustment Important?

Two patients present with the same amount of albumin in their urine.



# Urine Concentration Can Impact Albumin Results and Cause False-Positive or False-Negative Results



**Getting Ready to Test**

# **CLINITEK Micoalbumin 2 Urine Test**

# What You Will Need to Perform the Test

- Patient urine sample
- CLINITEK Microalbumin 2 test strip bottle
- CLINITEK Status® analyzers
- Paper towels

**Note:** This test strip cannot be read visually and is not available on the CLINITEK Advantus® Urine Chemistry Analyzer.



**CLINITEK  
Status+ Analyzer**

- Urinalysis platform supports a broad strip menu and includes rapid test for hCG pregnancy testing



**CLINITEK  
Status Connect System**

- Results automatically transmitted to LIS/HIS/EMR
- QC and operator management function

# Sample Handling Recommendations

- First morning specimens are recommended and random urine specimens are acceptable.
- Urine specimen should be tested as soon as possible.
- If testing cannot be performed within 2 hours after voiding, immediately refrigerate.
- Boric acid at concentration of 1.0 g/L is the only preservative that can be used.
- Specimens can be stored at 0–8°C for one week or at -20°C for one month.
- Refrigerated specimens must be returned to room temperature before testing: 15–30°C (59–86°F).
- Collect specimen in a clean, dry container.





# Test Strip Storage and Handling Recommendations

- Bottles must be stored at 15–30°C (59–86°F).
- Keep unused test strips in bottle with cap securely closed at all times.
- Use test strips before the expiration date printed on bottle label.
- Do not store bottles in direct sunlight.
- Do not remove desiccant included inside the bottle.

**Note:** Protection against exposure to light, heat and ambient moisture is mandatory to guard against altered reagent reactivity.



# Proper Testing Technique for Patient Testing

- Do not touch the test pads on the test strip.
- Dip all the test pads\* into the urine and immediately remove the test strip.
- Follow the 4-step technique shown.
- Do not begin the dipping process until after you press the Start button on the CLINITEK Status analyzer.
  - ✓ Dipping the test strip before pressing the Start button may affect test results.



\*The ID band can be dipped into the urine and control specimens.

# Avoiding Errors

- Can only be read on CLINITEK Status analyzer.
- Record the opening date on the bottle label when opening a new bottle.
- Use a bar-code reader to automatically record lot and expiration dating; analyzer will not allow expired strips to generate test results.
- Remove test strip from the bottle and replace the bottle cap to minimize humidity exposure.
- Do not test on visibly bloody urine or in the presence of hemoglobin or myoglobin  $\geq 5$  mg/dL.
- For best results, do not test on patients with protein results above 30 mg/dL.
- Avoid urine contamination with soaps, detergents, antiseptics, or skin cleansers.



- The presence of cimetidine (TAGAMET) may cause falsely elevated results with the creatinine test.
- Substances that cause abnormal urine color, such as drugs containing azo dyes (e.g., PYRIDIUM, Azo GANTRISIN, Azo GANTANOL), nitrofurantoin (MACRODANTIN, FURADANTIN), and riboflavin, may affect the readability of the reagent areas on urinalysis reagent strips.
- ✓ The color development on the reagent pad may be masked, or a color reaction may be produced on the pad that could be interpreted as a false positive.

# Quality-control Recommendations for ACR Testing

- Test negative and positive controls when opening a new bottle.
- For CLIA-waived labs:
  - ✓ Test negative and positive controls with new lots, new shipments, when opening a new bottle, and monthly for bottles stored more than 30 days.
  - ✓ Run QC tests to train new users, confirm test performance, and when patient's clinical condition do not match test results.
- If QC test results fail, do not test patient samples until the problem is addressed.
- Repeat QC tests until acceptable results are achieved.

## Recommended QC Materials to Use

Vendor	Form Supplied	Shelf Life	Use Life
Quantimetrix Dipper Urine Dipstick Control	Liquid ready	Stable for 7–8 months at 2–8°C, or until expiration date on bottle	Do not freeze. After initial use, each tube of control is stable for 3 months or 20 dipstick immersions, whichever occurs first.
Bio-Rad QUANTIFY Plus Control	Liquid ready	Stable for 2 years at 2–8°C	Opened bottles is stable for 31 days when stored tightly capped at 2–25°C. Do not freeze or store in direct light.
Bio-Rad QUANTIFY Control	Liquid ready	Stable for 12–15 months at 2–8°C, or until expiration date on bottle	Opened bottle is stable for 31 days when stored tightly capped at 2–25°C. Do not freeze.

