

DCA Vantage Analyzer and HbA1c

In-service Training

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Point-of-care Diabetes Testing: DCA Vantage Analyzer



The DCA Vantage® Analyzer helps monitor glycemic control and detect early kidney disease in patients with diabetes.

- Results in minutes enable actionable physician-patient conversations at the time of visit.
- CLIA-waived HbA1c test results in 6 minutes with 1 μ L of whole-blood fingerstick.
- Fully quantitative albumin-to-creatinine ratio test in 7 minutes.
- Connected solution with datamanagement options to transmit to LIS/HIS or EMR.



In-service Training Agenda



- System and test overview
- Setting up the analyzer
- Performing testing:
 - ✓ System calibration
 - ✓ Quality-control (QC) testing
 - ✓ Patient testing
- Performing maintenance
- Supplemental information:
 - ✓ Ordering information
 - ✓ References

HbA1c Testing during Office Visit Shown to Improve Consultation Effectiveness and Patient Outcomes





Results in

MINUTES

Immediate HbA1c results during the office visit have been shown to improve glycemic control in type 1 and type 2 diabetic patients.^{1, 2}

ACCURATE and

ACTIONABLE Information

IMMEDIATELY

Assess and Adjust Treatment

^{1.} Miller CD, Barnes CS, Phillips LS, Ziemer DC, Gallina DL, Cook CB, et al. Rapid A1c availability improves clinical decision-making in an urban primary care clinic. Diabetes Care. 2003;26:1158-63.

^{2.} Cagliero E, Levina EV, Nathan DM. Immediate feedback of HbA1c levels improves glycemic control in type 1 and insulin-treated type 2 diabetic patients. Diabetes Care. 1999;22:1785-9.

Why the DCA Vantage Analyzer?



Improve diabetes quality measures with simple, accurate, and immediate results during the patient visit.



HbA1c Albumin-to-Creatinine Ratio (ACR)

DCA Vantage® Analyzer

- Improved workflow: 6 minutes for HbA1c,
 7 minutes for ACR
- Accurate and precise, with central laboratory-quality results
- Simple to operate, with no sample or reagent preparation
- Comprehensive tools for on-site patient consultations:
 - √ HbA1c patient-trend graph, eGFR, ACR
- Reference range and out of range flags printed with each result
- Connectivity options for capturing results in LIS/HIS/ERM

Leading Innovative Features



Key Features:

- Bar-coded data entry
- Operator access restrictions
- QC management and lockout
- Onboard printed record
- Connectivity
- Searchable database
- Patient-trending graph
- Remote access via data-management solution



Overview:

DCA HbA1c Testing Supplies



Analyzer/Tests (supplied by Siemens Healthineers)

- ✓ DCA Vantage Analyzer
- ✓ DCA™ HbA1c Test Kit



Consumables and Accessories (supplied by Siemens Healthineers)

- ✓ Optical test cartridge*
- ✓ Thermal paper rolls*
- ✓ Lint-free swabs*
- ✓ Air filters*
- ✓ Quality-control (QC) materials
- ✓ Optional bar-code scanner

Recommended Supplies (not supplied by Siemens Healthineers)

- ✓ Lancing devices
- ✓ Gloves
- √ Gauze
- ✓ Bandages
- √ Sharps bin
- ✓ Alcohol wipes

Overview: DCA HbA1c Reagent Test Kit



Reagent components shipped in box

- Each kit contains materials to run 10 A1c tests and includes:
 - √ 10 test cartridges (in foil)
 - √ 10 sample capillary holders (individually wrapped)
 - √ 1 calibration card

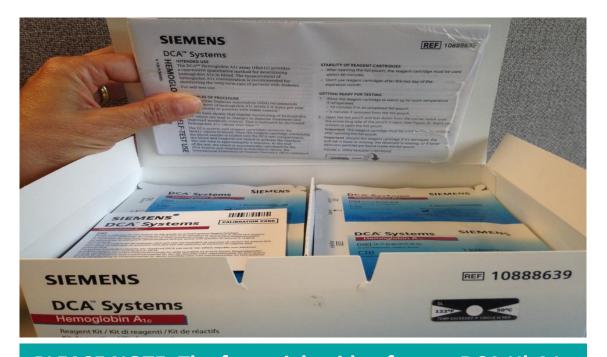
Instructions for use available in electronic format.



