

Point of Care Testing
i-STAT Chem 8, CG4, EG7, PT/INR
Special Isolation i-STAT Education Module

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i-STAT/Laboratory Support

- **Greg Pomper, MD** Medical Director Clinical Laboratory
 - Office 716-7442, Pager 8009
- **Clinical Pathologist On-Call During Off-hours or for Emergent Need**
 - Use Wake On-Call to reach the Clinical Pathologist on-call
 - Select "Attending 2nd Call"
- **Angie Thayer Point-of-Care Testing**
 - Office 713-4136

i-STAT/Laboratory Support

- **Ray Dyer Point-of-Care Testing**
 - Office 713-4137

- **Jane Houska**
 - Office 716-3252

- **i-STAT Tech Support 1-800-366-8020**

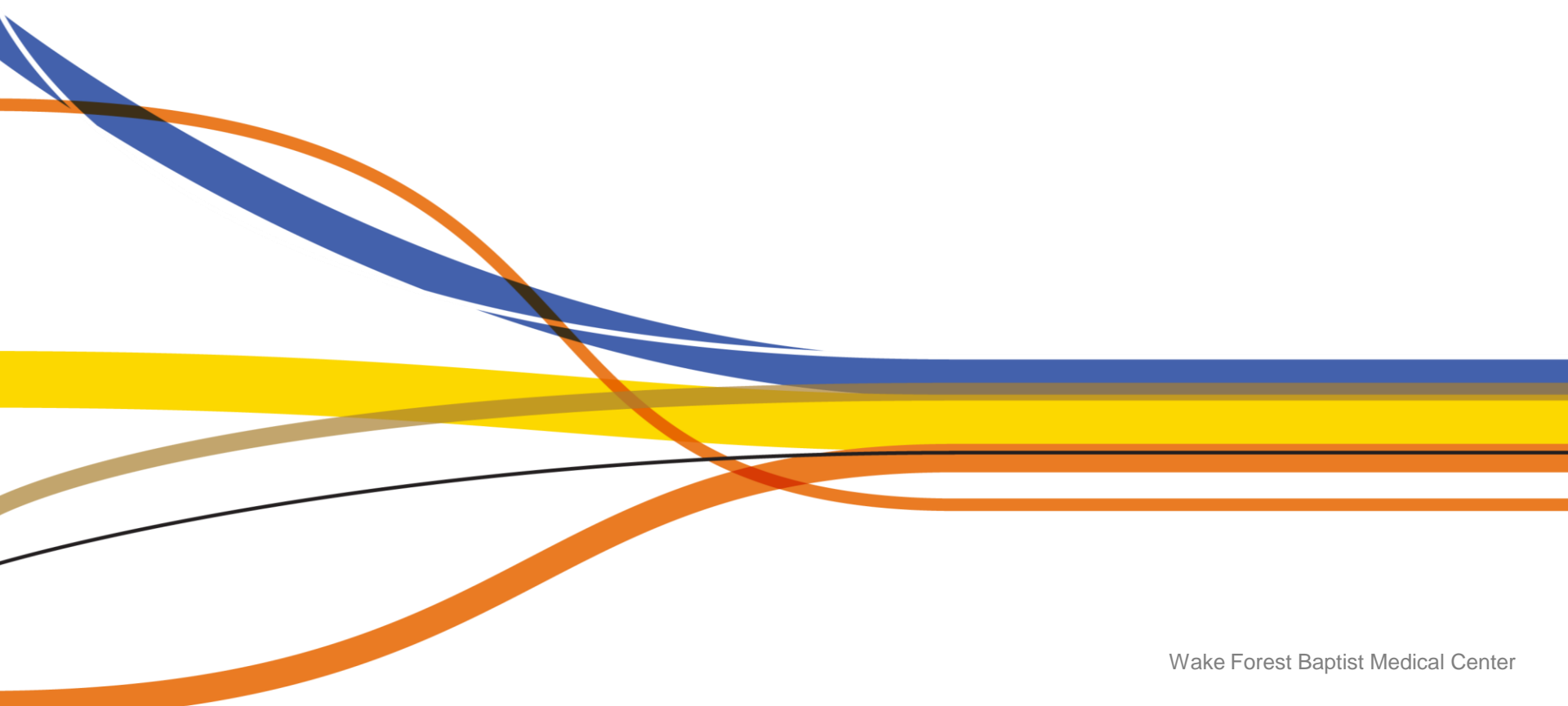
- **WFBMC POCT web site**

<http://intranet.wakehealth.edu/Departments/Pathology/POCT>

i-STAT Components

- Analyzer
- Cartridge
- Simulator (Electronic Quality Control)
- Liquid Quality Control Materials
- Downloader
- Recharger

Analyzer



i-STAT Analyzer (Handheld)

- Volt Meter
- Testing occurs on the test cartridge bio-sensors
- Rechargeable batteries are utilized—care should be taken to keep batteries charged—do not discard rechargeable batteries

i-STAT Testing on Suspect Ebola Patients

- For patients classified as, suspect Ebola patients, i-STAT testing should ONLY occur in the Special Isolation Unit located on 9 North Tower
- Use the designated i-STAT analyzer and equipment
- i-STAT testing on patients classified as suspect Ebola patients should NOT occur in the Emergency Department or other areas.

Analyzer

- One i-STAT analyzer will be located in the Special Isolation Unit

i-STAT Analyzer

- Will turn off after 2 minutes of non-use
- Can be turned on by pressing the on/off keypad—circle with line
- If operator or patient information has been entered, the analyzer will remain on for 15 minutes

