### **Kesler-Cribb, Sigrid**

From: Kesler-Cribb, Sigrid

Sent: Tuesday, December 11, 2018 2:42 PM

To: Ballister, Kim; Barr, Kimberly; Beaman, Jeff; Bennett, Crystal (MHC-MC-Phlebotomy

> Services); Boyer, Mike; Cleveland, Thomas; Creasman, Tammy; Cruthis, Sheila; Dyson, Quanisha; Farmer, Jacee; Garcia, Amber; Hamlett, Paula; Hicks, Teri; Hogan, Donna; Holmes, Karen; Ingle, Esther (WL); James, Kelly; 'John (jdpatrick@auroradx.com)'; Kennedy, Tonya; Kish, Joshua; Kriegel, Patti; Lane, Derick; Lawson, Shelley; Lax, Amy; Lineberry, Ryan W; Manuel, Kathy; Mitchell, Shirley; Mohr, Mel; Morton, Melinda; Mullins, Tammy; O'Laughlin, Theresa; Olney, Mary S; Pegram, Jill; Roy, Sherry (Solstas); Rubinas, Tara C; Singletary, Demetria; Strickland, Marti; Turner, Wendy; Vanhoorne, Sara; Woolard, Kerri; Wright, Teresa; Younts-Meredith, Amy; Edens, Charlie; Shue, Amanda; 'Kish, Joshua'; Vestal, Mathieu; Wilkins, Vincent; Lyrla, Kathleen; Bialek, Sandy

Kesler-Cribb, Sigrid

Cc: Subject: STOP Notifications Effective December 18,2018

**Attachments:** 12.18.18 STOP notification Dry Ice safety ay Inspection checklist changes .pdf; 12.18.18

> STOP Notification UDS Result Comment.pdf; 12.18.18 STOP Notification ARMC moving to 24 hr DXC 660i QC.pdf; 12.18.18 STOP Notification Sunguest GUI resulting .pdf; 12.18.18 STOP Notification MC Implementing PBP2.pdf; 12.18.18 STOP Notification WL performing Lipid panel.pdf; 12.18.18 STOP Notification ARMC Xpress GAS PCR on

Infinity .pdf

# **STOP's Notifications Effective December 18, 2018**

### System Wide STOP Dry Ice safety and Safety Inspection Changes

New CAP checklist question requires a policy for the safe handling of dry ice along with documented training. The monthly and quarterly safety checklists were updated to reflect these changes along with additional changes for clarity.

### **System Wide STOP Drug Screen Report**

Urine Drug screen report will identify the detected drugs as parent compounds, metabolites or impurities to comply with CAP updated standard.

#### ARMC: STOP Moving to 24 hours DXC 660i QC

ARMC main is changing from QC every 12 hours to once every 24 hours on the DxC660i.

### **Greensboro/Reidsville STOP Sunquest GUI resulting**

Change from Flexilab OEM and MEM to GUI resulting in Sunquest.

#### **Moses Cone Microbiology STOP PBP2 Latex Agglutination**

PBP2 issued as a confirmatory test for MRSA due to an advisory notice that was sent by Biomerieux.

### Wesley Long STOP WL will begin performing Lipids

Wesley Long to perform Lipid panels in house

### ARMC STOP Xpress GAS (Group A Strep) PCR testing on Infinity at ARMC

Express GAS testing on the Infinity. The POCT testing rapid strep A perfume in the ED will cease and PCR testing will begin in the main laboratory.

Thanks

Sigrid© Sigrid Kesler-Cribb, MT (ASCP)

Cone Health | Laboratory Quality Manager Direct Dial: 336.832.7571 | Fax: 336.832.8270