Overview: DCA HbA1c Reagent Kit Storage



- Store unopened reagent cartridges at 2–8°C (36–46°F). Note: DO NOT FREEZE.
- Unopened test cartridges are stable until the expiration date printed on the test kit outer box, if stored refrigerated.
- Unopened test cartridges can be kept up to 3 months at room temperature any time before the expiration date.
- On average, DCA HbA1c Reagent kits have a shelf life of up to 15 months (varies by country).



PLEASE NOTE: The front right side of every DCA HbA1c Reagent kit has a temperature indicator. If discolored, indicates reagents have exceeded proper temperature.

Getting Started: Simple as 1, 2, 3



Setting Up the Analyzer	How to unpack/install the analyzerHow to customize the analyzerHow to perform an optical test
Performing Testing	 How to calibrate the system How to prepare and run QC samples How to test patient samples
Performing Maintenance	 What should be done weekly What should be done quarterly What should be done as needed



DCA Vantage Analyzer

Setting Up the Analyzer

Setting Up the Analyzer: Unpacking



Check that the following components are shipped in analyzer box:

- ✓ Operator's guide (manual and CD-ROM)
- ✓ Quick-reference guides (HbA1c and ACR testing)
- ✓ Power cord
- ✓ Optical test cartridge
- ✓ Fuse pack
- ✓ Printer paper (thermal, adhesive)
- ✓ Air filters (2-pack) and one in analyzer
- ✓ Cleaning swabs
- ✓ Bar-code scanner (optional)



Setting Up the Analyzer: Installation



This should take ~15 minutes.

- 1. Review unpacking guide.
- 2. Unpack and plug in analyzer.
- 3. Record serial number in the operator's manual.
- 4. Load paper.
- 5. Connect handheld bar-code reader (optional).
- 6. Turn analyzer ON.
- 7. Perform system setup wizard (follow onscreen instructions).
- 8. Perform optical test and record results on the optical test log sheet.



Setting Up the Analyzer: Customize System Settings

Flexible settings to meet needs:

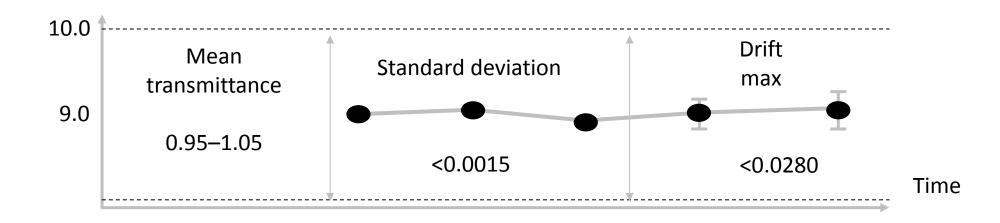
- Record patient name/ID
- Record operator ID
- External bar-code scanner (optional)
- Stores up to 4000 patient results
- Operator and QC lockout (optional)
- Patient/QC files transferable to USB stick
- Patient/QC files can be uploaded to PC
- Data search function

Refer to DCA Vantage Analyzer operator's manual to leverage system capabilities.

Setting Up the Analyzer: Performing an Optical Test

Monitor system optics.

- Ensures the analyzer's optics are in working condition
- Ensures the quality of results
- Optical test results in three key readings



Setting Up the Analyzer: Perform the Optical Test*



Scan optical test cartridge when at Home screen in Ready state.

- Optical cartridge provided with analyzer.
- Optical cartridge is reusable.
- Do not discard.
- 1. Remove the optical test cartridge from the analyzer compartment.
- 2. Use onboard scanner to scan optical test cartridge.
- 3. Insert cartridge into system and close door.

Results are displayed on the screen within 6 minutes and must be recorded on the optical test log sheet.





Setting Up the Analyzer: Perform Optical Test



Record optical test results.

- Print the optical test results and record on the optical test cartridge result log.
- Ensure the values provided—mean transmittance (mean T), standard deviation of transmittance (SDT), and drift max—are within the acceptable performance limits.
- Optical test should be performed quarterly as part of routine maintenance and should be within the following limits:

✓ Mean T: 0.9500 to 1.0500

✓ SD T: <0.0015

✓ Drift max: <0.0280

DCA Vantage® Analyzer Optical Test Cartridge Results Log Sheet Compare the new values obtained with the results recorded initially for your system. The Mean Transmittance should be within the range of 0.9500 to 1.0500, and should not vary more than plus or minus 0.0100. The Standard Deviation should be less than 0.00150 and the drift, or with the DCA Vantage drift max, should be less than 0.0280. Standard Deviation: Date Standard Deviation Drift or Drift Max Mean transmittance NOTE: Electronic copy of this log is available through Siemens. Please contact your Siemens representative if you are interested in receiving file. Thank you.