Patient ID/Barcode Scanner

- The patient ID should be scanned to ensure correct ID entry
- Press and hold the SCAN key pad
- **CAUTION: Laser light**—do not stare into beam or point at anyone
- Patient ID can also be manually keyed into the analyzer—requires duplicate entry
- **Use the admission CSN**

Information Entered into i-STAT

- A temperature corrected blood gas can be obtained
 - Make sure any entries made at this prompt are true and correct
- The FIO₂ can also be entered
 - Can be entered as percent, liters, or decimal entries

Information Entered into i-STAT

- The sample type should be entered—
- Choices are:
 - Arterial
 - Venous
 - Capillary
 - Cord
 - Mixed Venous
 - CPB (cardio-pulmonary bypass)—select NO
 - Hematocrit results will be altered if CPB is selected. If CPB is selected in error, do NOT use the hematocrit results

Analyzer Display

- ‘Cartridge Locked’—cartridge or simulator locked in analyzer. DO NOT remove when this message is displayed
- Flashing battery icon or ‘Low Battery’ indicates battery voltage is low and batteries need to be re-charged

Menu Options

- **Analyzer Status**

- Allows viewing of battery voltage-recommend maintaining charge above 8 volts

- **Data Review**

- Allows review/print of data stored in analyzer

- **Quality Tests**

- Quality control checks are performed utilizing this menu

Analyzer Download

- ONLY use the downloader located in the Special Isolation unit

Analyzer Download

- The analyzer will display “Communication in Progress” indicating a successful download of data
- An error message will display on the analyzer if results do not successfully transmit
- Problems should be reported to the Point-of-Care Testing office. 3-4136 or 3-4137
- Manually enter results into Wake One if downloader is not functioning

