Document History:

Title:	DCA Vantage System Operation and Maintenance	Site(s):	HSC and Kidney Check Program
Document #:	**100-41-65**	**Version #:**	**02**
Section:	**General Operations**	**Subsection:**	**HSC Lab Central Services**

Approved by:	A Sokoro	**Date:**	1 Feb 2021

Approved by:	L Thorlacius	**Date:**	1 Dec 2021
Signature:	Approval in File		
		Effective Date:	9 Dec 2021

#	Details of Revisions:	Approval:	Date:
1	New document; replaces 100-41-54, F100-41-54A, F100-41-54B, JA100-140-06A, JA100-140-06B, JA100-140-06C, JA100-140-09, JA100-140-11	A Sokoro	1 Feb 2021
2	Amended section 8.2 to include additional instructions for Kidney Check Workbook. Minor spelling corrections throughout.	A Sokoro	29 Nov 2021
3			

1.0 PURPOSE:

1.1. To provide instruction for use of the DCA Vantage analyzer.
1.2. Non-Shared Health sites may use this SOP if they have a Memorandum of Understanding (MOU) with Shared Health. The MOU will clarify the responsibilities of both the external organization and Shared Health.
1.3. Sites may only perform tests which are on their approved test menu.

2.0 GENERAL INFORMATION:

2.1. Use of the analyzer will vary depending on the site test menu or service agreement in place.
2.2. External Proficiency Testing (EPT) must be done for each analyte being tested for on the DCA Vantage analyzer. See Section 8.0 for details.
2.3. All staff utilizing the DCA Vantage analyzer must have initial training and annual competency assessment.
2.4. All staff must be re-certified annually.
2.5. For additional information on operation or troubleshooting of the DCA Vantage analyzer, refer to the vendor operations manual.

3.0 SAFETY:

Wear personal protective equipment, including safety glasses and gloves. Use universal precautions. Warning. ACR reagent cartridge contains components that may be harmful if swallowed or inhaled and may cause skin burns and eye damage.

Safety data sheets (SDS) are available at https://www.siemens-healthineers.com/en-us/services/laboratory-diagnostics/service-and-support/technical-documentation.

4.0 MATERIALS / EQUIPMENT:

- Siemens DCA Vantage analyzer
- Reagent kit containing Hemoglobin A1c reagent cartridge and capillary holder, Ref # 10698915
- Reagent kit containing Albumin/Creatinine reagent cartridge and capillary holders with plungers (packaged separately), Ref # 01443699 (6011A)
- Biorad Liquichek Diabetes Control levels 1 and 2, Ref # 171 and 172
- Siemens DCA Systems Hemoglobin A1c controls levels 1 and 2, Ref # 03714363 (5068A)
- Siemens DCA Systems Microalbumin/Creatinine controls levels 1 and 2, Ref # 6012A
- Lint-free tissue

5.0 REAGENTS:

Upon receipt of new reagent shipments, check the temperature indicator located in the front of the carton. If the indicator has turned red, do not use the reagent cartridges and inform a supervisor.

Reagent cartridges are stored in the fridge between 2 – 8 ºC. Individual cartridges must warm to room temperature unopened in the foil pouch for at least 15 minutes before being used for patient testing. Do not stack foil pouches during warming process as this may result in incomplete warming of reagents.

Do not return reagent cartridges to the fridge after warming or if foil pouch has been opened. Cartridges may be left at room temperature (20 – 25 ºC) for up to 3 months or until the expiration date on the carton, whichever is sooner. The shortened expiry date must be written on the foil pouch or reagent box.

Do not use scissors to open foil pouches and use caution to not puncture the reagent cartridge during or after opening the pouch.

6.0 SAMPLE REQUIREMENTS:

Whole Blood:

- The Hemoglobin A1c can be performed from either a venipuncture sample collected in an EDTA tube, or from a finger poke.
- At HSC, sample type will be indicated by physician on requisition.
- Confirm patient identity prior to the blood collection. Instructions on patient identification, venipuncture collection and finger poke can be found Shared Health document # 100-10-79 Phlebotomy Manual.

Urine:

- The Albumin/Creatinine Ratio test is performed on a fresh mid-stream urine sample collected in a sterile 50 mL orange top urine container with no preservative.
- Do not use the specimen if it is cloudy (turbid) in appearance.
- Confirm patient identity prior to collection. Collection container should be appropriately labeled with unique patient identification.

