WAIVED TESTING TRAINING AND COMPETENCY QUICK REFERENCE

General

- All waived testing and quality control must be performed according to the manufacturer recommendation. QC recommendations and test procedures are included in the package insert or instructions for use (IFU).
- Policies and procedures can be found in a binder in the laboratory and in the Point of Care folder on the server.
- Two patient identifiers (name and date of birth) should be used to verify patient ID prior to testing.
- Wash hands before and after each patient.
- Wear gloves when collecting & handling specimens.
- Patient results may not be reported if QC in not acceptable
- Proficiency testing is performed for all waived tests.

Whole Blood Glucose: Abbott Freestyle Precision Pro

Reference Range:	Critical Values:	Measurement (Reportable) Range:	Reporting Results:
Fasting: 74 – 106 mg/dL 1-hr postprandial: <160 mg/dL Patient ID: 8-digit account number. Scan wristband or enter by keypad. If urgent and no account number available, enter any 8 digits (such as DOB or current date as MMDDYYYY).	≤40 mg/dL and ≥400 mg/dL Repeat test to verify critical values. Notify the provider ASAP and document notification and read-back using comment code 04 MD/RN notified. This is a regulatory requirement.	20 to 500 mg/dL Numeric results will not be displayed if glucose is <20 or >500 mg/dL. Result will be displayed as high or low. Contact the laboratory to confirm results outside of the reportable range. Enter comment code 3 or 03: LAB DRAW.	Document in diabetic record. Dock meter to upload results weekly. Comment Codes: Required for failed QC, critical values, and results above or below the instrument range. 1 or 01: REPEATED TEST 2 or 02: PROCEDURE ERROR 3 or 03: LAB DRAW 4 or 04: MD/RN NOTIFIED

Quality Control

- High and low QC must be performed once every 24 hours. Meter will indicate when QC is required.
- Strips and controls may be obtained from the laboratory. New lot numbers of test strips and controls must be entered by the lab.
- QC should also be performed for troubleshooting, if meter is dropped, patient result is higher or lower than expected, or if a new lot of strips is opened.
- QC ranges are programmed into the meter. If the QC test passes, the meter display reads **"PASSED"**. If the QC test fails, the meter display reads **"FAILED"**.
- Controls are stable for 90 days after opening. Record date opened and expiration date (+90 days) on bottle. This is a regulatory requirement.
- If QC fails, verify that strips and control solution are not expired and that batteries are not weak. Repeat test. If it still fails, try a fresh bottle of control. If controls still fail, contact the laboratory.

Specimen	Capillary Puncture	Interferences
▪ Fresh whole blood ▪ Do not use serum or plasma ▪ Test fingerstick blood immediately ▪ Test venous and arterial blood immediately ▪ Do not use collection tubes with	▪ Middle or ring finger preferred ▪ Cleanse site with alcohol and allow to dry ▪ Puncture the cleansed site, and then use a gauze pad to wipe away the first drop of blood. Apply the blood to the testing strip.	▪ Falsely decreased results may be obtained if patient is severely dehydrated, severely hypotensive, in shock, or in a hyperglycemic-hyperosmolar state. ▪ Hematocrits <25% or >60% may cause false results. Accurate glucose results should be obtained by laboratory-based analysis. ▪ Venous samples tested in capillary/arterial mode can give falsely high results. ▪ Avoid exposing strips to air or moisture. Do not open foil pouch until ready

fluoride or oxalate		to use.

Quidel QuickVue In-Line Rapid Strep A

Reagents and Materials

Kits are dispensed by lab.
Store at room temperature.
Do not mix contents of kit with other lots.
Use only the swab included in the kit.

Specimen Collection

Rub the swab on the back of the throat, on the tonsils, and in any other area where there is redness, inflammation or pus. Do not touch the tongue, sides, or top of mouth with the swab.

Quality Control

- Positive and negative control swabs are tested with each new shipment or lot. This is performed by the lab and documented on the box. If QC is not written on the box and/or positive and negative control swabs are still in the box, contact the laboratory to verify that external controls have been tested.
- The internal control (built-in control) should be recorded with each test. Internal controls consist of three parts.
    - The extraction reagent should turn from clear to green when the ampule is crushed and the solution is mixed. Do not use the extraction reagent if it does not turn green.
    - A blue line should appear next to the letter “C” on the test cartridge. If the control line does not develop within 5 minutes, the test is invalid.
    - A negative background control is provided by the clearing of background color in the result window. This area should be white to light pink within 5 minutes and not interfere with the reading of the. If background color remains in the Result Window which interferes with reading the test result, the result may be invalid.
- Internal controls must be documented during order entry. Order the test in Evident and answer “passed” or “failed” at the “Internal QC” prompt.
- Do not report patient testing if internal controls fail.

Test Procedure

Refer to the package insert or the procedure card in the kit for instructions, if needed.

1. Assemble test cartridge and extraction reagent.
2. Swab throat as described above. Use only the swab included in the kit.
3. Insert swab into the swab chamber.