DCA Vantage Analyzer

Performing Calibration, QC, and Patient Testing

Performing Testing: How to Calibrate the System

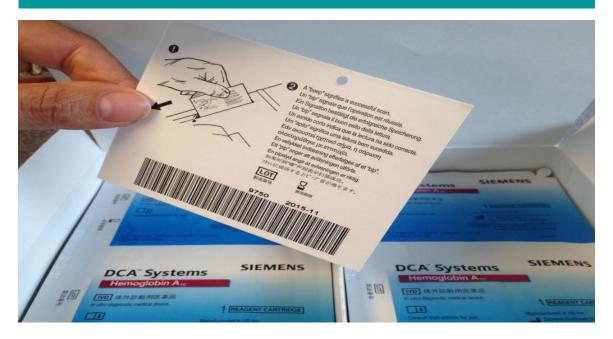


Locate calibration card.

- Calibration card is provided in every test kit box and contains:
 - ✓ Lot number
 - ✓ Expiration date
 - ✓ Lot-specific values used to calculate results
- Calibration information must be scanned only once with every new lot of reagent kit.
- Calibration data for the lot is stored, and there is no need to scan the calibration card again until a new kit lot is opened.

IMPORTANT NOTE:

- ✓ Analyzer will not allow tests to be performed if calibration card for new lot is not scanned (do not lose cards).
- ✓ Analyzer prevents testing of expired reagents.
- ✓ DCA Vantage Analyzer stores 16 distinct calibrations for the DCA Hemoglobin A1c Assay. Each calibration is for a different lot.



Performing Testing: How to Calibrate the System

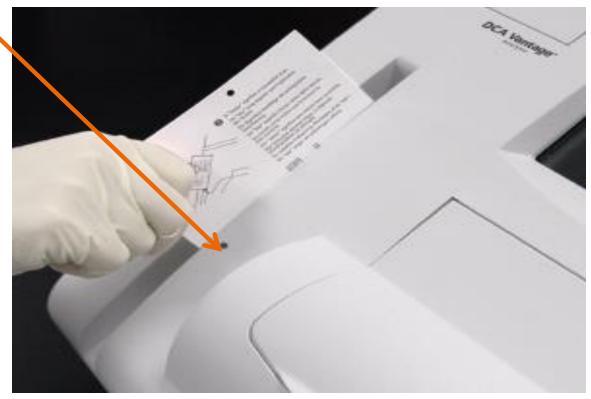


Scan calibration card when at Home screen in Ready state.

- 1. Remove calibration card from the reagent test kit box.
- 2. To the right of the bar-code track, locate the dot.
- 3. Hold the calibration card so that the bar code is facing to the right of the bar-code track.
- 4. Insert the calibration card into the top of the barcode track.
- 5. Hold the calibration card gently against the right side and smoothly slide down the track.
- Press OK to return to main menu.

IMPORTANT NOTE:

An audible beep confirms a successful scan. If no beep sounds, repeat the procedure.

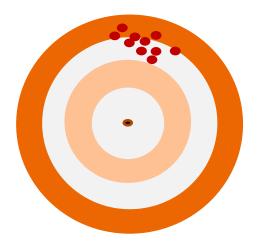


Performing Testing: Importance of Quality-control Testing

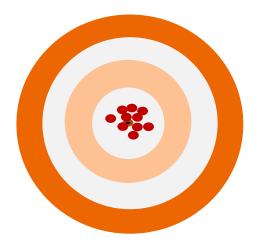


- Quality control is a solution of artificial blood with HbA1c of a known concentration that is used to verify system performance.
- Quality-control testing is important for testing analyzer, reagent, and operator performance.