7.0 CALIBRATION:

There may be batch-to-batch variation in the reagent cartridges. Calibrating the analyzer for each lot of reagent cartridges ensures the accuracy of the system is unaffected by this variation.

Each box of reagent cartridges is supplied with a calibration card that must be scanned before analysis using a new lot number of cartridges. This procedure need not be done between boxes – only if the lot number changes. If a new lot of reagent cartridges are used without scanning the calibration card, the analyzer will show an error code.

To perform a lot-to-lot calibration:

1. Remove the calibration card from the reagent cartridge pack.
2. Locate the dot (on the instrument) next to the barcode track.
3. Locate the barcode on the calibration card
    a. Hemoglobin A1c card only has 1 barcode
    b. Albumin/Creatinine calibration card has 2 barcodes, labeled Barcode 1 and Barcode 2. Both barcodes must be scanned for the calibration to be successful.
4. Hold the card so the barcode faces right.
5. Insert the card into the barcode track.
6. Hold the card gently against the right side of the track and smoothly slide the card down past the dot.
7. A beep sounds to signal a successful scan. If no beep sounds, repeat the procedure. If a beep repeatedly fails to sound, refer to the Operator's Guide.
8. If calibrating Albumin/Creatinine Reagent cartridges, a pop-up window on the analyzer will prompt to run Barcode 2. Turn the card around and repeat steps for the second barcode.
9. To return to the home screen, select OK.

8.0 QUALITY CONTROLS:

Two levels of controls are run for each test in accordance with Shared Health policy 110-10-21, QC Monitoring, Review and Troubleshooting.

QC samples must be run once on each day of analyzer operation prior to testing first patient, after changing reagent cartridge lot number, each time a calibration card is scanned, after maintenance and at any time there is suspicion the analyzer is not working correctly.

8.1. QUALITY CONTROL FOR HSC:

Use Biorad Liquichek Diabetes Controls Cat # 171 and 172.

Run controls in the same manner as patient samples (see Appendix 1 – DCA Vantage Job Aid Hemoglobin A1c Testing). After running controls, record results on QC Log (see Appendix 3) and evaluate results against in-house established ranges for presence of any flags or failures. Senior technologist will enter results daily into Biorad Software for external comparison. If no flags are present, proceed with patient testing.

If QC failures or flags are present:

- Consult with Senior Laboratory Technologist assigned to the area.
- Do not test patient samples until the issue is resolved.
- If warning flags are present, ensure to bring this to the attention of the Senior Laboratory Technologist at the end of the run.

Biorad Liquichek Diabetes L1 and L2 Handling and Preparation:

This product has been provided in liquid form. Allow the frozen product to stand at room temperature until completely thawed. Before sampling, gently swirl the vials several times to ensure homogeneity. Do not shake. After each use promptly replace the stopper and return to 2-8 °C storage.

Storage and Stability:

Unopened at -10 to -70 °C:	up to the stated expiration date
Thawed and unopened at 2-8 °C:	6 months
Thawed and opened at 2-8 °C:	14 days

Do not refreeze product.

EPT: CAP Hemoglobin A1c GH5 program

- Method code – not required
- Manufacturer code – 3338
- Instrument code – not required
- Units – %

8.2. QUALITY CONTROL FOR KIDNEY CHECK:

Use Siemens DCA Systems Hemoglobin A1c controls Ref 03714363 (5068A) and Siemens DCA Systems Microalbumin/Creatinine controls Ref 6012A.

The DCA Vantage analyzer may be set up to evaluate quality control results automatically. With each new lot of controls, use the DCA Control Card found in the Control Kit. The Control Card, one side for each level, is used in exactly the same way as the Reagent Calibration Card. The barcode on the card contains the means and acceptable ranges for each specific lot of control.

The means and acceptable ranges found on the Control Card, along with the QC results, must be entered into the Kidney Check QC Workbook # WB01 for monitoring.

