

## Standardized Testing / Operating Protocol Request

General Information			
Title of STOP:	INVALID Reporting of Alere C difficile Quik Chek Complete		
Requestor Name:	Jeff Beaman	Submission Date:	06/27/19
Description:	Updating procedure to give direction on how to report INVALID results from the Alere Quik Chek Complete and to order a C diff PCR	Target Date:	07/30/19
X	Performing Location(s)	X	Affected Location(s)
	Alamance Cancer Center		Alamance Cancer Center
	High Point Cancer Center		High Point Cancer Center
	Wesley Long Cancer Center		Wesley Long Cancer Center
X	Alamance Regional	X	Alamance Regional
X	Annie Penn Hospital	X	Annie Penn Hospital
	MedCenter @ High Point		MedCenter @ High Point
	MedCenter @ Mebane		MedCenter @ Mebane
X	Moses Cone Hospital	X	Moses Cone Hospital
X	Wesley Long Hospital	X	Wesley Long Hospital
	Women's Hospital		Women's Hospital
		X	Affected Department(s)
			Blood Bank
			Cytology
			Flow Cytometry
			Histology
		X	Microbiology
			Phlebotomy
			Point Of Care
			Rapid Response Lab
			Respiratory Therapy
			Specimen Processing
Training / Competency			Section Not Applicable
	Yes *	No	*If Yes, Explain
Training Required?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
Training checklist needs to be created or revised?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Ryan updated checklist regarding Invalid Results
Competency Log, Observation form or Blind Sample form needs to be created or revised?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
Quiz need to be created or revised?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Ryan has the updates ready to load on go-live
Quality			Section Not Applicable
Document updates needed?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
	New / Revised Docs: 77420.707 Alere C. diff Quik Chek Antigen and A/B Toxin (ARMC) MICRO-722 C. diff Quik Chek Complete		
	Retired Documents:		
Does Current Test have a IQCP?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Will New Test need a IQCP?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
Memo/Notification to Client Needed?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	* If yes, mark below & include with Request
			GSO/Reidsville Medical Staff
			ARMC Medical Staff
			Pharmacy - DeAnne Brooks / Jim Hasspacher
			#Nursing Leadership (Director., Asst. Director, Clin Nurse Mgr)
			Infection Prevention - Melissa Morgan
<i>Memo/Notification Notes:</i>			
CAP/COLA Test Menu Changes?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
CMS Analyte Form Changes Needed?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
PT Survey Changes / Orders Needed?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	


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<b>Safety: Chemicals / Reagents</b>		<input checked="" type="checkbox"/>	<b>Section Not Applicable</b>
<b>Chemical Inventory Changes Needed?</b>	<input type="checkbox"/>	<input type="checkbox"/>	<i>If Yes, Send Chemical Inventory Update Form to Mathieu Vestal</i>
	Name of Product(s):		
	Retired Product(s):		
<b>Billing</b>		<input checked="" type="checkbox"/>	<b>Section Not Applicable</b>
	Yes *	No	<b>*If Yes, Explain</b>
<b>Billing Changes Required?</b>	<input type="checkbox"/>	<input type="checkbox"/>	CPT/LOINC Code:
	CDM #:		CDM Modifier:
<b>Technical Changes</b>		<input checked="" type="checkbox"/>	<b>Section Not Applicable</b>
Select One: <input type="checkbox"/> New Test / Instrument <input type="checkbox"/> Existing Test / Instrument Please indicate any necessary changes / additions below or mark "X" under N/A <i>Explain Changes / Additions &amp; Attach patient report example or instrument printout</i>			
N/A			
Reference Range:	<input type="checkbox"/>		
Critical Result:	<input type="checkbox"/>		
Delta Check:	<input type="checkbox"/>		
Technical/Clinical Range:	<input type="checkbox"/>		
Autodilution:	<input type="checkbox"/>		
Middleware Rules:	<input type="checkbox"/>		
Text/Comment Code:	<input type="checkbox"/>		
QC Code:	<input type="checkbox"/>		
Specimen Requirements:	<input type="checkbox"/>		
Specimen Type:	<input type="checkbox"/>		
<b>Container/ Tubes:</b>	Preferred:		
	Acceptable:		
	Required Volume:		
	Minimum Volume:		
Special Collection Instructions:			
	Yes *	No	N/A
Autoverification Desired:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ITS Tech Review been initiated / scheduled? Required if on Network	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Technical Description of Change			