Website: conehealth.com

	General Information			
	Xpress GAS PCR testing	ng on Infinity at ARMC		
Requestor Name:	Jacee Farmer		Submission Date:	11/30/18
Description:	Express GAS testing on the Infinity. The POCT testing rapid strep A performed in the ED will cease and PCR testing will being in the main laboratory.		Target Date:	12/18/18
Perforn	ning Location(s)	Affected Location(s)	Affected De	partment(s)
High Point Wesley Lor Alamance F Annie Penr MedCenter	n Hospital @ High Point @ Mebane e Hospital g Hospital	Alamance Cancer Center  High Point Cancer Center  Wesley Long Cancer Center  ✓ Alamance Regional  Annie Penn Hospital  MedCenter @ High Point  MedCenter @ Mebane  Moses Cone Hospital  Wesley Long Hospital  Women's Hospital	Blood Bank Cytology Flow Cytometr Histology Microbiology Phlebotomy Point of Care Rapid Respons Respiratory Th Specimen Proc	se Lab erapy
		Training / Competency		
	Training	Training Required?	✓ YES*	NO
		Training checklist needs to be created or revised?	✓ YES *	□ NO
	Competency Forms	Competency Log, Observation form or Blind Sample form needs to be created or revised?	✓ YES *	□ NO
Quizzes		Quiz needs to be created or revised?	✓ YES*	□ NO
* If Yes to the above, Explain:		Modified existing checklist for differences between BacTAlert and Virtuo.  Training to be complete by 12/17/18.		
		Training / Competency	Section	Not Applicable
	Document Control	Document updates needed?	✓ YES *	NO
		If Yes, Have docs been submitted to MD?	✓ YES	□ NO
		New / Revised Docs: MICRO-727 Xpress Strep A		
		Retired Documents: N/A		
		Does Current Test have a IQCP?	✓ YES *	NO
		Will New Test need a IQCP?	✓ YES*	NO
* If Yes, Explain: Risk Assessment performed and documented. IQCP will be in place. Refer to Micro IQCP procedu MICRO-150.			Micro IQCP procedure	
		Memo/Notification Needed?	✓ YES *	□ NO
	* If yes, mark Distribution below and include memo/notification with STOP Request  GSO/Reidsville Medical Staff  ARACTION Prical Staff - Melissa Morgan Pharmacy - DeAnne Brooks / Jim Hasspacher  #Nursing Leadership (Directors, Asst. Directors, Clinical Nurse Manager)			
	Memo/Notification Notes:			
	Accreditation:	CAP Test Menu Changes Needed?	✓ YES *	NO

Xpress GAS PCR testing on Infinity at ARMC			
	CMS Analyte Form Changes Needed?	YES *	✓ NO
3 (1986) 14 (1986) 1 E-1 (1986)		✓ YES *	□ NO
20 PH 1988 - CONTROL OF THE PROPERTY OF THE PR		ved) added to test menu	
	* If Yes, Explain:	CMS Analyte Form Changes Needed? PT Survey Changes / Orders Needed?	CMS Analyte Form Changes Needed?  PT Survey Changes / Orders Needed?  ▼ YES *  * If Yes, Explain: Strep A, nucleic acid amplification (FDA-approved) added to test menu

Title of STOP: Xpress GAS PCR testing on Infinity at ARMC					
ACTUAL CONTRACTOR OF THE PROPERTY OF THE PROPE			Billing	Sectio	п Not Applicable
Changes		Billing Changes Rec	quired?	YES *	□NO
* If Yes, Explain:					
		CPT/LOINC Code:		87651	
		CDM #		CDM Modifier	<b>第四百十二十二十二十二十二十二十二十二十二十二十二十二十二十二十二十二十二十二十二</b>
		Techni	cal Changes	Sect	ion Not Applicable
Assigned System Administrator:					
Select One:  New Test / Instrument  Please indicate any necessary changes / additions below or mark N/A  Explain Changes / Additions & Attach patient report example or instrument printout					
Reference Range:	N/A	Detected - Not Dete	ected		et the same of the same
Critical Result:	✓ N/A			AND ASSESSMENT	
Delta Check:	✓ N/A				
Technical/Clinical Range:	✓ N/A				
Autodilution:	✓ N/A				
Middleware Rules:	✓ N/A		Mark Control of the Control		
Text/Comment Code:	✓ N/A				
QC Code:	✓ N/A				
Specimen Requirements:	N/A	Eswab			
Specim	nen Type:	Eswab (Throat)			
		Preferred:			
Containo	r/Tubosi	Acceptable:			
Containe	r/ rubes:-	Required Volume: N/A			
		Minimum Volume: N/A			
Special Collection Inst	ructions:				
Autoverification Desired:		✓ YES* NO	N/A		
ITS Tech Review been initiate	d / sched	luled? *	YES NO	□ N/A	* Required if test is on
		IT Info	rmation	Secti	on Not Applicable
6		Sunquest	Harvest	Order Code:	OIT NOT Applicable
Computer Systems Involved:		PowerPath	WindowPath	Worksheet:	
Anaiyzer <sub>F</sub>	Interface Required?	✓ YES * NO	* If Yes, Please explain	WOTKSHEET.	
nterface Middleware	Needed?	YES * NO	res, ricase expiain		
Test Info Order Code A	Assigned?	✓ YES * NO	Test Code(s) Assigned:	GASPCR	
Pre-Live Documentation Comp	olete:	YES NO	□ N/A		
		STATE OF THE PERSON NAMED IN THE PERSON NAMED IN	Model to Jones to State of the		