If QC failures or flags are present:

- Troubleshoot as per Appendix 5 – QC Troubleshooting Flow Chart
- Do not proceed with patient samples until the issue is resolved.
- If issue cannot be resolved on site, call Siemens Hotline for technical support.
    - Siemens 24/7 Hotline – 1-888-303-3353, (1-English; 3-POCT)

Siemens DCA Systems Hemoglobin A1c Controls, Normal and Abnormal:

Reconstitution:

1. Remove the appropriate control bottle from the refrigerator just prior to reconstitution.

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

3. Carefully remove the cap from the control bottle.

4. Holding the Reconstitution Fluid dropper bottle vertically, add six (6) drops of fluid to the control bottle.
   Note: Discard the first drop to ensure a constant volume of drops thereafter.

5. Carefully replace the original cap to the control bottle and swirl several times. Let stand at room temperature for 15 minutes.

6. After 15 minutes, coat all surfaces of the control bottle by rotating and inverting the bottle. Continue mixing until the solution is homogeneous and all lyophilized material is reconstituted.

7. Remove and discard cap. Replace with colour-coded Eyedropper Cap Assembly (white for normal, black for abnormal controls).

Procedure:

1. From a DCA Hemoglobin A1c Reagent Kit, obtain a Capillary Holder and remove it from the plastic wrap.
2. Unscrew the Eyedropper Cap Assembly from the control bottle. While applying only slight pressure to the bulb, insert the tip of eyedropper into the Control Solution (tilt bottle as necessary). Release pressure on bulb to aspirate a very small amount of Control Solution.
3. Hold the glass capillary tube to the Control Solution collected in the eyedropper and completely fill the 1 µL tube. Touch only the tip of the tube to the Control Solution. If an air bubble (bubbles) is present in the filled tube, discard the Capillary Holder and refill a new one.
   Important: Do not allow the Control Solution to come in contact with the wider plastic part of the Capillary Holder. Any Control Solution adhering to the Capillary Holder may be transferred into the reaction buffer, along with the 1 µL Control Solution in the glass capillary tube. If Control Solution comes in contact with the plastic of the Capillary Holder, discard the Capillary Holder.
4. Do not touch the eyedropper to any other surfaces. Squeeze any excess Control Solution out of the eyedropper back into Control Solution bottle. Carefully replace and screw the Eyedropper Cap Assembly back onto control bottle.
5. Using a lint-free tissue, carefully wipe any Control Solution off the sides of the glass capillary tube. Do not allow the tissue to touch the open end of the tube. Contact with the open end could result in loss of sample. If sample loss is obvious, discard the Capillary Holder and refill a new one.
6. Carefully insert the Capillary Holder into a DCA Hemoglobin A1c Reagent Cartridge and proceed with testing as per Appendix 1.

Storage and Stability:

Unopened at 2-8 °C:	up to the stated expiration date
Reconstituted at 2-8 °C:	3 months
Reconstituted at 20-25 °C:	30 minutes, before returning to refrigerator

Do not freeze product. Do not allow to stand uncapped.
Do not use past the expiration date.

Siemens DCA Systems Microalbumin/Creatinine Controls, Low and High:

Reconstitution:

1. Remove the appropriate control vial from the refrigerator just prior to reconstitution.
2. Gently tap the bottom of the control vial on the counter to collect as much material as possible on the bottom of the vial.
3. Carefully remove the foil crimp and stopper from the control vial.
4. From the Reconstitution Fluid vial, transfer the entire contents into the control vial using the provided transfer pipette. Do not draw the control back into the transfer pipette. Dispose of the pipette.
5. Carefully replace the control vial stopper and swirl the vial several times. Let stand at room temperature for 15 minutes.
6. After 15 minutes, coat all surfaces of the control vial and stopper by rotating and inverting the vial to get all the lyophilized material into solution. Continue mixing until the solution is homogeneous and all lyophilized material is reconstituted.
7. Remove and discard stopper. Replace the Dropper Tip Assembly (snap it onto the vial).

Procedure:

1. From a DCA Microalbumin/Creatinine Reagent Kit, remove a capillary holder and plunger from the plastic wrap.
2. Remove the white cap from the Dropper Tips Assembly. Tilt the control vial to allow control solution to fill the dropper. Squeeze air bubbles out of the dropper, if necessary, to ensure that no bubbles are trapped in the dropper.
3. Insert the end of the glass capillary tube 3 mm into the tip of the dropper and fill the capillary tube with control solution by gently squeezing the dropper. If an air bubble is present in the filled tube, discard the capillary holder and refill a new one.
   Important: Do not allow the Control Solution to come in contact with the wider plastic part of the Capillary Holder. Any Control Solution adhering to the Capillary Holder may be transferred into the reaction buffer, along with the control solution in the glass capillary tube. This may cause an invalid result. If Control Solution comes in contact with the plastic of the Capillary Holder, discard the Capillary Holder.
4. Do not touch the dropper to any other surfaces. Carefully replace the white cap back onto the control vial dropper tip.
5. Using a lint-free tissue, carefully wipe any control solution off the sides of the glass capillary tube. Do not allow the tissue to touch the open end of the tube. Contact with the open end could result in loss of sample. If sample loss is obvious, discard the Capillary Holder and refill a new one.
6. Carefully insert the Capillary Holder into a DCA Microalbumin/Creatinine Reagent Cartridge and proceed with testing as per Appendix 2.

Storage and Stability:

Unopened at 2-8 °C:	up to the stated expiration date
Reconstituted at 2-8 °C:	3 months
Reconstituted at 20-25 °C:	30 minutes, before returning to refrigerator

Do not freeze product. Do not allow to stand uncapped.
Do not use past the expiration date.

EPT: CAP Hemoglobin A1c GH5 program
- Method code – not required
- Manufacturer code – 3338
- Instrument code – not required
- Units – %

EPT: CAP Urine Chemistry(SI) U program
- Method code – 1637 (Urine Albumin), 1157 (Urine Creatinine)
- Reagent code – not required
- Instrument code – 1996
- Units – mg/L (Urine Albumin), mmol/L (Urine Creatinine), mg/mmol (ACR)

9.0 PROCEDURE:

For instructions on running Hemoglobin A1c tests, see Appendix 1 – DCA Vantage Job Aid Hemoglobin A1c Testing.

For instruction on running Urine Albumin/Creatinine tests, see Appendix 2 – DCA Vantage Job Aid Urine Albumin/Creatinine Testing.

10.0 REFERENCE INTERVALS:

Hemoglobin A1c (Whole Blood): 4 – 6 % of total hemoglobin

In addition to being a management tool, the 2013 Canadian Diabetes Association Clinical Practice Guidelines stipulate Hemoglobin A1c as a diagnostic marker of type II diabetes in the absence of certain conditions. To ensure correct interpretation, the result is reported with the comment “Please consult the Canadian Diabetes Association Clinical Practice Guidelines at http://guideline.diabetes.ca for the interpretation of the Hemoglobin A1c in various clinical conditions.”

Reference Value Source: Canadian Diabetes Association Guidelines 2008

Urine Albumin/Creatinine Ratio:

Random Collection (Male)

Normal:	< 2.0 mg/mmol creatinine
Microalbuminuria:	2 - 20 mg/mmol creatinine
Overt nephropathy:	> 20 mg/mmol creatinine

Random Collection (Female)

Normal:	< 2.8 mg/mmol creatinine
Microalbuminuria:	2.8 - 28 mg/mmol creatinine
Overt nephropathy:	> 28 mg/mmol creatinine

Reference Value Source: CMAJ Sept. 3, 2002; 167(5): 499-503

11.0 RESULTS REPORTING:

For Delphic Sites:

- Enter patient demographics.
- Enter test code <HA1> for point of care Hemoglobin A1C along with any other tests that are ordered.
- Use the format HA1 to enter the patient's point of care Hemoglobin A1C result.

For non-Delphic Sites:

- Record the results in the patient's file and staple the printout to the inside of the folder, as per protocol.

12.0 MAINTENANCE:

Maintenance is to be done as per maintenance schedule on a weekly and quarterly time frame, or as needed. Record all maintenance on DCA Vantage Maintenance Log (Appendix 5) or in the Kidney Check QC Workbook (document # WB01).

Weekly:

1. Clean the exterior:
    a. Disconnect the power cord before cleaning.
    b. Dampen a lint-free cloth with water and wipe down the analyzer.
    c. Connect the power cord after the exterior is clean and dry.

2. Clean the barcode reader:
    a. Disconnect the power cord before cleaning.
    b. Dampen a lint-free cloth with water and clean the barcode window. Do not allow liquid to drip into the system.
    c. Connect the power cord after the barcode reader is clean and dry.

