Purpose

To describe the steps necessary to operate and maintain the DCA Vantage analyzer used for the quantitation of Hemoglobin A1c.

Clinical Significance

The DCA Vantage Analyzer is a semi-automated bench top system used for the quantitative determination of hemoglobin A1C in blood. The measurement of hemoglobin A1c concentration is recommended for monitoring the long-term care of persons with diabetes. Elevated levels of HbA1c are associated with poor glycemic control.

Scope

All KPNW personnel who operate the Siemens DCA Vantage Analyzer.

Specimen Requirements

Acceptable Specimen Type(s):

- Capillary blood (1uL)
- Whole blood venipuncture with the following anti-coagulants: EDTA, Heparin, citrate, or fluoride/oxalate

Specimen stability:

- Stable two weeks refrigerated (2-8°C)
- Stable one week at room temperature (18-25°C)

Equipment and Materials

- **Equipment**
  - Siemens DCA Vantage analyzer
  - Capillary holders (not lot specific)
  - Printer paper
  - Calibration Card
  - Optical Test Cartridge
  - Air Filters
  - Cleaning Kit (part number 95001901)

- **Reagents**

Reagent	Stability Unopened	Stability Opened	Preparation
Siemens A1C Cartridge	Until expiration stored at 2-8°C	3 Months stored at room temperature-up to the expiration date	• Allow cartridges to warm to room temperature prior to testing: 10 minutes in unopened foil or 5 minutes opened. • Use within one hour of removing from foil.
Siemens A1C Control Kit	Until expiration stored at 2-8°C	3 months stored at 2-8°C. • Do not leave reconstituted control out at room temp for longer than 30 minutes. • Do not freeze	• Remove control bottles from refrigerator and gently tap on the counter to ensure QC material is at the bottom of the bottle. • Add 6 drops of reconstitution fluid, discard the first drop and use the next 6. • Replace the cap, gently swirl and allow to sit for 15 minutes. • Rotate the control bottle and replace the cap with the dropper. • Record the date and expiration on the bottle.

Procedure-Patient Testing

A. Adding Sample to the Cartridge

1. Make sure the reagent cartridge is at room temperature and use within one hour of removing from the foil pouch.
2. Remove and unwrap the capillary holder from the reagent kit.
3. **For finger stick collection:**
   - With the capillary holder at an angle, touch only the tip of the capillary to a small drop of blood on the finger until the capillary fills.
   - Using a lint-free tissue, carefully wipe the outside of the glass capillary making sure not to wick any of the sample out of the capillary.
4. **For venipuncture collections:**

- Invert the tube of blood several times to prevent separation of red blood cells and plasma.
- Remove the stopper from the blood collection tube so that a small sample of blood remains on the stopper.
- Holding the capillary holder at an angel, touch only the tip of the capillary to a small drop of blood on the stopper until the capillary fills.

    - **Note:** Do not attempt to fill the capillary by inserting the capillary holder into the blood collection tube. This will result in blood touching the capillary holder. If blood touches the capillary holder, discard the capillary holder and use a new one.

- Using a lint-free tissue, carefully wipe the outside of the glass capillary making sure not to wick any of the sample out of the capillary.

5. Inspect the glass capillary for the presence of bubbles. If bubbles are obvious, or if blood has been wicked out of the capillary, discard the capillary and repeat the procedure using a new capillary holder.
6. After filling the capillary with sample, testing must begin within 5 minutes.

