CONE HEALTH

STANDARDIZED TESTING / OPERATING PROTOCOL REQUEST/ANNOUNCEMENT

Annual 2018 Stago Lot Conversion

Description:	The laboratories will convert to the following lot numbers of PT, PTT, and Controls: STA-Neoplastin Cl 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:** ☒Alamance Regional ☒Med Center Mebane ☒Annie Penn Hospital ☒Moses Cone Hospital ☒Med Center at High Point ☒Wesley Long Hospital ☒Women's Hospital
Affected Locations:	**Click on the boxes that apply:** ☒Alamance Regional ☒Med Center Mebane ☒Annie Penn Hospital ☒Moses Cone Hospital ☒Med Center at High Point ☒Wesley Long Hospital ☒Women's Hospital

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

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

Technical Staff Update:	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. **Greensboro/Reidsville locations** • Refer to COAG-0540-CH *Parallel Testing with Coagulation Annual Lot Conversion* • See updated Stago information sheet **Alamance Medical locations** • Refer to *Annual Lot to Lot Conversion for PT and APTT- Stago Compact Instrument – Set up and Running Test Samples* • See updated Stago Compact Reagents and Controls for ARMC Clinical Laboratory **All Cone Health laboratories:** 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.** • See Stago Lot Conversion QC Sign Off 7-Refer to Stago Lot Conversion Tasks list
STOP Initiator:	Kimberly Barr, MT (ASCP)
Alamance Medical Director Signature	Quality Department will obtain signature: 8/17/18
Mebane Medical Director Signature	MD 8/17/18
Greensboro/ Reidsville Medical Director Signature:	MD 8/17/18

CONE HEALTH

TO: Cone Health Medical and Nursing Staff

FROM: Joshua Kish, MD, FCAP, FASCP 8/17/18

Chief of Pathology, Cone Health

John Patrick, MD, FCAP, FASCP John Patrick, MD 8/17/18

Greensboro and Reidsville Hospital Laboratories Medical Director, Cone Health

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

2018 Lot Conversion Tasks:

1. Build QC files in SunQuest. **Use historic standard deviations.**
2. Delete Patient files on the Stago.
    a. Stago Compact Max: Test Panel · Patient Analyses · Patient files ☒ Select Waste Basket/Delete ☒ Select All files
    b. Stago Compact: Files menu · Delete Patient Files ☒ Press F4 to delete
3. Load new lot of reagents and QC. **See COAG-0540-CH*: Parallel Testing with Coagulation* (Greensboro/Reidsville) and *Annual Lot to Lot conversion for PT and APTT- Stago Compact Instrument – Set up and Running Test Samples* (Alamance Medical) for complete instructions for Stago Compact and Stago Compact Max.**
4. Update ISI and Geometric mean in Stago following the procedures listed above:
    Change Mean from 13.2 to 13.1<>
    Change ISI from 1.25 to 1.28<>
5. Run QC.
6. Before you release the first patient, the new INR **must** be verified. To perform INR verification:
    Remember to use a scientific calculator.
    You can change the calculator on Windows PCs to be scientific by selecting View ☒ Scientific
    The formula for INR calculation:

$$\left(\frac{\text{Patient PT}}{\text{Geometric Mean}}\right)^{\text{ISI}} = \text{INR}$$

    PT result divided by the geometric mean raised to the ISI = INR
7. Print screenshots of calibration screens for: PT, PTT, and FIBR
8. File calibration screen shots and INR verification in your 2018 lot conversion notebook.

Post Lot Conversion Tasks:

1. Discard any old reagent.
2. Label new lot reagent and QC with green "Ready to Use" sticker.
3. Perform QC every 4 hours for 5 days to assess control stability.
    See attached schedules to post at bench top:
    AP, AR, MC, MHP, WH, and WL Stago Lot Conversion QC Sign Off
    MedCenter Mebane Stago Lot Conversion QC Sign Off
4. At the end of 5 days, print LJs and adjust means to reflect recovery.
    Fill out QM-1508F-CH Quality Control Lot Verification form. (This is an assayed control.)
    Once signed by Manager, Site Director and CLIA* Medical Director, file QM-1508F in lot conversion notebook
5. Continue to monitor QC during monthly LJ review and adjust if necessary.

AP, AR, MC, MHP, WH, WL

Stago Lot Conversion QC Sign Off						
	N/A	N/A	**1000**	1400	**1800**	2200
Tech						
	200	600	**1000**	1400	**1800**	2200
Tech						
	200	600	**1000**	1400	**1800**	2200
Tech						
	200	600	**1000**	1400	**1800**	2200
Tech						
	200	600	**1000**	1400	**1800**	2200
Tech						
	200	600	**1000**	N/A	N/A	N/A
Tech						

***Shaded times indicate when new QC is to be made**

Med Center Mebane

Stago Lot Conversion QC Sign Off						
	N/A	N/A	**1000**	1400	**1800**	2200
Tech						
	200	600	**1000**	1400	**1800**	2200
Tech						
	200	600	**1000**	1400	**1800**	2200
Tech						
	200	600	**1000**	1400	**1800**	2200
Tech						
	200	600	**1000**	1400	**1800**	2200
Tech						
	200	600	**1000**	N/A	N/A	N/A
Tech						

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