



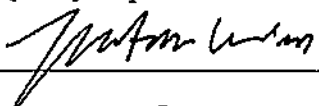


STANDARDIZED TESTING / OPERATING PROTOCOL REQUEST/ANNOUNCEMENT

Annual 2018 Stago Lot Conversion

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| Description: | The laboratories will convert to the following lot numbers of PT, PTT, and Controls: STA-Neoplastin CI Plus Lot 253023 Exp 11/30/2019 STA-PTT Automate Lot 253196 Exp 12/31/2019 STA-Fibrinogen Lot 253102 Exp 11/30/2019 STA-Coag N&ABN Plus Lot 253184 Exp 12/31/2019 |
| Implementation Date: | August 28,2018 @10:00am |
| Performing Locations: | Click on the boxes that apply: <input checked="" type="checkbox"/> Alamance Regional <input checked="" type="checkbox"/> Med Center Mebane <input checked="" type="checkbox"/> Annie Penn Hospital <input checked="" type="checkbox"/> Moses Cone Hospital <input checked="" type="checkbox"/> Med Center at High Point <input checked="" type="checkbox"/> Wesley Long Hospital <input checked="" type="checkbox"/> Women's Hospital |
| Affected Locations: | Click on the boxes that apply: <input checked="" type="checkbox"/> Alamance Regional <input checked="" type="checkbox"/> Med Center Mebane <input checked="" type="checkbox"/> Annie Penn Hospital <input checked="" type="checkbox"/> Moses Cone Hospital <input checked="" type="checkbox"/> Med Center at High Point <input checked="" type="checkbox"/> Wesley Long Hospital <input checked="" type="checkbox"/> Women's Hospital |

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| <p>Affected Departments:</p> | <p>Click on the boxes that apply:</p> <p><input type="checkbox"/> Blood Bank <input type="checkbox"/> Cytology <input type="checkbox"/> Flow Cytometry <input type="checkbox"/> Histology <input type="checkbox"/> Microbiology <input type="checkbox"/> Phlebotomy <input type="checkbox"/> Point of Care <input checked="" type="checkbox"/> Rapid Response Lab <input type="checkbox"/> Respiratory Therapy <input type="checkbox"/> Specimen Processing</p> |
| <p>Specimen Type:</p> | <p>Sodium Citrate Plasma</p> |
| <p>Updated Clinical Lab Procedures:</p> | <p>Alamance Procedures: Stago Compact Reagents and Controls for ARMC Clinical Laboratory</p> <p>Greensboro/ Reidsville Procedures: COAG-0716C-CH Stago Information Sheet</p> |
| <p>Retired Clinical Lab Procedures:</p> | <p>N/A</p> |
| <p>Notification to Client:</p> | <p>Click on the boxes that apply: <input checked="" type="checkbox"/> Section Not Applicable</p> |

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| | <p><input checked="" type="checkbox"/> Memo Needed</p> <p>Distribution of Memo:</p> <p><input checked="" type="checkbox"/> Medical Staff Alamance and Greensboro/Reedville</p> <p><input type="checkbox"/> Allied Health Professionals (PA, Nurse Practitioners)</p> <p><input type="checkbox"/> Anesthesia</p> <p><input type="checkbox"/> Annie Penn (Primary Source Physicians)</p> <p><input type="checkbox"/> Dentist</p> <p><input type="checkbox"/> Emergency Department/Urgent Care Centers</p> <p><input type="checkbox"/> Family Practice</p> <p><input type="checkbox"/> Infectious Docs #ID Docs (John Campbell, Robert Comer, Jeffrey Hatcher, Cynthia Snider, Kees Van Dam)</p> <p><input type="checkbox"/> OB/GYN</p> <p><input type="checkbox"/> Pathology</p> <p><input type="checkbox"/> Pediatricians</p> <p><input type="checkbox"/> Psych</p> <p><input type="checkbox"/> Radiology</p> <p><input type="checkbox"/> Surgery</p> <p><input type="checkbox"/> #Nursing Leadership (Directors, Asst. Directors, Clinical Nurse Manager)</p> <p><input checked="" type="checkbox"/> Pharmacy - Send to DeAnne Brooks, Jim Hasspacher, Jackie Rowe, and Randy Abasher</p> <p><input type="checkbox"/> #IM Residents</p> <p><input type="checkbox"/> Phlebotomy Managers and Supervisors</p> <p><input type="checkbox"/> Point of Care: Sheila, Kim & Marty</p> |
| <p>Accreditation Section:</p> | <p>Click on the boxes that apply:</p> <p><input checked="" type="checkbox"/> Section Not Applicable</p> <p><input type="checkbox"/> CAP Test menu change needed</p> <p><input type="checkbox"/> CMS Analyte form change needed</p> <p><input type="checkbox"/> Proficiency Testing surveys changes needed or ordered</p> |
| <p>Laboratory IT section:</p> | <p>Click box and type needed changes/additions:</p> <p><input checked="" type="checkbox"/> Section Not Applicable</p> <p><input type="checkbox"/> LIS changes</p> <p><input type="checkbox"/> Reference range change/addition</p> <p><input type="checkbox"/> Technical Failure change/addition</p> <p><input type="checkbox"/> Critical Value change/add</p> <p><input type="checkbox"/> Text comments needed</p> <p><input type="checkbox"/> Specimen collection instructions</p> <p><input type="checkbox"/> Need to monitor TAT</p> <p><input type="checkbox"/> CPT code for tests(s)</p> |