Re-charger

- Can charge battery in compartment and battery in analyzer

Cartridges

- Chem 8
- EG7
- CG4
- PT/INR

i-STAT Cartridges

- Testing occurs in the cartridge
- Cartridges have bio-sensors that “measure” the analytes tested
- Chem 8, EG7, CG4, and PT/INR will be used for Special Isolation

i-STAT Cartridges –Chem 8

- Includes
 - Sodium
 - Potassium
 - Chloride
 - Ionized Calcium
 - Glucose
 - BUN
 - TCO₂
 - Creatinine
 - Hemoglobin/Hematocrit

i-STAT Cartridges—EG7

- Includes
 - Blood Gas—pH, pCO₂, pO₂, HCO₃, TCO₂, BE, O₂Sat
 - Sodium
 - Potassium
 - Ionized Calcium
 - Hemoglobin/Hematocrit

i-STAT Cartridges—CG4

- Includes
 - Blood Gas—pH, pCO₂, pO₂, HCO₃, TCO₂, BE, O₂Sat
 - Lactate

i-STAT Cartridges—PT/INR

- Includes
- PT/INR

Cartridge Handling—All Cartridges

- Store 2-8°C until manufacturer's expiration date
- Can be stored at room temperature (18-30°C) per manufacturer instructions.
 - DO NOT use past room temperature expiration date!
 - Individual cartridges can be used after 5 minutes at room temperature
- Open by tear symbol
- Use cartridge IMMEDIATELY after opening
- Fill to blue triangle—leave “blood dome”
- Insert into analyzer immediately after filling with sample

Cartridge Handling-DO NOT's

- DO NOT use “quick heating”—holding close to body or near a warm surface
- DO NOT store or expose cartridges to extreme cold or heat such as freezing or stored above lights or computers
- Do NOT re-refrigerate cartridges once they have warmed to room temperature
- Do NOT touch bio-sensors
- Do NOT pre-rupture silver calibrant disc
- Do NOT re-use cartridges
- Do NOT leave exposed to air and moisture
- Do NOT use expired cartridges for patient testing

Quality Controls (QC) and Maintenance

- Simulators
- Liquid QC
- Maintenance

Simulators

- Electronic Quality control that is used to validate the i-STAT analyzer—Pass or Fail
- QC results are automatically documented when the i-STAT analyzer is downloaded

Simulators-Internal

- An INTERNAL electronic simulator is performed automatically by the analyzer every 8 hours of use with each cartridge type.
- The internal simulator is performed when a patient cartridge is inserted.
- Results will not be given if the simulator fails.
- If the simulator passes, patient results will be displayed.

Simulators-External

- The EXTERNAL electronic simulator is the same as the internal simulator but is an external device and can be tested upon demand.

Simulators-External

- The external simulator should be used:
 - If the analyzer is dropped
 - If the internal simulator fails
 - If an error code occurs that indicates the simulator should be tested.
 - If analyzer performance is in question

