



STANDARDIZED TESTING / OPERATING PROTOCOL REQUEST/ANNOUNCEMENT

C. difficile Testing Algorithm Change

Description:	The Cone Health laboratories will standardize their <i>C. difficile</i> testing algorithm.
Implementation Date:	07/05/2017 10 AM
Performing Locations:	<p>Click on the boxes that apply:</p> <input checked="" type="checkbox"/> Alamance Regional <input checked="" type="checkbox"/> Annie Penn Hospital <input checked="" type="checkbox"/> Moses Cone Hospital <input type="checkbox"/> Med Center at High Point <input checked="" type="checkbox"/> Wesley Long Hospital <input type="checkbox"/> Women's Hospital
Affected Locations:	<p>Click on the boxes that apply:</p> <input checked="" type="checkbox"/> Alamance Regional <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 Departments:	<p>Click on the boxes that apply:</p> <input type="checkbox"/> Blood Bank <input type="checkbox"/> Cytology <input type="checkbox"/> Flow Cytometry <input type="checkbox"/> Histology <input checked="" 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 checked="" type="checkbox"/> Specimen Processing
Specimen Type:	Stool, sterile cup
Updated Clinical Lab Procedures:	<p>GREENSBORO/REIDSVILLE:</p> MICRO-2895-CH Alere Quik Chek Complete Antigen and A B Toxin MICRO-2819-MC GeneXpert Infinity-48 Operating Procedure

	<p>ALAMANCE REGIONAL: MICRO-722-CH (Alere CDIFF) MICRO-725-CH (Cepheid CDPCR)</p>
Retired Clinical Lab Procedures:	N/A
Notification to Client:	<p>Click on the boxes that apply: <input type="checkbox"/> Section Not Applicable <input checked="" type="checkbox"/> Memo Needed Memo sent on 06/27/17 to applicable parties.</p> <p>Distribution of Memo: <input checked="" type="checkbox"/> Medical Staff <input checked="" type="checkbox"/> Allied Health Professionals (PA, Nurse Practitioners) <input checked="" type="checkbox"/> Anesthesia <input checked="" type="checkbox"/> Annie Penn (Primary Source Physicians) <input checked="" type="checkbox"/> Dentist <input checked="" type="checkbox"/> Emergency Department/Urgent Care Centers <input checked="" type="checkbox"/> Family Practice <input checked="" type="checkbox"/> Infectious Docs #ID Docs (John Campbell, Robert Comer, Jeffrey Hatcher, Cynthia Snider, Kees Van Dam) <input checked="" type="checkbox"/> OB/GYN <input checked="" type="checkbox"/> Pathology <input checked="" type="checkbox"/> Pediatricians <input checked="" type="checkbox"/> Psych <input checked="" type="checkbox"/> Radiology <input checked="" type="checkbox"/> Surgery</p> <p><input checked="" type="checkbox"/> #Nursing Leadership (Directors, Asst. Directors, Clinical Nurse Manager) <input checked="" type="checkbox"/> Pharmacy - Send to DeAnne Brooks & Jim Hasspacher & Jeremy Frenz <input checked="" type="checkbox"/> #IM Residents <input checked="" type="checkbox"/> Kim Helsabeck <input checked="" type="checkbox"/> Phlebotomy Managers and Supervisors <input checked="" type="checkbox"/> Point of Care: Sheila, Kim & Marty</p>
Accreditation Section:	<p>Click on the boxes that apply: <input checked="" type="checkbox"/> Section Not Applicable <input type="checkbox"/> CAP Test menu change needed <input type="checkbox"/> CMS Analyte form change needed <input type="checkbox"/> Proficiency Testing surveys changes needed or ordered</p>
Laboratory IT section:	<p>Click box and type needed changes/additions: <input type="checkbox"/> Section Not Applicable</p>

- 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)

Alere Quik Chek Interpretations:

GDH Antigen	A/B Toxin	Result Code	Interpretation
POS	POS	TCDP	Toxin producing C. difficile detected
NEG	NEG	TCDN	No C. difficile detected
POS	NEG	TCDAN	Results are indeterminate. See PCR results.
NEG	POS	TCDAN	Results are indeterminate. See PCR results.