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IT Information						X	Section Not Applicable			
						Pre-live Docs Needed?			Completed?	
						Yes	N/A	Yes	No	
Computer Systems Involved:	Sunquest	Yes	No	Sunquest	Yes	N/A	Yes	No		
	CHL			CHL						
	PowerPath			PowerPath						
	WindowPath			WindowPath						
						Instrument / Manual Test				
Analyzer Interface Required?										
Middleware Needed?										
Order Code Assigned?								Order Code:		
						Worksheet:				
<p style="text-align: center;"><b>Select the necessary Medical Director Approval below</b></p> <p style="text-align: center;"><i>Signatures completed in MediaLab</i></p>										
						Yes	No			
Alamance Regional Medical Director						X				
MedCenter Mebane Medical Director							X			
Greensboro/Reidsville Medical Director						X				
Cancer Centers Medical Director							X			

Approved and current. Effective starting 6/27/2019. 77420.613 (version 3.0) STOP Request/Notification Template  
 Blank copy 2736765. Last reviewed on 6/25/2019. Printed on 6/27/2019 2:13 PM (EDT). Page 2 of 2

 <p><b>STOP Notification</b></p>	<h2 style="text-align: center;">INVALID Reporting of Alere C difficile Quik Chek Complete</h2>	
<p><b>When:</b></p>	<p style="text-align: center;"><b>Tuesday, July 30, 2019</b></p>	
<p><b>What?</b></p>	<p style="text-align: center;"><b>Updating procedure to give direction on how to report INVALID results from the Alere Quik Chek Complete and to order a C diff PCR</b></p>	
<p><b>Who is Affected:</b></p>	<p style="text-align: center;"><b>Affected Location(s)</b></p> <p style="text-align: center;">Alamance Cancer Center                  High Point Cancer Center                  Wesley Long Cancer Center</p> <p style="text-align: center;"><b>X</b> Alamance Regional  <b>X</b> Annie Penn Hospital                  MedCenter @ High Point                  MedCenter @ Mebane  <b>X</b> Moses Cone Hospital  <b>X</b> Wesley Long Hospital                  Women's Hospital</p>	<p style="text-align: center;"><b>Department(s)</b></p> <p style="text-align: center;">Blood Bank                  Cytology                  Flow Cytometry                  Histology  <b>X</b> Microbiology                  Phlebotomy                  Point Of Care                  Rapid Response Lab                  Respiratory Therapy                  Specimen Processing</p>
<p><b>Why?</b></p>	<p style="text-align: center;"><b>Updated procedure to reflect how to result INVALID results.</b></p>	
<p><b>What you will need to do to prepare:</b></p>	<p style="text-align: center;"><b>Read the STOP Announcement and Procedure and sign off on both.</b></p>	
<p><b>Manager / Supervisor Responsibility:</b></p>	<p style="text-align: center;">Send Post Live Documentation to IT Manager within 5 days of the effective date for test systems marked with an "X"</p>	
	<p style="text-align: center;">Sunquest</p>	<p style="text-align: center;">WindowPath</p>
	<p style="text-align: center;">CHL</p>	<p style="text-align: center;">Instrument / Manual Test</p>
	<p style="text-align: center;">PowerPath</p>	
<p><b>Need Help?</b></p>	<p style="text-align: center;">Contact your Manager / Supervisor</p>	