



### STANDARDIZED TESTING / OPERATING PROTOCOL REQUEST/ANNOUNCEMENT

### Xpress Flu Testing

Description:	Cone Health will switch to the Xpress Flu Cepheid PCR test. The Xpress flu has a more rapid TAT (positives 20 minutes and negatives in 30 minutes).
Implementation Date:	10/31/2017 1000
Performing Locations:	Click on the boxes that apply:  ⊠Annie Penn Hospital  ⊠Moses Cone Hospital  □Med Center at High Point  ⊠Wesley Long Hospital  □Women's Hospital  ⊠Alamance
Affected Locations:	Click on the boxes that apply:  ⊠Annie Penn Hospital  ⊠Moses Cone Hospital  ⊠Med Center at High Point  ⊠Wesley Long Hospital  ⊠Women's Hospital  ⊠Alamance
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:	Universal Transport Media (UTM)
Updated Clinical Lab Procedures:	Alamance MICRO-723 Cepheid Xpert Flu PCR Greensboro/Reidsville: MICRO-2819-MC GeneXpert Infinity 485 System Operating Procedure MICRO—2043-CH Microbiology Computer Entry MICRO-2837CL-CH Influenza Cepheid Parallel Test Log MICRO-2837C-AP Cepheid GeneXpert Flu
Retired Clinical Lab Procedures:	N/A
Notification to Client:	Click on the boxes that apply:  □ Section Not Applicable  □ Memo Needed  Memo to be sent on 10/26/17  Kenny Miller to distribute nursing notification of specimen requirement change.  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)  □ OB/GYN  □ Pathology  □ Pediatricians  □ Psych  □ Radiology  □ Surgery  □ #Nursing Leadership (Directors, Asst. Directors, Clinical Nurse Manager)  □ Pharmacy - Send to DeAnne Brooks & Jim Hasspacher  □ #IM Residents  □ Kim Helsabeck  □ 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  Add Flu testing (Test menu code 3224) to WL test menu on go live date

	☐CMS Analyte form change needed
	⊠Proficiency Testing surveys changes needed or ordered
	Wesley Long: Proficiency Testing survey (ID3) was ordered on 10/25/17 CAP
	reference code 3206718 and will be shipped on Dec 4, 2017.
	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
	Please remove canned comment from H1NP1 test and add to INFBP
	Update comment verbiage to the following:
	The Xpert Xpress Flu assay is intended as an aid in the diagnosis of influenza and
	should not be used as a sole basis for treatment. This assay is FDA approved for
I alamatamı IT azətinmi	nasopharyngeal swab specimens only. Nasal washings and aspirates are unacceptable
Laboratory IT section:	for Xpert Xpress Flu testing.
	Specimen collection instructions  Places and the following instructions to FI UPCP:
	Please add the following instructions to FLUPCR:
	Nasopharyngeal (NP) swab provided in Flu Nasal Collection kit placed in VTM
	immediately upon collection. Transport to the lab immediately. Swabs not collected
	in Flu Nasal Collection will be rejected. Flu swabs are not interchangeable with
	other types of swabs/kits.
	Nasal Aspirates/Washings (NA/W) are unacceptable for testing.
	□ Need to monitor TAT
	$\Box$ CPT code for tests(s)
	Cons Health will switch to the Vances fly Conheid DCD test. The Vances fly has a
	Cone Health will switch to the Xpress flu Cepheid PCR test. The Xpress flu has a more rapid TAT (positives 20 minutes and negatives in 30 minutes). The follow are
	the major changes in the procedure:
	Read the procedure for all changes.
	<ul> <li>Nasopharyngeal swabs in UTM are the ONLY acceptable specimen. Nasal</li> </ul>
	washing are not validated for the Xpress flu test.
Technical Staff	• The binding reagent is not included in the test. Only place the specimen in the sample well (large hole).
Update:	<ul> <li>The H1N1 component is not tested. Results will be reported as either</li> </ul>
	Influenza A or B positive or negative.
	<ul> <li>MC, WL, APH and Alamance are the performing locations.</li> </ul>
	The, we, mil it and maintained are the performing rocations.
	Important Note:
	On the day of go live, each site will need to update their instrument to send the
	appropriate codes for Flu Xpress.

### **Infinity Analyzer** (see attached screenshot page 6):

- 1. To do this, go to System Configuration → Host Test Code → Scroll to Xpert Flu assay (current cartridge)
- 2. Make note of the following:

Assay Host Test Code Result Name Flu A Result Name Flu B

- 3. You will be changing the Xpert Xpress Flu Assay Host Test Code, Result Name Flu A, and Result Name Flu B to match the current cartridge setup.
- 4. Select Edit from top right of screen.
- 5. Uncheck Enable box for Xpert Flu assay.
- 6. Next, scroll to Xpert Xpress Flu Version 1.
- 7. Select Edit from top right of screen.
- 8. Enter Assay Host Code, Result Name Flu A, and Result Name Flu B in appropriate boxes.
- 9. Enter PASS for Result Name QC Check.
- 10. Check Enable box.