Notes:

TCDP: Flag as critical value

TCDAN: Reflex CDPCR

CDPCR Results:

Add the following comments to POS/NEG CDPCR results:

C. Diff	
Positive	Enter POS at CDIFP prompt The following comment will automatically be added: "Positive for toxigenic C. difficile with little to no toxin production. Only treat if clinical presentation suggests symptomatic illness"
Negative	Enter NEG at CDIFP prompt The following comment will automatically be added: "Patient is colonized with non-toxigenic C. difficile. May not need treatment unless significant symptoms"

Notes:

Remove Failed Verify flag for CDPCR POS results

Technical Staff Update:	The Cone Health Laboratories will standardize <i>C. difficile</i> testing between Greensboro/Reidsville and Alamance Regional. The new algorithm is as follows:				
	CDIFF Kit Interpretations:				
	GDH Antigen	A/B Toxin	Result Code	Interpretation	Critical Value Yes/ No
	POS	POS	TCDP	Toxin producing <i>C. difficile</i> detected	Yes
	NEG	NEG	TCDN	No <i>C. difficile</i> detected	No
	POS	NEG	TCDAN	Results are indeterminate. See PCR results.	No
NEG	POS	TCDAN	Results are indeterminate. See PCR results.	No	
In the event that there is a discrepancy between the GDH and A/B Toxin, i.e. antigen positive/toxin negative or antigen negative/toxin positive, Sunquest will automatically reflex CDPCR on the Cepheid.					
CDPCR Interpretations:					
POS	The following comment will automatically be added: “Positive for toxigenic <i>C. difficile</i> with little to no toxin production. Only treat if clinical presentation suggests symptomatic illness”				
NEG	The following comment will automatically be added: “Patient is colonized with non-toxigenic <i>C. difficile</i> . May not need treatment unless significant symptoms are not present.”				
All comments will automatically be added for both CDIFF and CDPCR.					
Annie Penn and Wesley Long should continue to send CDPCR to Moses Cone.					

STOP Initiator:	Jackie Hobbins
Alamance Medical Director Signature:	Quality Department will obtain signature:
Greensboro/Reidsville Medical Director	Quality Department will obtain signature:



TO: Cone Health Hospital Providers

FROM: Joshua B. Kish, MD, FCAP, FASCP
Chief of Pathology, Cone Health

John Patrick, MD, FCAP
Medical Director, Clinical Pathology, Cone Health

Tara C. Rubinas, MD, FCAP, FASCP, Medical Director, Anatomic and Clinical Pathology
Laboratories, Alamance Regional – Cone Health

DATE: June 27, 2017

RE: **Clostridium Difficile Testing & Interpretation of Results.**

Clostridium difficile continues to be a serious healthcare associated infection that carries significant morbidity and mortality to patients. Reducing unnecessary antibiotic exposure is the only way to minimize the acquisition of *C. difficile* infection.

A few tips about *C. difficile*:

- Be a good diagnostic steward. Only test those who meet criteria for *C. difficile* infection since many patients can be colonized with *C. difficile* (toxicogenic and non-toxicogenic strains)
- Avoid testing anyone who is on laxatives in last 24 hours.
- Patients who have had *C. difficile* colitis within the last 4 weeks can still be shedding spores and will continue to test positive.
- Patients with non-toxicogenic *C. difficile* do not necessarily need treatment.
- Minimize or discontinue other antibiotics while treating for *C. difficile*.

How to interpret testing results:

- As of July 5th, all tests that are GDH positive/ toxin negative, will automatically reflex to PCR.

GDH	Toxin	PCR	Toxicogenic <i>C. difficile</i> (header in CHL)	Interpretation
Positive	Positive		POSITIVE	Toxin producing <i>C. difficile</i> detected
Negative	Negative		NEGATIVE	No <i>C. difficile</i> detected
Positive	Negative	Negative	Negative, see comment	Patient is colonized with non-toxicogenic <i>C. difficile</i> . May not need treatment unless significant symptoms are present
Positive	Negative	Positive	Positive, see comment	Positive for toxicogenic <i>C. difficile</i> with little to no toxin production. Only treat if clinical presentation suggests symptomatic illness
Negative	Positive		REPEAT Testing Indicated	Results will be based upon options listed above

If there are questions regarding interpretation result or management, feel free to call ID physician on call or CHAMP (Cone Health Antimicrobial Management Program) pharmacist @ 336-832-5955.