Quarterly:

1. Clean the cartridge compartment:
    a. Disconnect the power cord before cleaning.
    b. Refer to the DCA Vantage Analyzer Operator's Guide, p 91-95.
2. Change the air filter:
    a. Remove the filter holder from the back of the unit by pulling the holder off from the tip.
    b. Dispose of the old air filter and place a new filter into the filter holder.
    c. Place the filter holder back onto the unit.
3. Perform the Optical Test:
    a. Refer to the DCA Vantage Analyzer Operator's Guide, p. 97-98.

Upon Movement of the Equipment:

1. Cleaning of the cartridge compartment and performing the Optical test must be performed every time the analyzer is moved offsite or to a new location.

13.0 INTERFERING SUBSTANCES:

Analyte	Interferent
HbA1c	- Patients with severe anemia may have very low hemoglobin (<70 g/L) and patients with polycythemia may have a high hemoglobin (>240 g/L). These patients should have HbA1c measured using an alternative method. - Patients with HbF > 10% would result in an HbA1c that is lower than expected. - Hemolytic anemia, polycythemia, homozygous HbS and HbC can result in decreased lifespan of red blood cells. This would result in an HbA1c that is lower than expected based on their glycemic control. - The following compounds do not interfere with the assay up to the specified concentrations: Bilirubin (0.5 mmol/L), triglycerides (13.5 g/L) and Rheumatoid factor (1:33000 titer). - The following medications do not interfere: Diabinese, Orinase, Tolinase, Micronase, Dymelor, glipizide.
Albumin	- The amount of albumin excreted may vary due to posture, amount of hydration, physical activity, blood pressure in an individual and during pregnancy. Samples should not be obtained after strenuous activity. - No high dose hook effect up to a concentration of 2000 mg/L - Avoid urine specimens that are visibly hemolyzed or highly pigmented. - Test should not be performed if sample exhibits significant bacterial growth or if patient shows signs of a urinary tract infection. - No cross reactivity with IgG, hemoglobin, transferrin or macroglobulin. - Glucose (up to 138.8 mmol/L) and urea (up to 400 mmol/L) does not affect the assay - Commonly prescribed drugs for diabetic patients do not interfere with the assay.
Creatinine	- Avoid urine specimens that are visibly hemolyzed or highly pigmented. - The following compounds do not affect the assay when present below the concentrations specified: Glucose (138.8 mmol/L), Urea (400 mmol/L), ascorbate (4.5 mmol/L), bilirubin (0.06 mmol/L), acetoacetate (7.8 mmol/L) and hemoglobin (<84.7 mmol/L) - Commonly prescribed drugs for diabetic patients do not interfere with the assay.

14.0 REFERENCES:

14.1. Shared Health document # 100-10-79 Phlebotomy Manual
14.2. DCA Vantage Analyzer Operator's Guide
14.3. DCA Systems Hemoglobin A1c reagent kit instructions, 2017
14.4. DCA Systems Urine Albumin/Creatinine reagent kit instructions, 2015
14.5. Biorad Liquichek Diabetes Controls package insert, 2019-03
14.6. Biorad Liquichek Microalbumin Controls package insert, 2020-01
14.7. Kidney Check QC Workbook

15.0 APPENDICES:

Appendix 1 – DCA Vantage Job Aid – Hemoglobin A1c Testing
Appendix 2 – DCA Vantage Job Aid – Urine Albumin/Creatinine Testing
Appendix 3 – DCA Vantage QC Log
Appendix 4 – DCA Vantage Maintenance Log
Appendix 5 – QC Troubleshooting Flow Chart
Appendix 6 – DCA Vantage Analyzer Troubleshooting

Appendix 1 – DCA Vantage Job Aid Hemoglobin A1c Testing

Specimen Requirements for HbA1c Testing:

- Use the collection device provided with reagent kit (capillary holder and capillary)
- Refer to Blood Collection – Skin Puncture Job Aid for patient and skin preparation prior to collection

Quality Control:

- QC samples must be run every 24 hours or before running patient samples (if analyzer is not in use every day)

Ensure reagent cartridges have been at room temperature at least 15 minutes prior to use

Note - After opening the foil pouch, the reagent cartridge must be used within 1 hour

Step	Action	
1	Turn the analyzer and wait for the unit to warm up; the on/off switch is located in the lower left corner below the printer. It will display a READY message when it is ready to use.	
2	Check the lot number of the reagent; if the lot number is different from the previous lot, perform calibration. Ensure QC has been run prior to analyzing patient samples.	
3	Tear open foil Reagent Kit package containing reagent cartridge remove; do not touch or otherwise contaminate the optical window or erroneous test results may be generated. Discard if the cartridge is damaged, the pull tab is loose or missing, or if loose desiccant particles are found inside the foil pouch. Capillary holders are packaged separately in a blister package.	

