



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:	<p>Click on the boxes that apply:</p> <ul style="list-style-type: none"> <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 <input checked="" type="checkbox"/> Alamance
Affected Locations:	<p>Click on the boxes that apply:</p> <ul style="list-style-type: none"> <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 <input checked="" type="checkbox"/> Alamance
Affected Departments:	<p>Click on the boxes that apply:</p> <ul style="list-style-type: none"> <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 type="checkbox"/> Rapid Response Lab <input type="checkbox"/> Respiratory Therapy <input checked="" type="checkbox"/> Specimen Processing

Specimen Type:	Universal Transport Media (UTM)
Updated Clinical Lab Procedures:	<p><u>Alamance</u> MICRO-723 Cepheid Xpert Flu PCR</p> <p><u>Greensboro/Reidsville:</u> 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</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 to be sent on 10/26/17 Kenny Miller to distribute nursing notification of specimen requirement change.</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 <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 type="checkbox"/> Section Not Applicable <input checked="" type="checkbox"/> CAP Test menu change needed Add Flu testing (Test menu code 3224) to WL test menu on go live date</p>

	<p><input type="checkbox"/> CMS Analyte form change needed</p> <p><input checked="" type="checkbox"/> Proficiency Testing surveys changes needed or ordered</p> <p>Wesley Long: Proficiency Testing survey (ID3) was ordered on 10/25/17 CAP reference code 3206718 and will be shipped on Dec 4, 2017.</p>
<p>Laboratory IT section:</p>	<p>Click box and type needed changes/additions:</p> <p><input type="checkbox"/> Section Not Applicable</p> <p><input checked="" type="checkbox"/> LIS changes</p> <p><input type="checkbox"/> Reference range change/addition</p> <p><input type="checkbox"/> Technical Failure change/addition</p> <p><input type="checkbox"/> Critical Value change/add</p> <p><input checked="" type="checkbox"/> Text comments needed</p> <p>Please remove canned comment from H1NP1 test and add to INFBP</p> <p>Update comment verbiage to the following:</p> <p>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.</p> <p><input checked="" type="checkbox"/> Specimen collection instructions</p> <p>Please add the following instructions to FLUPCR:</p> <p>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.</p> <p>Nasal Aspirates/Washings (NA/W) are unacceptable for testing.</p> <p><input type="checkbox"/> Need to monitor TAT</p> <p><input type="checkbox"/> CPT code for tests(s)</p>
<p>Technical Staff Update:</p>	<p>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:</p> <ul style="list-style-type: none"> • Read the procedure for all changes. • Nasopharyngeal swabs in UTM are the ONLY acceptable specimen. Nasal washing are not validated for the Xpress flu test. • The binding reagent is not included in the test. Only place the specimen in the sample well (large hole). • The H1N1 component is not tested. Results will be reported as either Influenza A or B positive or negative. • MC, WL, APH and Alamance are the performing locations. <p><u>Important Note:</u></p> <p>On the day of go live, each site will need to update their instrument to send the appropriate codes for Flu Xpress.</p>

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):

1. 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 style="list-style-type: none"> 7. Select Edit button next to Xpert Xpress Flu assay (new cartridge). 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. 11. Select Ok.
<p>STOP Initiator:</p>	<p>Jeff Beaman MT(ASCP), MHA For questions regarding instrument changes, please call Jackie Hobbins (919-523-1611)</p>
<p>Alamance Medical Director Signature:</p>	<p>Quality Department will obtain signature:</p>
<p>Greensboro/Reidsville Medical Director Signature:</p>	<p>Quality Department will obtain signature:</p>

GeneXpert Host Communications Settings Window

The screenshot shows the 'Host Communication Settings' window in the GeneXpert System Configuration software. The window has a title bar 'System Configuration' and a close button. The 'Host Communication Settings' tab is selected, with other tabs being 'General', 'Archive Settings', 'Folders', and 'Xpress Settings'. The 'Enable Host Communication' checkbox is checked. The 'Host ID' field contains 'LIS'. Under 'Automatic Host Query After Sample ID Scan', 'Automatic Test Order Download', and 'Use Instrument Specimen ID' are unchecked, while 'Automatic Result Upload' is checked. The 'Communication Settings' section has 'Protocol' set to 'ASTM' (radio button selected) and 'Run Host As' set to 'Client' (radio button selected). The 'Server IP Address' field is empty, and the 'Port #' field contains '10015'. The 'Order/Result Management' section contains three buttons: 'Delete Cancelled Orders', 'Expire Results', and 'Reset Communication Buffer'. The 'Host Test Code' section contains a table with four rows, each with an 'Enable' checkbox, an 'Assay' name, a 'Host Test Code', and an 'Edit' button. All 'Enable' checkboxes are checked.

Enable	Assay	Host Test Code	
<input checked="" type="checkbox"/>	Xpert MRSA G3 Version 6	MRSA	Edit
<input checked="" type="checkbox"/>	Xpert SA Nasal Complete G3 Versio...	MRSAP	Edit
<input checked="" type="checkbox"/>	Xpert Xpress Flu Version 1	FLUP	Edit
<input checked="" type="checkbox"/>	Xpert-C, difficile G2 Version 2	CDIFP	Edit

Infinity Host Test Code Window

System Configuration

Cartridge Retention | Host Communication Settings | Host Test Code

General | Folders | Archive Settings | Exclude Modules From Test | Automation

Define Host Test Codes:

Enable	Assay	Host Test Code
<input checked="" type="checkbox"/>	Xpert SA Nasal Complete G3 Version 25	INRSPP
<input type="checkbox"/>	Xpert vanA vanB Version 20	
<input type="checkbox"/>	Xpert Xpress Flu Version 1	FLUP
<input type="checkbox"/>	Xpert-C, difficile Version 20	
<input checked="" type="checkbox"/>	Xpert-C, difficile G2 Version 20	CDIFF

Xpert Xpress Flu Version 1

Assay Host Test Code

Result Name	Result Test Code
Flu A	INFAP
Flu B	INFBP
QC Check:	PASS

Edit

Close

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

INTERIM REPORT

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

INFLUENZA A by PCR

NEGATIVE

[NEG]

{MC}

INFLUENZA B by PCR

NEGATIVE

[NEG]

{MC}

(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

Joshua B. Kilmer
10/30/17

FLU, COMMENT

END OF REPORT

PAGE 1

PRINT DATE: 10/30/2017

PRINT TIME: 13:19



TO: Cone Health Hospital Providers

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

Joshua B. Kish 10/27/17
John Patrick, MD 10/27/17

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: 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 31st, 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: jbkish@auroradx.com or 336-832-7533

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

Dr. John Patrick: jdpatrick@auroradx.com or 336-832-7531

JK
DR Rubinas

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

Acceptable Specimen



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.