4. Squeeze to crush the glass ampule inside the extraction solution bottle. Shake vigorously to mix.
5. Remove cap and quickly fill swab chamber to the rim with green extraction reagent (about 10 drops). Begin timing. *Do not move test cartridge.*
6. If sample does not migrate across result window within one minute, completely remove and reinsert swab.
7. Read results at 5 minutes. Some positive results may be seen earlier. Negative may not be reported until 5 minutes have elapsed.

Interpretation of Results

- The appearance of any pink-to-purple line next to the letter "T" in the Result Window, along with a blue Control Line next to the letter "C" means that the test is positive for group A *Streptococcu*s.
- The appearance of only the blue Control Line next to the letter "C" in the Result Window means the test is negative.
- If the blue Control Line does not appear next to the letter "C" at 5 minutes, the test is considered INVALID and the test result cannot be used.

Proficiency Testing Procedure

Proficiency testing is required by COLA.

1. Follow the procedure for proficiency testing that is outlined in the package insert. DO NOT insert proficiency swab into test cassette as you would be a patient swab. The swab is not designed to work with the kit.
2. Crush the extraction reagent ampule and mix the contents. Dispense 8 drops into the plastic test tube provided in the kit.
3. Place the proficiency swab into the tube with the extraction solution. Squeeze the bottom of the tube to lightly compress the swab, while rotating the swab three times. Wait one minute.
4. Express **all** of the liquid from the swab head in the Tube by rolling the swab against the inside of the Tube and pressing slightly as it is withdrawn from the Tube. Discard the swab.
5. Fill included transfer pipet to the fill line with the solution in the tube. Add solution in dropper to the test cassette swab chamber. Read results at 5 minutes.

Limitations

- Since no rapid test has been approved as a stand alone test, the FDA requires negative rapid diagnostic Strep A results to be backed-up with culture.
- In rare cases, test specimens heavily colonized with *Staphylococcus aureus* can yield false positive results.

Reporting Results

Order STREP SCREEN RAPID STREP. Enter result. Document that the internal control passed (blue control line, clear background, green solution). DO NOT report results if internal QC fails.

Hemoccult Sensa

WAIVED TESTING TRAINING AND COMPETENCY QUICK REFERENCE

Purpose
To detect occult blood in stool.

Reagents and Materials
Test cards and developer are dispensed by the laboratory
Store at room temperature in original packaging. Do not refrigerator or freeze. Protect from heat and light.

Quality Control
Quality Control is performed on each test card by developing the positive and negative Performance Monitors under the sample area of the card. This is the internal QC. Do not report results if performance monitors do not perform as expected.

Patient Preparation
- For ***seven*** days before and during the stool collection period, **avoid** non-steroidal anti-inflammatory drugs such as ibuprofen, naproxen or aspirin (more than one adult aspirin a day).
- For ***three*** days before and during the stool collection period, **avoid** vitamin C in excess of 250 mg a day from supplements, and citrus fruits and juices.
- For ***three*** days before and during stool collection period, **avoid** red meats (beef, lamb and liver).

Specimen Collection
Stool in clean container

Test Procedure
Steps are included on each test card.
1. Label slide with patient name and identifier. Open the green tab on the label side of the card.
2. Use an applicator stick to apply a thin smear of stool in Box A.
3. Reuse applicator stick to obtain a second sample from a different part of the stool and apply to Box B.
4. Close cover. *Wait 3 to 5 minutes after sample application before developing test.*
5. Turn card over and open small flap on back. Apply two drops of developer over each smear.
6. Read results within 60 seconds. Any trace of blue on or at the edge of the smear is positive for occult blood.
7. Develop performance monitors. Apply one drop of developer between the (+) and (-) Performance Monitors areas. Interpret within 10 seconds. A blue color is considered positive, while the absence of any blue color indicates a negative result.
8. If performance monitors perform as expected, report patient results. Order OCCULT BLOOD DIAGNOSTIC in Evident.

Interfering Substances
Substances which can cause false-positive test results:
• Red meat (beef, lamb and liver)
• Aspirin (greater than 325 mg/day) and other non-steroidal anti-inflammatory drugs such as ibuprofen, indomethacin and naproxen. Acetaminophen is not

expected to affect test results.
- Corticosteroids, phenylbutazone, reserpine, anticoagulants, antimetabolites, and cancer chemotherapeutic drugs
- Alcohol in excess
- The application of antiseptic preparations containing iodine (povidone/iodine mixture)

NOTE: Dietary iron supplements **will not** produce false-positive test results

Substances which can cause false-negative test results:15
- Ascorbic acid (vitamin C) in excess of 250 mg per day
- Excessive amounts of vitamin C enriched foods, citrus fruits and juices
- Iron supplements which contain quantities of vitamin C in excess of 250 mg per day

Gastroccult

Purpose

To detect occult blood and determine the pH of gastric vomitus.

Reagents and Materials

Test cards and developer are dispensed by the laboratory

Store at room temperature. Do not refrigerator or freeze. Protect slides from open air. Store slides in plastic wrapper until use. Protect developer from heat.

Quality Control

Quality Control is performed on each test card by developing the positive and negative Performance Monitors under the sample area of the card. This is the internal QC. Do not report results if performance monitors do not perform as expected. Quality control of the pH indicator is performed and documented by the laboratory upon opening each new shipment or lot of test cards.