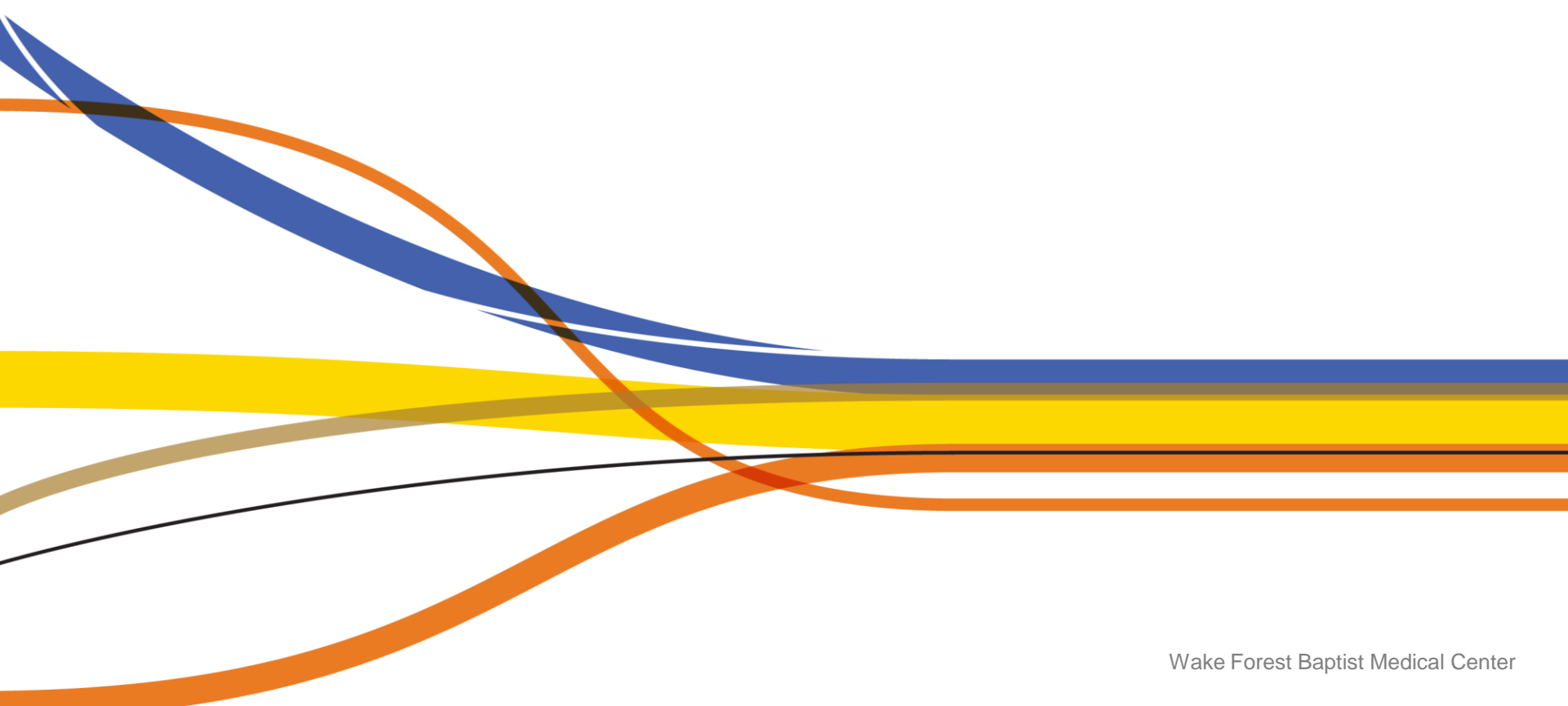
Liquid Quality Control

- Used to validate performance of test cartridges
- Consists of multiple levels—test specific
- Should be performed:
 - On each new cartridge shipment, per cartridge type, per cartridge lot #, PRIOR to patient use—by Clinical Lab staff
 - Monthly—by testing site staff
 - If cartridge/analyzer performance is in question

i-STAT Maintenance, etc.

- Recharge batteries
- Disinfect outside of analyzer
 - Do not get moisture inside of the analyzer

Sample Information



Sample Requirements CHEM 8

- **ONLY whole blood should be tested on the i-STAT**
- Arterial, venous or capillary is acceptable
- A plain syringe or heparinized syringe may be used
- Samples collected in a plain syringe with no additive/anticoagulant/heparin should be tested within 3 minutes of collection
- Remove ALL excess heparin from the syringe, prior to collecting the i-STAT sample.
- Heparinized whole blood should be tested within 10 minutes of collection
- Heparin is the ONLY acceptable anti-coagulant which may be used with the i-STAT
- Samples should Never be transferred from one collection container to another and then tested on i-STAT

Sample Requirements EG7

- **ONLY whole blood should be tested on the i-STAT**
- Arterial, venous or capillary is acceptable
- Syringe or capillary collection containers may be used
- Heparinized whole blood can be used for blood gas and electrolyte testing—test within 10 minutes of collection
- Samples collected in a plain syringe with no additive/anticoagulant/heparin should be tested within 3 minutes of collection
- Heparin is the **ONLY** acceptable anti-coagulant which may be used with the i-STAT
- Samples should **Never** be transferred from one collection container to another and then tested on i-STAT

Sample Requirements CG4

- Test **IMMEDIATELY** after collection
- **ONLY whole blood** should be tested on the **i-STAT**
- Arterial, venous or capillary is acceptable
- Syringe or capillary collection containers may be used
- Heparin is the **ONLY** acceptable anti-coagulant which may be used with the i-STAT
- Samples should **Never** be transferred from one collection container to another and then tested on i-STAT