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| <p>Technical Staff Update:</p> | <p>The Cone Health laboratories will convert to the new lot of (Neoplastin) PT, PTT, Fibrinogen, and QC on August 28, 2018 at 10:00 am.</p> <p>Greensboro/Reidsville locations</p> <ul style="list-style-type: none"> • Refer to COAG-0540-CH <i>Parallel Testing with Coagulation Annual Lot Conversion</i> • See updated Stago information sheet <p>Alamance Medical locations</p> <ul style="list-style-type: none"> • Refer to <i>Annual Lot to Lot Conversion for PT and APTT- Stago Compact Instrument – Set up and Running Test Samples</i> • See updated Stago Compact Reagents and Controls for ARMC Clinical Laboratory <p>All Cone Health laboratories:</p> <ol style="list-style-type: none"> 1-No new reference interval adjustments were required based on the lot conversion studies. 2-New Geometric Mean: 13.1 s 3-New ISI: 1.28 4-Each site must update each Stago with new ISI 1.28 and new Geometric mean 13.1s 5-Before reporting the first patient tested after the conversion, each site must calculate the INR manually, compare to printed analyzer INR, and document in lot conversion notebook. 6-After go live, sites should perform QC every 4 hours for 5 days. <ul style="list-style-type: none"> • See Stago Lot Conversion QC Sign Off 7-Refer to Stago Lot Conversion Tasks list |
| <p>STOP Initiator:</p> | <p>Kimberly Barr, MT (ASCP)</p> |
| <p>Alamance Medical Director Signature</p> | <p>Quality Department will obtain signature:  8/17/18</p> |
| <p>Mebane Medical Director Signature</p> | <p> 8/17/18</p> |
| <p>Greensboro/Reidsville Medical Director Signature:</p> | <p> 8/17/18</p> |



TO: Cone Health Medical and Nursing Staff

FROM: Joshua Kish, MD, FCAP, FASCP

Chief of Pathology, Cone Health

John Patrick, MD, FCAP, FASCP

Greensboro and Reidsville Hospital Laboratories Medical Director, Cone Health

Mary Olney, MD, FCAP, Med center at Mebane Medical Director, Cone Health

John Patrick, MD 8/17/18
Mary Olney, MD 8/17/18

Date: August 21, 2018

The Cone Health hospital laboratories conducted new coagulation reagent correlation studies and found no clinically significant differences between the two lot numbers. Reference ranges for the Greensboro/Reidsville and Alamance campuses are as seen below.

The laboratory will update the ISI of the new PT reagent (Lot 253196) to 1.28 on August 28, 2018 at 10:00am.

| Assay | Range for all Cone Health laboratories | Units |
|------------------------------------|--|---------|
| Unfractionated Heparin | 0.30-0.70 | IU/mL |
| Low Molecular Weight Heparin | 0.50-1.20 | IU/mL |
| Prothombin Time (PT) | 11.4-15.2 | Seconds |
| Partial Thromboplastin Time (aPTT) | 24 – 36 | Seconds |
| Fibrinogen | 210 – 475 | mg/dL |

The following assays are available to monitor anticoagulants:

| Assay | Anticoagulant |
|--|--|
| Prothombin Time (PT) | Warfarin (Coumadin) |
| Activated Partial Thromboplastin Time (aPTT) | *Unfractionated Heparin, Direct Thrombin Inhibitors (Bivalirudin and Argatroban) |
| Heparin Assay (Anti-Xa) | *Unfractionated Heparin |
| Low Molecular Weight Heparin (Anti-Xa) | Enoxaparin, Dalteparin, Tinzaparin |

Recommendations for monitoring anticoagulant therapy:

For an anticoagulant naïve patient a baseline PT and PTT should be performed before choosing anticoagulant therapies. If the baseline results are not within the normal range, it is recommended that a patient risk assessment be done before proceeding with therapy. Direct oral anticoagulants (apixaban, edoxaban, dabigatran or rivaroxaban) interfere with routine coagulation tests. Interpretation of lab results should be done with caution without knowing the time of when the patient's last dose was taken.

*Heparin levels are measured by an anti-Factor Xa assay and reported in IU/mL of activity. This is a direct measurement of the patient drug level and avoids the lack of specificity inherent in the aPTT assay. Studies indicate that monitoring of heparin therapy using anti-Xa levels, as opposed to the aPTT, can more quickly achieve patient therapeutic ranges and shorten hospital stays. If a patient heparin level is not in the expected range, and patient dosage has been confirmed, the Antithrombin III assay is available to assess possible heparin resistance.

Monitoring of the Factor Xa Inhibitors Fondaparinux, Rivaroxaban, Apixaban, and Edoxaban appear to be unnecessary for most patients. Assay techniques and target ranges for FXa Inhibitors have not been rigorously standardized and there is very little information relating anti-Xa levels to clinical outcomes. Currently, Cone Health laboratories do not perform specially-calibrated assays to monitor FXa Inhibitors.