4	• If EDTA venous collection:
	  • Ensure sample is well mixed by gently inverting the tube several times.
	  • Remove lid from the tube, hold the capillary holder at an angle and touch only the tip of the capillary to the rubber stopper of the lid until the capillary is filled.
	• If finger poke:
	  • Prepare the patient as per SOP 100-10-79 Phlebotomy Manual.
	  • Hold the capillary holder at an angle and touch only the tip of the capillary to a small drop of blood on the finger until the capillary is filled.	

5	Using lint free tissue, carefully wipe the outside of the glass capillary, inspecting for the presence of bubbles. If any are present, discard the capillar holder and start again. Begin analysis within 5 minutes of filling the sample capillary.	
6	Carefully insert the capillary holder into the reagent cartridge until the holder gently snaps into place.	
7	Scan the reagent cartridge barcode 	1. Locate the dot (on the instrument) next to the bar code track; locate the bar code on the reagent cartridge. 2. Hold the reagent cartridge so that the bar code faces right; insert reagent cartridge into bar code track above the dot and quickly (within 1 second) and smoothly slide the reagent cartridge down past the dot. A beep sound will signal a successful scan; if no beep sounds, repeat the procedure.
8	Insert reagent cartridge into analyzer 	1. Open cartridge compartment door. 2. Hold reagent cartridge so the bar code faces right. 3. Insert reagent cartridge into the compartment until a snap is heard/felt. 4. Pull the pull-tab completely out of the reagent cartridge using a smooth, slow, continuous motion. 5. Close the compartment door; dispose of flexible pull-tab. A beep sounds and the assay begins 5 seconds after the door is closed**. If the door is closed before pulling the tab, this 5 seconds allows for the door to be re-opened, the tab pulled, and the door closed again.**
9	A pop-up window will appear on the touch screen to enter the demographics; once all data has been entered press **NEXT**.	
10	Once testing is complete (approx. 7 minutes), the result is printed by pressing the **PRINT** button on the screen.	
11	Open cartridge compartment door; press and hold down the button on the right side of the compartment while pushing the tab of the cartridge to the right; the cartridge can now be pulled out and discarded.	

Appendix 2 – DCA Vantage Job Aid – Urine Albumin/Creatinine Testing

Specimen Requirements for Urine Albumin/Creatinine

- Random mid-stream urine sample without preservative added; label specimen
  - **DO NOT** use sample if it is turbid (cloudy)

Ensure reagent cartridges have been at room temperature at least 15 minutes prior to use

Note - After opening the foil pouch, the reagent cartridge must be used within 10 minutes.