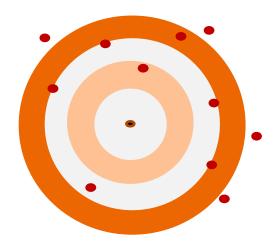
High precision, low accuracy



High precision, high accuracy



Low precision, low accuracy



Performing Testing: Quality-control Testing Recommendations



- It is recommended that quality- control specimens be tested with each new lot and new shipment of reagents, and monthly for reagents that have been stored for more than 30 days.
 - ✓ It is recommended that both NORMAL and ABNORMAL HbA1c levels of quality control be tested.
- Control materials must be prepared prior to use.

DCA Controls Kit Contents:

- ✓ 2 vials of A1c Normal control
- ✓ 2 vials of A1c Abnormal control
- √ 1 vial of reconstitution fluid
- √ 4 eye-dropper caps
- √ 1 control card with normal and abnormal values (double-sided)
- ✓ Instructions for use



Performing Testing: HbA1c Quality-control Storage Recommendations



- Unconstituted controls:
 - ✓ Store refrigerated at 2–8°C (36–46°F).
 - ✓ Can be used until the last day of the expiration month shown on the bottle by the manufacturer.
- Reconstituted controls:
 - ✓ Can remain at room temperature for only 30 minutes during testing.
 - ✓ Stable for 3 months when stored refrigerated at 2–8°C (36–46°F) when not being used for testing.
 - ✓ Should not be frozen.

IMPORTANT NOTE:

Refer to Instructions for Use provided in the Control Kit box for more detailed storage information.



Performing Testing: How to Prepare Quality-control Solutions



Step 1

Remove the qualitycontrol kit from the refrigerator.

Step 2

Gently tap the bottom of the control bottle on the counter in order to collect as much material as possible.

Carefully remove the cap.



Step 3

Add six (6) drops of RECONSTITUTION FLUID into the control bottle.

Note: Discard the first drop to ensure a constant volume of drops.



Step 4

Replace the cap (not the dropper) and swirl the control bottle several times.

Do not shake. Let stand at room temperature for 15 minutes.



Performing Testing: How to Prepare Quality-control Solutions



Step 5

After 15 minutes, swirl the control bottle several times to ensure the QC solution is homogeneous and all material is reconstituted.

Step 6

Remove and discard cap into clinical waste container. Replace with dropper cap.

Note: The white cap is for NORMAL CONTROL and the black cap is for ABNORMAL CONTROL.



Step 7

Use as required and return the quality-control kit to the refrigerator within 30 minutes for storage.



Performing Testing: How to Run Quality-control Tests



Step 1	Prepare the control materials.
Step 2	Locate the quality-control value card in the quality-control kit box.
Step 3	Scan in the control calibration card values for either NORMAL or ABNORMAL control.
Step 4	Add control material to tip of capillary.
Step 5	Place capillary holder into test cartridge.
Step 6	Scan test cartridge bar code.
Step 7	Insert cartridge and pull foil tab.
Step 8	Log values in control log sheet.

Quality Controls Reference Tools:

- 1. Guide to running quality controls
- 2. Quality control log sheet



Performing Testing: How to Run Quality-control Tests



Scan QC values.

- Scan the control card values prior to testing.
- Note: The control card has the NORMAL control bar code on one side and the ABNORMAL control bar code on the reverse side.
- You must scan the correct control information that corresponds to the NORMAL or ABNORMAL solution to be tested.
- QC testing fails if incorrect solution is run.



Performing Testing: How to Run QC Tests



Add control solution to capillary holder.

- 1. Remove and unwrap the capillary holder from the reagent kit.
- 2. Mix the sample well by manually moving the vial back and forth.
- 3. Open the control bottle and remove the dropper.
- 4. Squeeze the dropper bulb and insert the tip of the dropper into the control vial.
- 5. Release the pressure on the bulb to aspirate a small amount of control solution.
- 6. Add 1 μ L of control solution to the glass capillary tip by touching it to the control solution dropper.







Performing Testing: How to Run QC Tests



Add control solution to capillary holder (continued).

- 7. Squeeze any excess control material out of the dropper into the control bottle.
- Close the control bottle.
- 9. Wipe any control solution off the sides of the glass capillary using a lint-free tissue.
- 10. Inspect the glass capillary for the presence of any air bubbles.

Note: Touch only the glass capillary tip to the control material. If an air bubble is present in the filled tube, discard the capillary holder and fill a new one.

Performing Testing: How to Prepare the Cartridge for Quality-control Testing



Place the capillary holder into the test cartridge and scan the cartridge bar code.

