



STANDARDIZED TESTING / OPERATING PROTOCOL REQUEST/ANNOUNCEMENT

New Reagent and Control Lot Verification: D-Dimer, Heparin, and ATIII

Description:	Reagent and control verification: D-Dimer, Heparin, ATIII (GSO/Reidsville) ARMC will go live with procedural updates at a later date.
Implementation Date:	03/20/2018
Derfermine	Click on the boxes that apply:
	□Alamance Cancer Center
	⊠Alamance Regional
	⊠Annie Penn Hospital
Performing Locations:	⊠Moses Cone Hospital
Lucations.	⊠Med Center at High Point
	□Med Center at Mebane
	⊠Wesley Long Hospital
	⊠Women's Hospital
	Click on the boxes that apply:
	□Alamance Cancer Center
	⊠Alamance Regional
Affected Locations:	⊠Annie Penn Hospital
	⊠Moses Cone Hospital
	⊠Med Center at High Point
	Med Center at Mebane
	⊠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:	Greensboro/Reidsville Procedures: COAG-0535-CH Quantitative D-Dimer Assay STA Compact COAG-0538-AP Heparin Assay COAG-0701-CH Stago PT/PTT/FIBR General Procedure STA Compact COAG-0846-CH Stago PT/PTT/FIBR General Procedure STA Compact Max COAG-0848-CH Quantitative D-Dimer Assay STA Compact Max COAG-0849-CH STA-Liquid Anti-Xa Hybrid Assay STA Compact Max COAG-0850-MC ATIIII Stago Compact Max
Retired Clinical Lab Procedures:	N/A
Notification to Client:	Click on the boxes that apply: Section Not Applicable

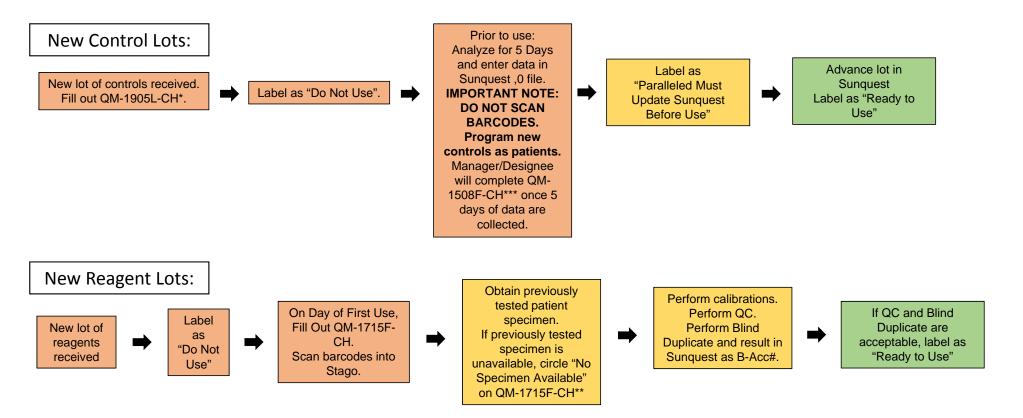
	□Memo Needed
	Distribution of Memo:
	□Medical Staff
	□ Allied Health Professionals (PA, Nurse Practioners)
	□ Anesthesia
	□ Annie Penn (Primary Source Physicians)
	Dentist
	Emergency Department/Urgent Care Centers
	Family Practice
	Infectious Docs #ID Docs
	(John Campbell, Robert Comer, Jeffrey Hatcher, Cynthia Snider, Kees
	Van Dam)
	Pediatricians
	□ #Nursing Leadership (Directors, Asst. Directors, Clinical Nurse Manager)
	□ Pharmacy - Send to DeAnne Brooks & Jim Hasspacher
	\square #IM Residents
	☐ Kim Helsabeck
	□ Phlebotomy Managers and Supervisors
	□ Point of Care: Sheila, Kim & Marty
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	Click on the boxes that apply:
	Section Not Applicable
Accreditation	CAP Test menu change needed
Section:	CMS Analyte form change needed
	□Proficiency Testing surveys changes needed or ordered
	Click box and type needed changes/additions:
	⊠Section Not Applicable
	□LIS changes
Laboratory IT section:	□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)
	The following instructions have been added to the Stago Compact and Stago Compact Max procedures for FIBR, DIMR, HPR/LMWH, and ATIII.
	New Quality Control Lot Verification:
	Follow procedure QM-1508-CH Corporate Quality Control Plan.
	Note: Only one lot per quality control can be loaded on the analyzers at one time. To perform testing on the new lot, perform quality control as patients. Enter this information in LIS under the appropriate new QC file (e.g. C-COAN,0, C-COAP,0). Since these are assayed controls, perform new lot verification for at least <u>five</u> days.
	New Reagent Lot Verification:
Technical Staff Update:	Record new lot and expiration date on QM-1517F-CH Reagent Verification Log. Obtain a specimen tested on the current lot of reagent. This can be a patient. If no patient sample is available, circle "No Specimen Available" on Reagent Verification Log.
	Once results have been obtained and resulted from the current reagent, unload current reagent and replace with new reagent. Perform calibration, if required, and quality control. Record control acceptability on QM-1517F-CH Reagent Verification Log. Perform testing on blind duplicate specimen and result per QM-1934-CH Blind Duplicates. Record acceptability of blind duplicate on QM-1517F-CH Reagent Verification Log. Reagent is acceptable for use if quality control and blind duplicate specimen (if available) are acceptable.
	<u>MedCenter High Point and Women's Hospital Only:</u> Sites with one analyzer will need to start performing patient blind duplicates during reagent lot changes. To result in Sunquest, BDUP QC files must be built. This can be done by copying either Annie Penn, Moses Cone, or Wesley Long BDUP files.
STOP Initiator:	Derick Lane and Jackie Hobbins
Alamance Medical Director Signature:	Quality Department will obtain signature: MUA-B. Kulas 2.6.18.
Greensboro/ Reidsville Medical Director Signature:	folen Partimel, un 2/12/18

Approved and current. Effective starting 6/14/2016. 1719F (version 1.0) QM-1719F-CH STOP Request.Annoucement Template Cone Health Laboratories QM-1719F-CH

MedCenter Mebane Medical Director Signature:
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ATIII, DIMR, and HPR/LMWH New Lot Verification



*QM-1905L-CH Miscellaneous Package Insert Verification Log **QM-1715F-CH Reagent Verification Log

***QM-1508F-CH Quality Control Lot Verification