Title of STOR V. CARDON	1 may 1 restrict the queet		
Title of STOP: Xpress GAS PCR testing on Infinity at ARMC			
Medical Director Approval			
Quality Department will obtain sigantures			
Alamance Regional Medical Director: (Signature/Date)	MedCenter Mebane Medical Director: (Signature / Date)		
ph/13/12/18	Not Applicable		
Greensboro/Reidsville Medical Director: (Signature/Date)	Cancer Centers Medical Director: (Signature / Date)		
Not Applicable	Not Applicable		

Cone Health Laboratories 1719F1

STOP Notification	Xpress GAS PCR Infinity testing at ARMC This has been approved by the Laboratory Medical Directors		
When:	December 18,2018		
What:	Xpress GAS testing - Rapid Strep A testi	ng conversion to PCR method at ARMC	
Who is Affected:	Location(s)  Alamance Cancer Center High Point Cancer Center Wesley Long Cancer Center Alamance Regional Annie Penn Hospital MedCenter @ High Point MedCenter @ Mebane Moses Cone Hospital Wesley Long Hospital Women's Hospital	Department(s)  □ Blood Bank □ Cytology □ Flow Cytometry □ Histology □ Microbiology □ Phlebotomy □ Point of Care □ Rapid Response Lab □ Respiratory Therapy □ Specimen Processing	
Why?	Current rapid kit test requires confirmation reflex testing of culture for negatives. New PCR method is more sensitive and does not require reflex testing.		
What you will need to do to prepare:  Need Help?	ED staff must learn the new collection device for PCR strep testing.  ED will be notified to discontinue POCT rapid strep testing on 12/18/18.  All ARMC lab staff trained and procedures reviewed.  LIS testing of test code to the Infinity and resulting.  Contact Jacee Farmer or Susan Rhew		
iveed neip:	Contact Jacee Fam	ilei di Susali Nilew	

### **Example of PreLive Sunquest Result**

Moses Cone Memorial Hospital 1200 N. Elm Street Greensboro, NC 27401

INTERIM REPORT

NAME: TEST, LABROB

MRN: 212907

LOC: 3WC ROOM: 3W01C-0 AGE: 23M

SEX: M

ACCT: 100033869

MD: SWORDS, BRUCE H DOB: 01/01/2017

T2094 COLL: 11/20/2018 17:00 REC: 11/20/2018 17:05 PHYS: LESCHBER, VALERI

Group A Strep by PCR

Group A Strep by PCR

\* DETECTED

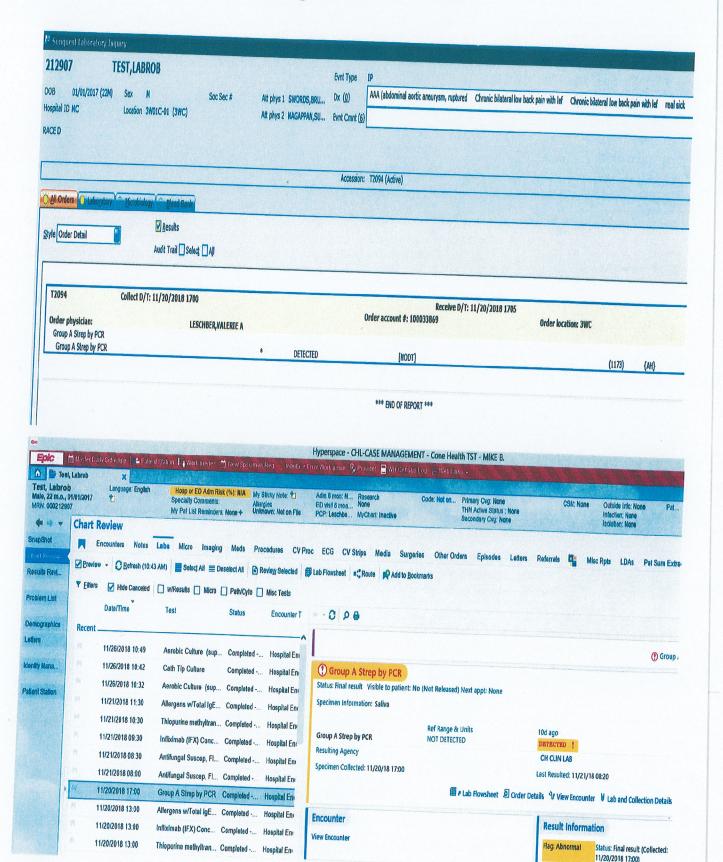
[NODT]

{AH}

{AH} = Performed at Alamance Hospital Lab, 1240 Huffman Mill Rd., Burlington, NC 27215

JAMAB : Kilus 12/11/18

### **Example of PreLive CHL Result**



## **Kesler-Cribb, Sigrid**

From: Shapcott, Sandy

**Sent:** Tuesday, December 11, 2018 1:25 PM

**Subject:** ARMC Memo Re: Rapid Strep Testing Performance

**Attachments:** 2018.12.18 Xpress GAS memo.docx

Sent on behalf of Dr. Kish.