- 1. Insert the capillary holder into the cartridge (face flat side of capillary toward cartridge) until the holder snaps into place.
- 2. Scan the cartridge using the bar-code scanner track:
 - ✓ Hold the cartridge so that the bar code faces to the right.
 - ✓ Insert the cartridge into the bar-code track above the dot.
 - ✓ Quickly and smoothly slide the cartridge down. A beep and display change indicate a successful scan.
 - ✓ Repeat if not successful.





Performing Testing: How to Run Quality Control Tests



1. Insert the cartridge into analyzer:

- Hold the cartridge so that the bar code faces to the right.
- Open the door and insert the cartridge into the compartment until you hear a click.
- Slowly and firmly pull to remove the foil tab.
- Close the door to start the test.
- Optional: Follow directions onscreen to enter operator ID, if customized with this feature.

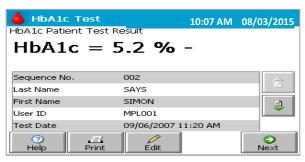
2. Recording the results:

- Wait until the test is complete (approximately 6 minutes).
- Print, record, and/or transmit the results.

3. Removing the cartridge:

- Hold plastic tab with your left hand and gently push down and to the right to unlock.
- Pull out and discard the used cartridge as per your site's biohazard disposal procedures.







Performing Testing: How to Run QC Tests



Record QC test results.

- Record QC results on QC log sheet or follow your site instructions.
- QC files can be downloaded to a USB memory stick and uploaded to a spreadsheet for analysis.
- QC results can be automatically uploaded to a data-management system, other DMS system, or LIS/HIS if DCA Vantage Analyzer is connected.

DCA Vantage® Analyzer



Quality Control Log Sheet

Control Level:

Date	Reagent Lot #	QC Lot#	Operator	Results/Action
	+			
	+			
	+			
	+			
	+			
	+			
_				
Note: An	electronic version of tl	his log is available	through Siemens He	althineers
Please co	ntact your representat	ive if you are inte	rested in receiving th	e file Thank
	intact your representat	ive if you are lifte	rested in receiving th	ic mc. mank
you.				
				

Performing Testing: How to Troubleshoot and Document Control Failures



- If the control value is outside the expected range, circle the value on the control log sheet and repeat the test.
- Keep documentation of the action(s) you took.
- If the result remains outside the range on the repeat test, contact Siemens Technical Solutions for assistance.
- DO NOT perform patient testing on the DCA Vantage Analyzer until all levels of controls have been tested and are within the expected range.

Performing Testing: How to Obtain Patient Samples



- 1 µL whole-blood sample is required.
- Sample can be a fingerstick or venipuncture.
- Due to the heparinized capillary, after the sample is added, you have up to 5 minutes to run a test without impacting result integrity.
- EDTA, heparin, fluoride/oxalate, and citrate anticoagulants can be used:
 - ✓ Preserved whole-blood samples can be stored at -70 to 5°C (-94 to 41°F) for 2 weeks, up to 25°C (77°F) for 1 week.



Performing Testing: How to Test Patient Samples



- Patient testing is simple and requires no sample or reagent preparation.
 - ✓ Obtain 1 µL patient fingerstick or venipuncture sample using capillary holder device.
 - ✓ Add capillary holder device to test cartridge.
 - ✓ Scan cartridge bar code.
 - ✓ Load and pull foil tab.

Sample

- Testing begins when compartment door is closed.
- Results are automatically printed after 6 minutes.

Add

Scan





DCA Vantage Analyzer

Performing Maintenance

Performing Maintenance: Routine Maintenance Overview



- Perform maintenance tasks to ensure optimal performance of DCA Vantage Analyzer.
- Maintenance is performed:
 - ✓ Weekly
 - ✓ Quarterly
 - ✓ As needed

IMPORTANT REMINDER:

Refer to DCA Vantage Analyzer operator's manual for more detailed information on this topic.

