


Approved and current. Effective starting 6/28/2019. 77420.613 (version 3.1) STOP Request/Notification Template
 Blank copy 3834411. Last reviewed on 6/25/2019. Printed on 6/2/2020 12:50 PM (EDT). Page 2 of 2

	<h2 style="text-align: center;">Hologic Panther Aptima SARS-CoV-2 Testing Emergency Use Authorization (EUA) Assay</h2>																							
When:	<p style="text-align: center;">Thursday, June 18, 2020</p>																							
What?	<p style="text-align: center;">To offer SARS-CoV-2 testing on the Hologic Panther</p>																							
Who is Affected:	<table border="1"> <thead> <tr> <th style="text-align: center;">Affected Location(s)</th> </tr> </thead> <tbody> <tr><td>Alamance Cancer Center</td></tr> <tr><td>High Point Cancer Center</td></tr> <tr><td>Wesley Long Cancer Center</td></tr> <tr><td>Alamance Regional</td></tr> <tr><td>Annie Penn Hospital</td></tr> <tr><td>MedCenter @ High Point</td></tr> <tr><td>MedCenter @ Mebane</td></tr> <tr><td><input checked="" type="checkbox"/> Moses Cone Hospital</td></tr> <tr><td>Wesley Long Hospital</td></tr> <tr><td>Women's Hospital</td></tr> </tbody> </table>	Affected Location(s)	Alamance Cancer Center	High Point Cancer Center	Wesley Long Cancer Center	Alamance Regional	Annie Penn Hospital	MedCenter @ High Point	MedCenter @ Mebane	<input checked="" type="checkbox"/> Moses Cone Hospital	Wesley Long Hospital	Women's Hospital	<table border="1"> <thead> <tr> <th style="text-align: center;">Department(s)</th> </tr> </thead> <tbody> <tr><td>Blood Bank</td></tr> <tr><td><input checked="" type="checkbox"/> Cytology</td></tr> <tr><td>Flow Cytometry</td></tr> <tr><td>Histology</td></tr> <tr><td><input checked="" type="checkbox"/> Microbiology</td></tr> <tr><td>Phlebotomy</td></tr> <tr><td>Point Of Care</td></tr> <tr><td><input checked="" type="checkbox"/> Rapid Response Lab</td></tr> <tr><td>Respiratory Therapy</td></tr> <tr><td><input checked="" type="checkbox"/> Specimen Processing</td></tr> </tbody> </table>	Department(s)	Blood Bank	<input checked="" type="checkbox"/> Cytology	Flow Cytometry	Histology	<input checked="" type="checkbox"/> Microbiology	Phlebotomy	Point Of Care	<input checked="" type="checkbox"/> Rapid Response Lab	Respiratory Therapy	<input checked="" type="checkbox"/> Specimen Processing
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Why?	<p style="text-align: center;">A EUA assay for the Aptima SARS CoV-2 assay on the Panther is now available. Bring more COVID-19 testing in-house.</p>																							
What you will need to do to prepare:	<p style="text-align: center;">The EUA validation/verification for SARS CoV-2 assay. Review procedures and training materials prior to go-live. Training for the RRL, MT's doing testing on 3rd shift and weekends by a Cytology Molecular staff with at least 1 year of experience as a Panther Operator. Sunquest LIS/DI communication with the Panther. Training for Cytology Molecular techs on resulting into Sunquest and calling Positive values. Testing Survey set up through CAP when available.</p>																							
Manager / Supervisor Responsibility:	<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>																							
	<input checked="" type="checkbox"/> Sunquest	WindowPath																						
	<input checked="" type="checkbox"/> CHL	<input checked="" type="checkbox"/> Instrument / Manual Test																						
	PowerPath																							
Need Help?	<p style="text-align: center;">Contact your Manager / Supervisor</p>																							

This has been approved by the Laboratory Medical Directors

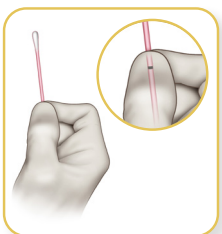
Aptima® Multitest Swab Specimen Collection Kit

Clinician collection procedure guide*

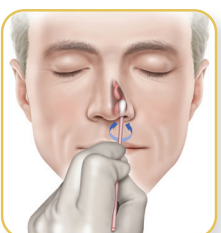
For COVID testing with nasal swab specimens

In addition to the Aptima Multitest Swab, a nasal swab can be collected and placed in VTM, UTM, STM, saline or liquid Amies for COVID testing.

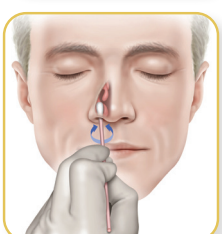
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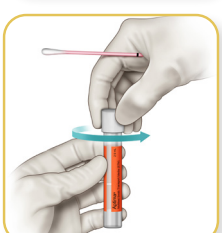
Partially open swab package and remove swab. Do not touch the soft tip or lay the swab down. If the soft tip is touched, laid down, or dropped, discard and get a new Aptima Multitest Swab Specimen Collection Kit. **Hold swab, placing thumb and forefinger in the middle of shaft covering black score line.** Do not hold shaft below score line.



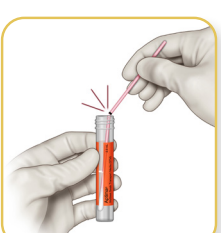
Carefully insert the swab into the first nostril until resistance is met at the level of the turbinates (less than one inch into the nostril). Rotate the swab a few times against the nasal wall and remove from nostril.



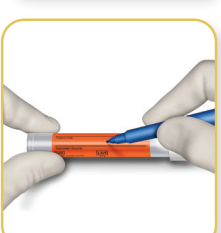
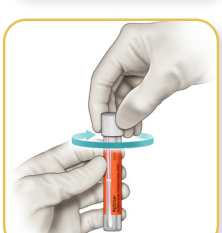
Using the same swab, carefully insert the swab into the second nostril until resistance is met at the level of the turbinates (less than one inch into the nostril). Rotate the swab a few times against the nasal wall and remove from nostril.



While holding swab in hand, unscrew tube cap. Do not spill tube contents. If tube contents are spilled, discard and replace with a new Aptima Multitest Swab Specimen Collection Kit.



Immediately place swab into transport tube so black score line is at top of tube. **Align the score line with top edge of tube and carefully break shaft.** Discard top portion of shaft.



Tightly screw cap onto tube. When collecting multiple specimens from the same patient, the tube label provides a specimen source field for unique identification for specimen location.

Specimens in the Aptima Multitest tube may be stored at 2°C to 30°C up to 6 days.

* Hologic provides this collection procedure guide as a general informational tool only; it is not an affirmative instruction or guarantee of performance. It is the sole responsibility of the clinician to read and understand the appropriate package insert and comply with applicable local, state and federal rules and regulations.

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