**Note:** Do not use water as a negative control.

## Results Interpretation

# CLINITEK Microalbumin 2 Urine Test

# Albumin-to-creatinine Results Interpretation by CLINITEK Status Analyzers



Parameter	Units	Instrument Results				
Albumin	mg/L	10	30	80	150	
Creatinine	mg/dL	10	50	100	200	300
Albumin-to-creatinine Ratio	mg/g	30 mg/g (normal)	30–300 mg/g (abnormal)	>300 mg/g (high abnormal)		

**Ordering and Reimbursement Information**

# **CLINITEK Microalbumin 2 Urine Test**



# CLINITEK Microalbumin 2 Test: Ordering Information

Siemens Healthineers Part #	Legacy Part #	Description	Hazard/Refrig.	Packaging
<b>CLINITEK Status® Analyzers and Accessories</b>				
10379675	1780	CLINITEK Status+ Analyzer	–	1
10376323	1790	CLINITEK Status Connector	–	1
10484591	1782	CLINITEK Status Upgrade Kit (includes Status Connector and Bar-code Reader)	–	1
10282579	6502880	Bar-code Scanner (CLINITEK Status Connect and DCA Vantage Analyzers)	–	1
10470849	1797	CLINITEK Status Connect System (includes CLINITEK Status+ Analyzer, Status Connector, and Bar-code Reader)	–	1
11046800	N/A	CLINITEK Status+ V2.62/2.4.2.0 SW UPG KIT U.S. USB (for instruments with connector base)	–	1
11046802	N/A	CLINITEK Status+ V2.62/2.4.2.0 SW UPG KIT U.S. MMC (for instruments without connector base)	–	1
10376825	1795	CLINITEK Status Wireless Adapter	–	1
10328736	5773	Thermal Printer Paper (CLINITEK Advantus, CLINITEK Status, and DCA Vantage Analyzers)	–	5/pk
10324219	1759	Label Printer Paper (CLINITEK Status and DCA Vantage Analyzers)	–	5/pk
<b>Urinalysis Tests and Accessories</b>				
10317439	2083	CLINITEK® Microalbumin 2 Reagent Test Strips (test for semiquantitative determination of microalbumin and creatinine in urine)	–	25s = 1 PC

# CLINITEK Microalbumin 2 CPT Codes

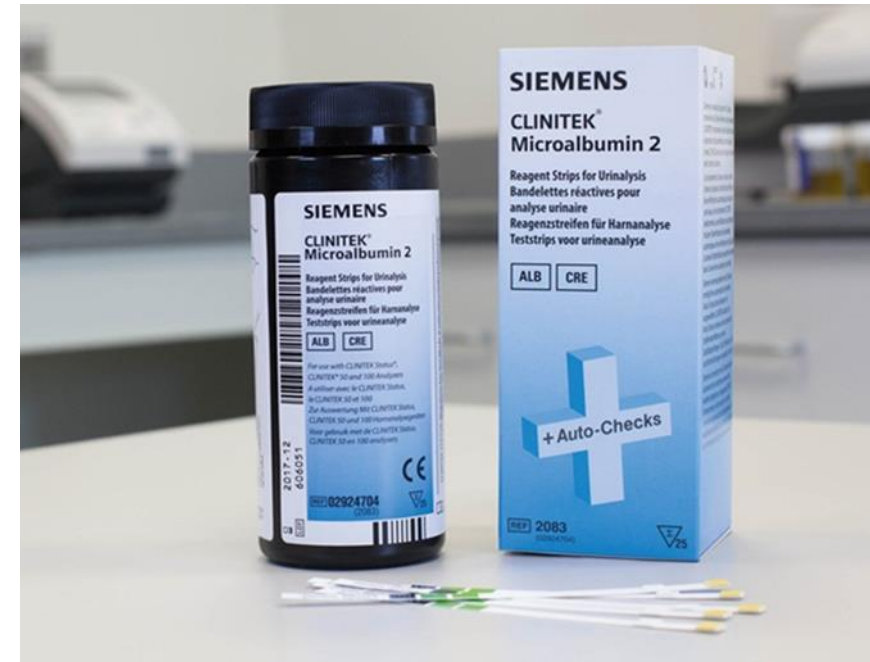


CLINITEK Microalbumin 2	CPT Code	Description*
	82044	Albumin; urine, microalbumin, semi-quantitative (e.g., reagent strip assay)
	82570	Creatinine, other source
	Code both: 82044 and 82570	

\*Abridged CPT code descriptors.

# Why Use the CLINITEK Microalbumin 2 Test?

- Easy to use, CLIA-waived
- Albumin results in 1 minute
- Adjusted for urine concentration
- Meets annual kidney check requirement
- Instrument-read and recorded
- Interfaced to LIS/HIS/EMR



# Thank You for Your Enthusiasm!

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## **Siemens Healthineers**

### **Point of Care**

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