Sample Requirements—PT/INR

- Test **IMMEDIATELY** after collection
- If testing a finger stick sample, test the **FIRST** drop of blood
- **ONLY whole blood should be tested on the i-STAT**
- Arterial, venous or capillary is acceptable
- Plain Syringe collection containers with **NO** additive/anti-coagulant may be used
- Samples should **Never** be transferred from one collection container to another and then tested on i-STAT
- **NOTE:** Heparin anti-coagulated collection containers should **NEVER** be used for PT/INR samples

In-Dwelling Line

- Back flush line with sufficient amount of blood to remove intravenous solution, heparin, or medications that may contaminate the sample.
- **i-STAT Recommendation:** five to six times the volume of the catheter, connectors, and needle.
- **Coagulation cartridges:** If blood must be drawn from an indwelling line, possible heparin contamination and specimen dilution should be considered. The line should be flushed with 5mL of saline and the first 5mL of blood or six dead space volumes of the catheter should be discarded.
- ***Accurate results depend on an adequate back flush to eliminate the possibility of sample contamination with IV fluids.***
- *Caution should be taken when collecting from lines which have had fluids that could adhere to the sides of the tubing. These lines may be difficult to adequately back flush.*

Sample/Testing Considerations

- Only test whole blood. No other specimen should be tested
- Do NOT use a needle to fill the i-STAT cartridge.
- Fill the cartridge directly from a syringe
- Do NOT move the analyzer once the cartridge has been inserted—keep flat and free of vibrations during test cycle

Sample Considerations

- ALWAYS use a well mixed sample
- Hematocrit is most affected by an improperly mixed sample
- Mix syringe or capillary samples for 15 seconds
- Always squirt out the first drop of blood from syringe or capillary samples
 - To check for clots and to get rid of any micro air bubbles
- NEVER ever run a sample that has or has had a clot. Inaccurate results may be obtained!

Sample Considerations—EG7 and CG4

- Any sample collected for pH, pCO₂, pO₂, ICa, or TCO₂ should not be contaminated with air.
- Samples should be capped immediately after collection and kept airtight
 - If not kept airtight, invalid results may be obtained

Sample Considerations-Capillary— NON PT/INR cartridges

- Capillary samples should always have the first drop of blood wiped away before collecting a sample for i-STAT blood gas, electrolyte, or lactate testing.
- Potassium results may be adversely affected if the first drop of blood is used from a capillary sample
- Capillary samples should be tested within 3 minutes of collection

Sample Considerations-Capillary— PT/INR

- Use the FIRST drop of blood
- Test PT/INR samples IMMEDIATELY after collection
 - If there is a delay in testing, false low results may be obtained

Sample Requirements PT/INR Cartridge

- If a collection container is used for a venous/arterial sample, the sample must be collected in a **plastic** syringe without anti-coagulant and tested IMMEDIATELY after collection.
- Transfer devices should not be used to transfer sample to the cartridge.
- **Metal needles** should not be used when filling an i-STAT cartridge.
- **If sample testing is delayed, results will be adversely affected.**

Important PT/INR Reminders

- Enter operator, patient, and cartridge information PRIOR to collecting the venipuncture sample
- The test cartridge **MUST** be Filled **IMMEDIATELY** after the skin puncture—**NO DELAY**—You cannot ‘reuse’ a finger stick—even if the finger is still bleeding
- If testing a venous sample, fill the i-STAT cartridge **PRIOR** to filling other sample collection tubes