B. Testing the Cartridge

1. Ensure that the system is in the **Home** screen.
2. Insert the capillary holder containing the sample into the reagent cartridge until the holder snaps into place. The open side of the capillary holder should face the foil pull tab.
3. Scan the reagent cartridge.
    i. Hold the reagent cartridge so that the barcode faces to the right.
    ii. Quickly and smoothly slide the reagent cartridge down.
    iii. A beep sound to signal a successful scan.
4. With the barcode facing to the right, insert the reagent cartridge into the cartridge compartment until a gentle snap is heard or felt. Do not force the cartridge into the system, it is designed to fit only one way into the compartment.
5. Holding the cartridge down into the compartment, use a smooth, slow, continuous motion to pull the flexible silver pull-tab completely out of the reagent cartridge.
6. Close the door. After a 5-second delay, the Sample Data menu screen displays indicating the test is in progress.
7. Follow the prompt to enter the patient barcode ID and drop down and enter operator ID.
10. After 6 minutes, the Result screen displays the patient results.
11. Press the "print" button on the screen to print results.
12. Enter patient results in KPHC

Calibration

Calibration is performed only once prior to using a new lot of reagent cartridges using the calibration card supplied in the kit. DO NOT discard the calibration card. The analyzer will store up to 2 lots of reagent.

To scan the calibration card into the analyzer:

1. Locate the dot on the instrument next to the barcode track.
2. Hold the card so that the barcode faces to the right. Insert the calibration card into the top of the barcode track above the dot.
3. Hold the calibration card gently against the right side of the track and smoothly slide the card down. A beep sounds to signal a successful scan. If no beep sounds, repeat the scan.
4. To return to the Home screen, select OK.

Maintenance

Document all maintenance on the DCA Vantage Maintenance Form.

Daily: No daily maintenance required.

Weekly

1. Clean the Exterior and the Bar Code Window.
    a. Turn off the power.
    b. Wipe the exterior of the instrument and barcode window with a clean lint free cloth. Cloth may be dampened with water or ethanol. Do not use sprays. Do not allow cleaning fluid to drip inside the instrument.
    c. Allow instrument to dry thoroughly.
    d. Turn the power back on.

Quarterly

1. Change the Air Filter (located on the back of the unit.)
    a. Remove the air filter holder by pulling the holder off from the top.
    b. Remove old air filter from holder and dispose.
    c. Place new filter in filter holder and replace the filter holder on the instrument.
2. Clean Cartridge Compartment.
    a. Turn off power and disconnect power cord.
    b. Open cartridge compartment door as wide as possible.
    c. Wipe inside of door and surfaces on both sides of cartridge holder with a lint free cloth dampened with water or ethanol.
    d. Dry all surfaces using a clean, dry, lint-free cloth.

e. Remove the cartridge return spring. Use a paper clip or similar object to insert in the holes on the top and bottom of the spring and gently pull the spring toward the center of the cartridge compartment.
f. Clean the cartridge return spring with a lint free cloth and water, water with mild detergent or ethanol.
g. Remove any spilled liquid from the cartridge holder using a DRY sponge swab from the cleaning kit. Rotate cartridge holder with door partially closed to get all liquid. Do not use cotton swabs, the fibers may harm the optics.
h. Dampen sponge swab with water or ethanol and clean cartridge holder. Rotate the cartridge holder as necessary. Do not allow any liquid to drip into the instrument.
i. Replace the cartridge return spring. Make sure it is oriented correctly with the top of the cartridge holder.
j. Connect the power cord and turn power on.
k. Run the Optical Test Cartridge after cleaning complete.

3. Optical Test Cartridge.
   The optical test cartridge should be run on initial set-up of the analyzer, quarterly after cleaning the cartridge compartment and changing the air filter or when instructed by a Service Representative.
   a. Hold Optical Test Cartridge with barcode facing right.
   b. Swipe cartridge past barcode reader. Display will read "Run Standard 1?"
   c. Press Enter.
   d. Open Cartridge compartment door.
   e. Insert Optical Test Cartridge in cartridge holder with barcode facing right, until it snaps into place and close the door.
   f. When complete, record mean transmittance, standard deviation, and drift on DCA Vantage Maintenance form. The acceptable evaluation criteria are on the maintenance log, initiate troubleshooting if results are not acceptable.
   g. Remove Optical Test Cartridge. Press button on right side of cartridge compartment, push plastic tab on cartridge to the right and pull up.