## Alamance Clinical Lab Notification

Cone Health Alamance Regional Medical and Nursing Staff TO:

FROM: Joshua Kish, MD, FCAP, FASCP - ARMC Clinical Laboratory Medical [

Rapid Strep Testing Performance RE:

DATE: December 11, 2018

What is going to happen:	Point of care rapid strep testing will be removed from the emergend department. The clinical lab will perform the testing by PCR method		
Who will be affected:	Testing will now be available to all ARMC patients, not just Emerge Department patients.  The change will impact the ED staff and Lab staff as well as patien		
When:	December 18, 2018 at 10am		
What you will need to do:	Emergency Department –     Rapid strep kits will be removed from the Emergency Depar     New Group A Rapid Strep swabs will be used for specimen     Place new order code for testing and submit the sample to t laboratory for testing  Group A Strep by PCR  LAB8383		
	Process and Complete Group A Strep testing from throat sw methodology		
Who to contact for assistance:	Jacee Farmer 336-538-7824 Wendy Turner 336-538-7820		
Why change is needed:	In order to become compliant with Regulatory Standards regarding testing, the laboratory will begin performing Group A Strep testing t swabs. The PCR methodology does not require a reflex culture wit results as is required with the current kit being used.		
Additional information:	Turn around time will be slightly longer due to the change in workflumethodology. Testing time is 30 minutes. This does not include pro-		

### Kesler-Cribb, Sigrid

From:

Kish, Joshua <jbkish@auroradx.com>

Sent:

Friday, December 07, 2018 9:38 AM

To: Cc: Kesler-Cribb, Sigrid Turner, Wendy

Subject:

RE: [EXTERNAL] - FW: 2018.12.18 Xpress GAS memo.docx

### This message was sent securely using Zix

#### approved

From: Kesler-Cribb, Sigrid [mailto:Sigrid.Kesler-Cribb@conehealth.com]

**Sent:** Friday, December 07, 2018 9:07 AM **To:** Kish, Joshua <jbkish@auroradx.com>

Cc: Turner, Wendy < Wendy. Turner@conehealth.com>

Subject: [EXTERNAL] - FW: 2018.12.18 Xpress GAS memo.docx

WARNING: This email is from an external source.

DO NOT CLICK on links or attachments unless you recognize the sender and know the content is safe.

REPORT suspicious emails to Support@AuroraDX.com ASAP.

### This message was sent securely using Zix\*

Dr. Kish Please approve memo via email.

Thanks Sigrid

From: Turner, Wendy

Sent: Thursday, December 06, 2018 6:39 PM

To: Kesler-Cribb, Sigrid < Sigrid.Kesler-Cribb@conehealth.com>

Subject: RE: 2018.12.18 Xpress GAS memo.docx

ok

From: Kesler-Cribb, Sigrid

Sent: Thursday, December 06, 2018 6:37 PM

**To:** Turner, Wendy < <u>Wendy.Turner@conehealth.com</u> > **Subject:** Re: 2018.12.18 Xpress GAS memo.docx

Let remove those two words sig

Get Outlook for iOS



### **Alamance Clinical Lab Notification**

TO: Cone Health Alamance Regional Medical and Nursing Staff

FROM: Joshua Kish, MD, FCAP, FASCP - ARMC Clinical Laboratory Medical Director

RE: Rapid Strep Testing Performance

DATE: December 11, 2018

What is going to happen:	Point of care rapid strep testing will be removed from the emergency department. The clinical lab will perform the testing by PCR methodology.		
Who will be affected:	Testing will now be available to all ARMC patients, not just Emergency Department patients.		
	The change will impact the ED staff and Lab staff as well as patients.		
When:	December 18, 2018 at 10am		
What you will need to do:	Emergency Department —     Rapid strep kits will be removed from the Emergency Department.     New Group A Rapid Strep swabs will be used for specimen collection     Place new order code for testing and submit the sample to the clinical laboratory for testing		
	Group A Strep by PCR LAB8383		
	<ul> <li><u>Laboratory</u> –</li> <li>Process and Complete Group A Strep testing from throat swabs by PCR methodology</li> </ul>		
Who to contact for assistance:	Jacee Farmer 336-538-7824 Wendy Turner 336-538-7820		
Why change is needed:	In order to become compliant with Regulatory Standards regarding strep reflex testing, the laboratory will begin performing Group A Strep testing from throat swabs. The PCR methodology does not require a reflex culture with negative results as is required with the current kit being used.		
Additional information:	Turn around time will be slightly longer due to the change in workflow and methodology. Testing time is 30 minutes. This does not include processing and handling time.		