Step	Action	
1	Turn the analyzer and wait for the unit to warm up; the on/off switch is located in the lower left corner below the printer. It will display a READY message when it is ready to use.	
2	Check the lot number of the reagent; if the lot number is different from the previous lot, perform calibration. Ensure QC has been run prior to analyzing patient samples.	
4	Tear open foil Reagent Kit package containing reagent cartridge; do not touch or otherwise contaminate the optical window or erroneous test results may be generated. Cartridge should be discarded if damaged, the pull tab is loose or missing, or if loose desiccant particles are found inside the foil pouch. Capillary holders and plungers are packaged separately in a plastic bag.	
5	Immerse the tip of the capillary tube in the urine sample; tilt the container and capillary holder to increase rate of flow into the capillary. Allow enough time for the urine specimen to flow into the capillary tube and come in contact with the starch plug.	
6	Remove capillary tube from specimen; using a lint-free tissue, carefully wipe the outside of the capillary tube. Do not allow tissue to touch the open end of the capillary as this may result in loss of sample. If sample loss is obvious, discard the capillary holder and begin again.	
7	Inspect capillary for presence of bubbles; if bubbles are obvious discard the capillary holder and begin again.	
8	Carefully insert the urine capillary holder into the reagent cartridge until the holder gently snaps into place.	
10	Scan the reagent cartridge barcode 	1. Locate the dot (on the instrument) next to the bar code track; locate the bar code on the reagent cartridge 2. Hold the reagent cartridge so that the car code faces right; insert reagent cartridge into bar code track above the dot and quickly (within 1 second) smoothly side the reagent cartridge down past the dot. A beep sound will signal a successful scan; if no beep sounds, repeat the procedure.
12	Instrument display reads: **LOAD CARTRIDGE, *INSERT PLUNGER*, PRESS [↵]** Insert reagent cartridge into analyzer: 	1. Open cartridge compartment door 2. Hold reagent cartridge so the bar code faces right 3. Insert reagent cartridge into the compartment until a snap is heard/felt 4. Insert plunger into the hole on top of capillary holder; depress plunger fully. The plunger will lock into the capillary holder; press **ENTER.**  5. Pull the pull-tab completely out of the reagent cartridge using a smooth, slow, continuous motion 6. Close the compartment door; dispose of flexible pull-tab. A beep sounds and the assay begins 5 seconds after the door is close**. If the door is closed before pulling the tab, this 5 seconds allows for the door to be re-opened, the tab to be pulled, and the door closed again**
13	A pop-up window will appear on the touch screen to enter the demographics; once all data has been entered press **NEXT.**	
14	Once testing is complete (approx. 6 minutes), the result is printed by pressing the **PRINT** button on the screen.	
15	Open cartridge compartment door; press and hold down the button on the right side of the compartment while pushing the tab of the cartridge to the right; the cartridge can now be pulled out and discarded.	

Appendix 3 – DCA Vantage QC Log (HSC Only)

QC Range Determination _____

Test Date	Cartridge Lot #	Cartridge Expiry Date	BioRad Liquichek Diabetes Control Results		Initials
			Level 1	**Level 2**	
			Lot #	Lot #	

Supervisor Review _____ Date_____

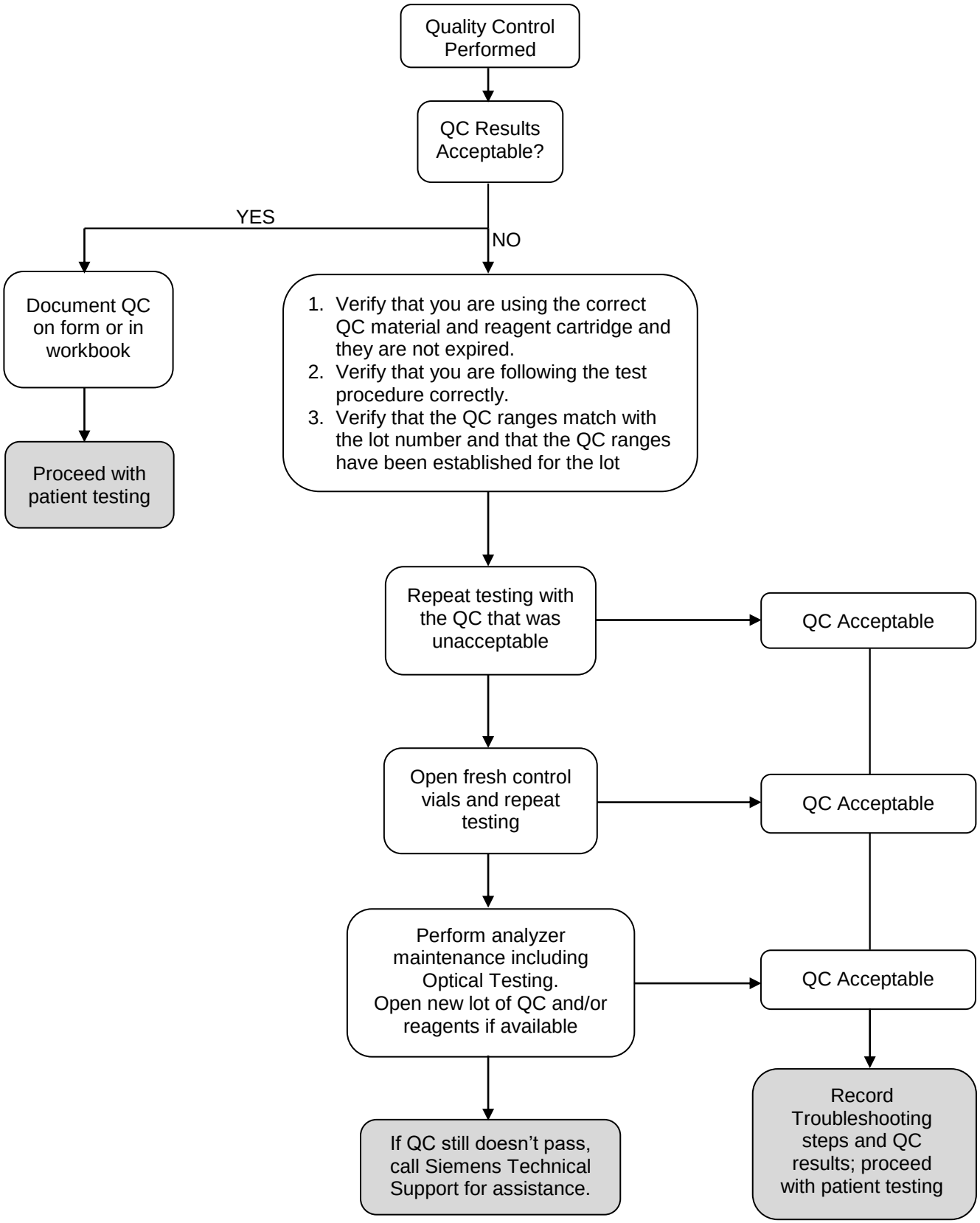
Appendix 4 – DCA Vantage Maintenance Log (HSC Only)