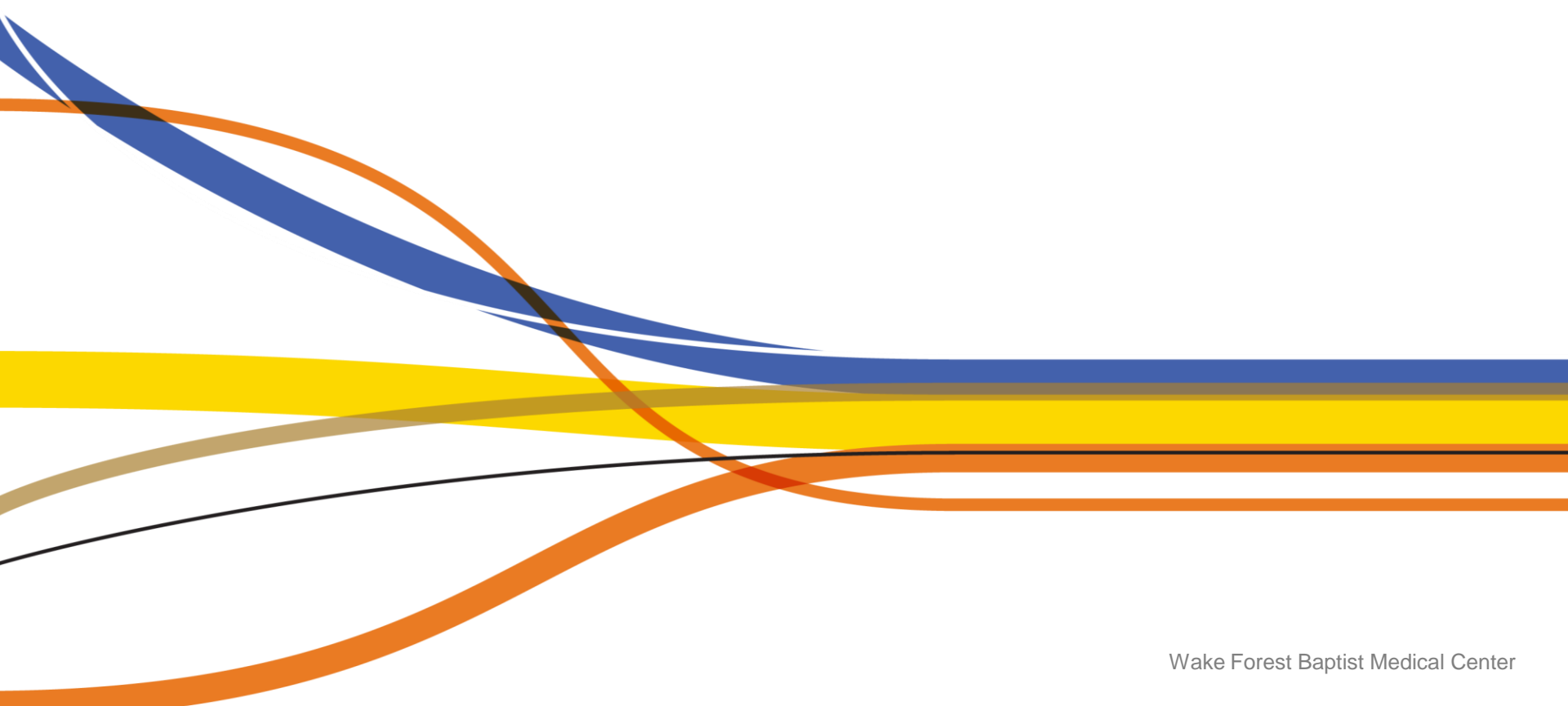
Important PT/INR Reminders

- The test cartridge **MUST** be inserted into the analyzer **IMMEDIATELY** after filling with blood sample—**NO DELAY**
- If an error code 19 occurs, the INR is most likely very high
- i-STAT PT/INR may report a false prolongation of the prothrombin time (PT) and an elevation of the INR on samples contaminated with Chlorhexidine Gluconate. *This chemical can be found in some skin cleansing solutions.*

When Multiple Cartridge Results are Needed at the Same Time:

- Test PT/INR and CG4 first, since they must be tested immediately after collection. Otherwise, inaccurate results may be obtained.