### **GeneXpert Analyzers (see attached screenshot page 7):**

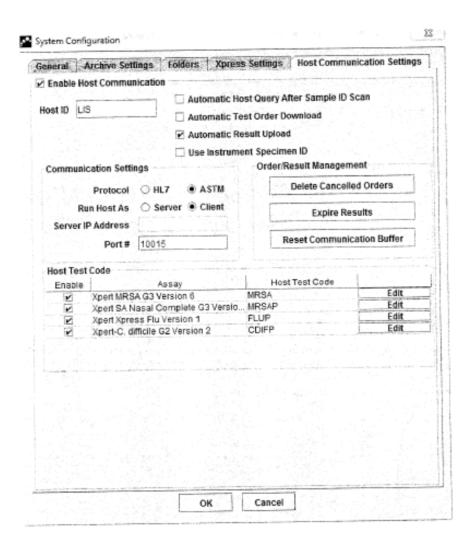
- Go to System Configuration → Host Communication Settings → Select Xpert Flu assay (current cartridge)
- 2. Make note of the following:

Assay Host Test Code Result Name Flu A Result Name Flu B

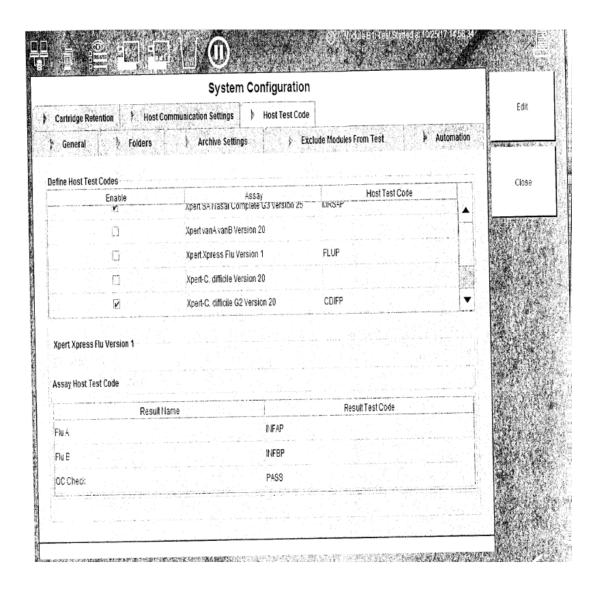
- 3. You will be changing the Xpert Xpress Flu Assay Host Test Code, Result Name Flu A, and Result Name Flu B to match the current cartridge setup.
- 4. Select Edit button next to Xpert Flu assay (current cartridge).
- 5. Uncheck Enable box for Xpert Flu assay.
- 6. Next, scroll to Xpert Xpress Flu Version 1.

	<ol> <li>Select Edit button next to Xpert Xpress Flu assay (new cartridge).</li> <li>Enter Assay Host Code, Result Name Flu A, and Result Name Flu B in appropriate boxes.</li> <li>Enter PASS for Result Name QC Check.</li> <li>Check Enable box.</li> <li>Select Ok.</li> </ol>
STOP Initiator:	Jeff Beaman MT(ASCP), MHA For questions regarding instrument changes, please call Jackie Hobbins (919-523-1611)
Alamance Medical Director Signature:	Quality Department will obtain signature:
Greensboro/Reidsville Medical Director Signature:	Quality Department will obtain signature:

## **GeneXpert Host Communications Settings Window**



## Infinity Host Test Code Window



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

NAME: FLU, COMMENT

MRN : TEST-26 LOC: TEST AGE: 45Y SEX: F ACCT: 111 MD: LAB, ORDER DOB: 01/01/1972

M778 COLL: 10/30/2017 13:04 REC: 10/30/2017 13:08 PHYS: LAB,ORDER

FLU PANEL, PCR

{MC} INFLUENZA A by PCR NEGATIVE [NEG] {MC} INFLUENZA B by PCR NEGATIVE [NEG] (NOTE)

The Xpert Xpress Flu assay is intended as an aid in the diagnosis of influenza and should not be used as a sole basis for treatment. This assay is FDA approved for nasopharyngeal swab specimens only. Nasal washings and aspirates are unacceptable for Xpert Xpress Flu testing.

{MC} = Performed at Moses Cone Hospital Lab, 1200 N. Elm St., Greensboro, NC 27401

MM 10:30.17

FLU, COMMENT PRINT DATE: 10/30/2017 PRINT TIME: 13:19

END OF REPORT

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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

Julis Ble Como 10/27/17

DATE:

October 26th, 2017

SUBJECT: New Flu PCR Assay and Updated Specimen Requirements

The Cone Health hospital laboratories will convert to the Cepheid Xpert Xpress Flu PCR assay on October 31<sup>st</sup>, 2017. This new assay provides early assay termination for positive results and will reduce turnaround times on Flu A and Flu B PCR.

On site testing will be available at Alamance Regional, Annie Penn, Moses Cone, and Wesley Long.

This new assay has only been approved by the FDA for testing on nasopharyngeal swabs. The laboratories will no longer accept nasal washings for Flu PCR testing.

For further information, please contact the following:

Dr. Joshua Kish: <a href="mailto:jbkish@auroradx.com">jbkish@auroradx.com</a> or 336-832-7533

Dr. Tara Rubinas: tara.rubinas@conehealth.com or 336-538-7832

Dr. John Patrick: <a href="mailto:jdpatrick@auroradx.com">jdpatrick@auroradx.com</a> or 336-832-7531

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# **ATTENTION NURSING STAFF**



# FLU PCR

# Specimen Requirements Update

Effective Date:

October 31, 2017

Due to new manufacturer's test requirements, the laboratory will be unable to accept nasal washings for Flu PCR testing The appropriate sample type is a nasopharyngeal swab.



Nasopharyngeal swab in universal transport media







Nasal washings

Unacceptable Specimen Laboratory will reject

NP swabs can be used to collect ALL respiratory (RSV, RVP and Flu) specimens.

Nasal washings can still be used if the provider orders an RSV sample ONLY.