Weekly				Weekly			
Date	Wipe outside of instrument	Clean Barcode reader	Initial	Date	Wipe outside of instrument	Clean Barcode reader	Initial

Every 3 Months				
Clean cartridge compartment				
Run Optical Test Cartridge; record values for:				
• Mean transmission (allowable range 0.9500 to 1.0500)				
• Standard deviation (should be less than 0.00150)				
• Drift (should be less than 0.01400)				
Every 3 to 6 months				
Change air filter				
Date and Initial				

Supervisor Review _____ **Date**_____

Appendix 5 – QC Troubleshooting Flow Chart



Appendix 6 – DCA Vantage Analyzer Troubleshooting

For a complete listing of analyzer error messages/codes, test flags, QC errors and corrective actions, refer to Operator's Guide(s)

NOTE: *any time a new sample is run or a new cartridge is used, document with a comment on the patient log*

If…	**Then,**
Results do not reflect the patient's condition (unexpected results)	Repeat the test using a fresh cartridge and sample
Results are still suspect	Send sample to the lab
The analyzer fails to provide a test result or displays an error code message	Repeat the test using a fresh cartridge and sample
The condition persists	DO NOT use the analyzer Log the error condition in the equipment log Call vendor support for assistance Send sample to the lab
The DCA Analyzer is turned off while testing	Retest the sample that was in process when turned off
DCA Vantage Messages / Codes	**Operator Action**
Database is full	Delete old data records
Barcode error	Select **OK**; enter barcode data; clean barcode window
Printer Failure	Acknowledge the error; restart the system; if still not functioning properly, contact vendor technical support
Sample error / cartridge error	Acknowledge the error; repeat the test with a new sample and cartridge If error persists, contact vendor technical support; send sample to the lab
Test Flags	**Operator Action**
Results are not reportable due to sensor errors or interfering substances	Collect a new sample and repeat test; document all results on log **Note:** if results flag again, send a sample to the lab
Results above or below the reportable range for the analyzer	Send sample to the lab for testing
QC Failures	**Operator Action**
Control results fall outside the values stated in the package insert	**DO NOT** test patient samples until all control results are within acceptable range Refer to QC troubleshooting flowchart for direction See below for possible sources of error
Sources of Random QC Error	**Sources of Systemic QC Error**
Bubbles in reagent	Replacement of reagent or reagent lot change
Sampling or reagent syringes	Improperly prepared reagents
Improperly mixed/dissolved reagents	Inadequate storage of reagents or calibrators
Clog in sampling device	Calibration (not performed or did not pass; calibration drift)
Power supply/fluctuations	Calibrator lot change or wrong calibrator values
Unstable temperature and incubation	Change in procedure from one operator to another
Individual operator variation	Environmental issues affecting reagents or instruments

Siemens DCA Vantage Technical Support: 1-888-303-3353, (1 for English; 3 for POCT)