Patient and Sample Identification



Patient Identity-Misidentifications

- Any misidentified samples/results should be reported to the Point of Care Testing office.
- Send an e-mail to all of the following individuals
 - athayer@wakehealth.edu
 - rddyer@wakehealth.edu
 - jhouska@wakehealth.edu

Results

- Factors affecting results
- Result considerations
- Result evaluation
- Critical Results
- Patient Credit Requests

Factors Affecting Results

- Refer to the i-STAT System Manual—Cartridge Test Information (CTI) sheets for factors which can adversely affect i-STAT results
- Example:
 - Increased patient lactate, hemodilution, and certain medications can affect results

i-STAT Cartridge and Test Information

- Here is the link to the cartridge and test information sheets for i-STAT analytes
- <http://www.abbottpointofcare.com/Customer-Info-Center/Cartridge-and-Test-Info-Sheets.aspx>

Result Considerations

- Samples diluted with IV fluids will give inaccurate results
- Results should be carefully evaluated
- Contamination may be indicated by:
 - Drop in hemoglobin and hematocrit
 - Falsely elevated sodium and decreased potassium if contaminated with saline
 - Blood gas results will be erroneous—low pCO₂ may be a possibility

Result Considerations

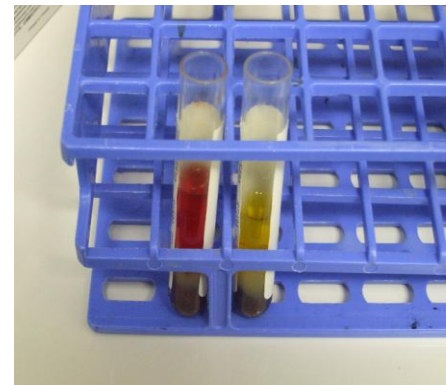
- The i-STAT tests whole blood. Hemolysis can Not be determined.
- Hemolysis will falsely elevate potassium results

What is Hemolysis?

- The destruction of red blood cells, caused by disruption of the cell membrane and resulting in the release of hemoglobin

How is Hemolysis Detected?

- The sample is spun in a centrifuge or the sample is allowed to sit until the red cells and plasma separate
- The supernatant/serum/plasma (**top layer** of fluid) should be evaluated for any pink or red color
- The presence of pink or red color in the serum/plasma indicates the presence of hemolysis



Which Value will be Adversely Affected by Hemolysis?

- Potassium
- When the red blood cell membrane is ruptured, potassium is released from the red cell into the blood sample.
- i-STAT tests whole blood and hemolysis cannot be determined when using i-STAT