DCA Vantage® Analyzer							SIEMENS : Healthineers :					
Maintenanc	e Lo	g Sh	eet									
Year:			-									
	Jan	Feb	Mar	Apr	May	Jun	July	Aug	Sep	Oct	Nov	Dec
Quarterly Change Air Filter	Г	Т	Т		T		T	Т	Т	Τ	Τ	Т
-		_							_			↓
Run Optical Test Cartridge												
As Needed (by spillage, tro		ting or cont	amination									
Inspect Air Filter	"											\pm
Clean Cart Compartm Healthi Clean Bar Window (neers.	Please	conta	ict you							n	
Run Optical Test												
	-	_	+	+	+	+	+-	+	+	+	+-	+
Cartridge Replace Fuse		- 1	- 1			1	- 1	1	1	1	1	1

Performing Maintenance: Weekly Overview



Clean the bar-code window with a cloth dampened with water or ethanol.

Clean the exterior with a cloth dampened with water or ethanol. Do not allow liquid to drip into the system.

Performing Maintenance: Quarterly Overview





Change air filter.

Run optical test cartridge.

Performing Maintenance: As Needed



Clean the exterior.

Change the air filter.

Clean the cartridge compartment; remove and clean the cartridge spring.

Clean the onboard bar-code reader window.

Perform an optical test.

Calibrate the touchscreen.

Replace the fuse.

Note: Refer to the operator's manual for detailed instructions.

DCA Vantage Analyzer Offers Flexible Connectivity Options

Offering	RAPIDComm® Data Management System	POCcelerator™ Data Management System	UniPOC™ Data Management System	RELAYMED Device Connectivity	QML Data Management System	RALS Connectivity
Company	Siemens Healthineers	Siemens Healthineers	Siemens Healthineers	Relaymed	Telcor	Abbott
Capability	Bidirectional interface available	Bidirectional interface available	Bidirectional interface available	Yes—interfaces to Epic, Allscripts, eClinicalWorks, NEXTGEN, GE Healthcare, Centricity, Greenway Health, Athena Health	Bidirectional interface available	Bidirectional with version 5.7 released in July 2015

Why the DCA HbA1c Test for Diabetes Testing?



Simple to use

Precise, lab-quality results

Comprehensive patient consultation tools

Convenient consultation

Laboratory testing compliance tools



References



- 1. Miller CD, Barnes CS, Phillips LS, Ziemer DC, Gallina DL, Cook CB, et al. Rapid A1c availability improves clinical decision-making in an urban primary care clinic. Diabetes Care. 2003;26:1158-63.
- 2. Cagliero E, Levina EV, Nathan DM. Immediate feedback of HbA1c levels improves glycemic control in type 1 and insulin-treated type 2 diabetic patients. Diabetes Care. 1999;22:1785-9.
- 3. World Health Organization (WHO). March 2013.
- 4. Diabetes Care. 2013 Jan;36(Supp.1):S18.
- 5. DCA Vantage Operator's Guide (Rev. E).
- 6. CAP Survey Results: http://www.ngsp.org/CAP/CAP14a.pdf
- 7. DCA HbA1c test procedure demonstration video: http://www.healthcare.siemens.com/point-of-care/dca-vantage-virtual-tour

Ordering Information

Siemens Healthineers Part #	Legacy Part #	Description	Hazard/ Refrig.	Packaging
DCA Vantage	® Analyzer, I	Reagents, Consumables, and Accessories		
10282969	5075US	DCA Vantage Analyzer	_	1
10282579	06502880	DCA Vantage, CLINITEK Status® Bar-code Scanner	_	1
10318429	122521	DCA™ Air Filter (2 packs)	_	2/pk = 1 EA
10337473	6488209	DCA Cleaning Lint-free Swabs	_	10/pk = 1 EA
10324219	1759	Label Printing Paper (DCA Vantage and CLINITEK Status Analyzers)	_	5/pk
10328736	5773	Thermal Printing Paper (DCA Vantage, CLINITEK Advantus®, and CLINITEK Status)	_	5/pk
10311134	5035C	DCA HbA1c Reagent Kit (cartridges)	REFRIG	10s = 1 PC
10311161	5068A	DCA HbA1c Normal and Abnormal Controls	REFRIG	4 = PC
10311480	6011A	DCA Microalbumin/Creatinine Reagent Kit	REFRIG	10s = 1 EA
10325406	6012A	DCA Microalbumin/Creatinine Low/High Controls	REFRIG	4s = 1 EA
10888741	N/A	DCA HbA1c Capillary Holder	_	10/pk = 1 EA/PC
10888739	N/A	DCA Microalbumin/Creatinine Capillary Holder	_	10/pk = 1 EA/PC

Thank You!

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