As Needed:

1. Replace Fuse.
   a. Turn instrument off and disconnect power cord.
   b. Locate fuse holder on the back of the instrument.
   c. Remove fuse holder from instrument by using a screwdriver to pry it out.
   d. Insert new fuse (250V, T-1.25A) into fuse holder.
   e. Insert the fuse holder into instrument.
2. Calibrate Touch Screen
   Calibrate the touch screen if it does not respond correctly when you touch the screen.
   a. At the System Test menu, select Calibrate Touch Screen.

b. Select the X target at the center of the screen.
c. Repeat when prompted at each corner.
d. The Touch Screen Calibration Complete screen displays.

Quality Control

Two levels of control are to be tested with each new lot of reagent cartridges and each day of instrument use.

Loading Control to Cartridge

Follow the QC preparation instructions under the Reagents and Materials section above.

1. Remove and unwrap the capillary holder from the reagent kit.
2. Thoroughly mix the control solution by inversion. Insert the tip of the dropper into the control solution and aspirate a small amount. Avoid air bubbles.
3. Fill the glass capillary tube by touching it to the tip of the dropper (touch only the tip of the capillary tube to the control material). Prevent the control material from coming into contact with the plastic part of the capillary holder. If this happens, discard and repeat with a new capillary.
4. Return any excess control material in the dropper to the control bottle.
5. Wipe any control solution off the sides of the glass capillary tube using a lint-free tissue making sure not to wick out any of the material.
6. Inspect the capillary holder for the presence of any bubbles. If present, discard the capillary and repeat.
7. Insert the capillary holder into the reagent cartridge until the holder gently snaps into place.

Testing the Controls after loaded to Cartridge

1. Scan the control card in the barcode track. One side of the control card is for a normal control and the other side is for an abnormal control.
    a. Hold the card so that the barcode of the QC level you are running faces to the right.
    b. Hold the control card gently against the right side of the track and quickly slide the card down. A beep sounds to signal a successful scan. Repeat if there is no audible beep.
2. Scan the reagent cartridge containing control solution with the barcode facing right.
3. Insert the reagent cartridge into the instrument.
    a. Open the cartridge compartment door.
    b. Hold the reagent cartridge so that the barcode is on the right.
    c. Insert the reagent cartridge into the cartridge compartment until a gentle snap is heard.

d. Holding the cartridge down into the compartment, use a smooth, slow, continuous motion to pull the flexible silver pull-tab completely out of the reagent cartridge and close the door.
e. The result will display on the screen.
f. Repeat all above steps for the other level of control.
g. Document the results on Form - DCA Vantage QC Log, POCT

Reporting

Reference Range

• For monitoring of diabetes control:	< 7.0% Low risk for complications 7.0-8.0% Some risk for long-term complications > 8.0% High risk of complications
• Screen for diabetes:	< 5.7% Non-diabetic 5.7-6.4% Increased risk for diabetes > 6.4% Diabetes, if confirmed
Reportable Range	4.0 % - 14.0 %

Limitations of Procedure

- Accurate A1c measurements will be made over a range of total hemoglobin of 7 to 24 g/dL.
- If Hgb F > 10%, A1c measurement will not accurately indicate glycemic control.
- Conditions that result in a decreased life span of red blood cells will result in A1c values that are falsely decreased.
- Conditions that result in an increased RBC life span will cause A1c values to be falsely elevated.
- Interferences:
  - Bilirubin up to 20 mg/dL does not interfere.
  - Triglycerides up to 1347 mg/dL do not interfere.
  - Rheumatoid factor up to 1:5120 titer, does not interfere.
- Contact POC Representative for troubleshooting assistance as needed.

References

- Siemens DCA Vantage Operator's Guide, Rev. E, 8/2012
- Siemens product insert for DCA Systems Hemoglobin A1c Normal and Abnormal Control Kit, 08/2008, Rev. B
- Siemens product insert for DCA Systems HbA1c Reagent Kit, 8/2008, Rev. B

Attachments

- Form - DCA Vantage Maintenance
- Form - DCA Vantage QC Log, POCT

Training Criteria

- Follow Training Plan, Waived Testing Platforms for the specific test system.