Patient Preparation

No special patient preparation is necessary.

Specimen Collection

Gastric aspirate obtained by nasogastric intubation or vomitus are appropriate specimens. It is recommended that samples be tested immediately after collection. Samples applied to the occult blood area of a slide are stable for 4 days before being developed. If samples are not applied immediately, they can be stored in a clean sealed container (glass or plastic) for 24 hours at room temperature15° to 25° C.

Test Procedure

1. Open the slide and apply one drop of gastric sample to pH test circle and one drop to occult blood test area.
2. Determine pH of sample by visual comparison of the test area to the pH test comparator within 30 seconds.
3. Apply two drops of Gastroccult Developer directly over the sample in the occult blood test area. **Some gastric samples may be highly colored and appear as blue or green on the test area. Test results should only be regarded as positive if additional blue is formed after Gastroccult Developer is added.**

4. Interpret occult blood results within 60 seconds. The development of any trace of blue color in the occult blood test area is regarded as a positive result.
5. If performance monitors perform as expected, report patient results. Order GASTROCCULTin Evident.

Limitations of Procedure

Many foods (e.g., incompletely cooked meat, raw fruits and vegetables, etc.) have peroxidase activity which can produce a positive gastroccult result. Thus, a positive result does not always indicate the presence of human blood. Results are not intended to replace other diagnostic procedures such as gastroscopic examination or x-ray studies, and should therefore be used in conjunction with other information relevant to the clinical status of the patient.

General Laboratory Procedures

Specimen Labels

All specimens for laboratory testing must be labeled at the bedside with at least two patient identifiers. The patient's first and last name are required. Secondary identifiers may include the 8-digit account number, date of birth, or medical record number. Pre-printed labels generated from the hospital information system are acceptable, provided that one label is applied per tube. Be sure to label the container and not the lid, as lids may be switched. Improperly labeled specimens will be rejected per COLA requirements.

Specimen Source

The source of the specimen should be documented whenever possible. This applies to cultures and urine specimens. Random urine specimens are not appropriate for culture and will be rejected per COLA requirements. The urine collection type or culture source may be documented during order entry.

Urine specimens should be delivered to the lab as soon as possible, as bacteria multiply rapidly at room temperature. If the specimen cannot be delivered to the laboratory within 20 minutes, or if it is outside of regular laboratory house, the specimen should be stored in the refrigerator.

Clean Catch Urine Collection

♂ Males:

1. Wash hands thoroughly using plenty of soap and hot water.
2. Remove specimen cup from wrapper. Be careful not to touch the inside of the cup or lid at any time. If you accidentally do this, ask for a new cup.
3. The uncircumcised patient should pull back the foreskin from the tip of the penis.
4. Using a benzalkonium chloride towelette, cleanse thoroughly beginning at the tip of the penis and working upward.
5. Pass the first portion of urine into the toilet . Then, while continuing to urinate, place a sterile cup into the stream of urine and catch the mid-portion in the sterile cup. Do not touch the inside of the cup.
6. Remove the cup from the stream of urine before the bladder is completely empty, and pass the last part of the specimen into the toilet. Replace lid securely.

♀ Females:

1. Wash hands thoroughly using plenty of soap and hot water.
2. Remove specimen cup from wrapper. Be careful not to touch the inside of the cup or lid at any time. If you accidentally do this, ask for a new cup.
3. Sit on the toilet and, using the fingers of one hand, spread the labia apart. Continue to hold them spread during the entire cleansing and collection process.
4. Using a towelette, wipe **once** from the front of the body to the back. Cleanse between the folds of skin as carefully as possible. Using a clean towelette, repeat this cleansing process a second time.

5. Hold the cup in the other hand, and begin to pass the first part of the urine into the toilet. While continuing to urinate, place the cup into the stream of urine and catch this portion of the specimen.
6. Remove the cup from the stream of urine before the bladder is completely empty, and pass the last part of the specimen into the toilet. Replace lid securely.

Blood Specimens

Tubes should be inverted gently after collection in order to mix any anticoagulant or clot activators.

In order to minimize cross contamination from additives, tubes should be collected in the following order.

Blood Culture – use Chloraprep to scrub venipuncture site vigorously and allow to air dry prior to drawing blood
Plain Red (glass – no additives)
Blue Top
Gold Top, Tiger Top, or Plain Red (plastic – contains clot activator)
Green Top (heparin anticoagulant)
Purple Top (EDTA anticoagulant)
Gray Top (Oxalate anticoagulant – used for lactic acid test)

Blood Bank Procedures

Specimens for blood bank testing must be labeled at the bedside with the patient's name, date of birth, blood bank wristband number, and medical record number by the person who collected the specimen. The blood bank wristband, which is required for transfusion, must be applied by the person who collected the specimen. Documentation of two-person verification must be completed prior to starting the transfusion. Start and stop times, vital signs, and the name of the person starting and stopping the transfusion should be recorded.

Contact the laboratory or on-call laboratory personnel whenever the blood bank remote alarms are activated.

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