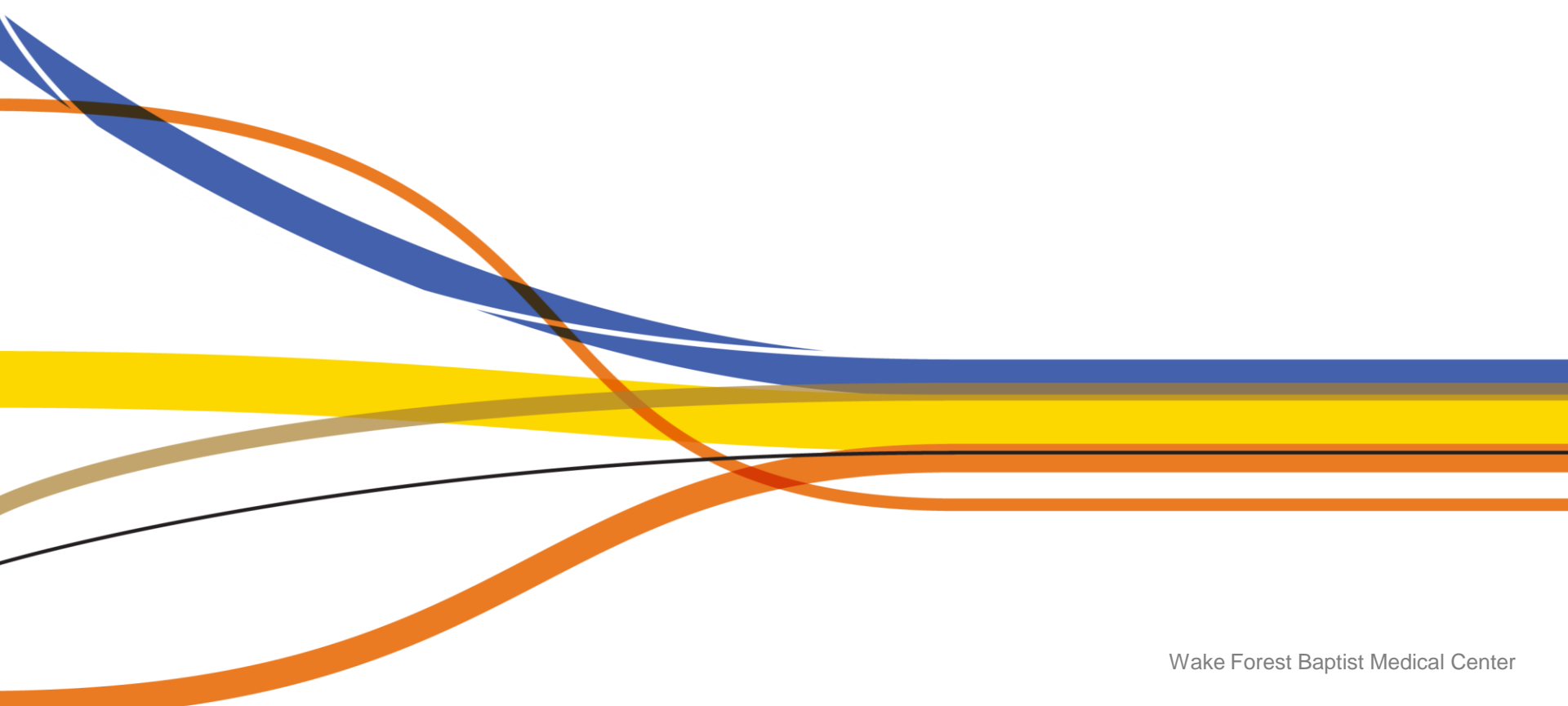
Estimated Glomerular Filtration Rate (eGFR)

- Estimated Glomerular Filtration Rate (eGFR) values are only reported when Creatinine results are downloaded into the electronic medical record.
- The i-STAT handheld will NOT report eGFR values.

When Results Not Given, etc.

- **Cartridge error**
 - Look at Technical Bulletin 'Analyzer Coded Messages' for details
 - If the same error code occurs over and over with no apparent code, notify the Clinical Laboratory POCT Coordinators
- **Star out**
 - Occurs when a specific bio-sensor is compromised or there is an interfering substance in the sample
- **Out of instrument range (>x value or <x value)**
 - Result is out of reportable range for the analyzer
- **Suppressed results (<>)**
 - Displays for calculated parameters, if the calculation is dependent on a result that is out of reportable range.

Miscellaneous Information



I-STAT Credit Requests

- All i-STAT testing should have a documented physician order.
- Any i-STAT result which has a valid medical record # and CSN is automatically ordered, billed, and resulted to that patient when the analyzer is downloaded.
- It is the responsibility of the testing personnel to request credit for any i-STAT testing which should not be resulted or billed.

i-STAT Supplies

- Refrigerated cartridges will be stored in the Pharmacy store room in the Special Isolation Unit
- Additional cartridges can be obtained from the OR Blood Gas Lab—First floor Clinical Sciences building---Code707*
- Care should be taken to only get the amount of cartridges which will be used within the room temperature expiration dating period

Hands On Experience

- Change batteries and check battery voltage
- Test External electronic simulator
- Test/Discuss Liquid QC
- Test patient sample
- Recall results
- Discuss Menu Options
- Download of results

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