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CLINICAL PATHOLOGY LABORATORIES
A Sonic Healthcare Clinical Laboratory

Client Communication

Molecular Testing for Sexually Transmitted Infections:

Phase 3 Transition to Roche Method and Collection Devices

As part of our comprehensive plan for molecular testing for sexually transmitted infections in reproductive and sexual health, Clinical Pathology Laboratories (CPL) will be transitioning *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (NG) and *Trichomonas vaginalis* (TV) testing to the Roche COBAS® 6800/8800 platform.

CPL has validated the Roche platform and determined that:

- The Roche® method is an FDA-approved nucleic-acid amplification technology (NAAT).
  - The Roche® method is qualitative real-time polymerase chain reaction (PCR). (The prior method uses qualitative target capture and Transcription-Mediated Amplification (TMA), an alternate NAAT method.)
- The Roche® method is considered analytically equivalent to other NAAT methods according to CDC and CPL evaluations.
- The Roche® method has been confirmed to be highly sensitive and specific.
- The collection instructions and handling of the Roche collection swab and the prior method are similar, and the stability is equivalent.

With this notification, client training, and user experience, CPL is working to ensure seamless transition to the Roche collection device.

Phase 3: Swab Specimens

Effective January 9, 2023. Clinical Pathology Laboratories will be transitioning from the Hologic Aptima® testing platform to the Roche COBAS® 6800 and 8800 for the detection of *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (NG), and *Trichomonas vaginalis* (TV) for swab specimens.

As part of the transition, select test or panel names will be edited to NAAT (nucleic-acid amplification technology) which includes both polymerase chain reaction (PCR) and transcription-mediated amplification (TMA) target amplification technologies. Order codes will remain the same for the tests affected in this phase.

Change in Collection Device

Beginning in January, distribution will begin transitioning from Aptima® Unisex Swab (Blue Aptima) and Aptima® Multitest (Orange Aptima) collection devices to COBAS® PCR media Dual-Swab collection devices.

	Current	New
Collection Device	Aptima® Multitest (Orange Aptima) and Aptima® Unisex (Blue Aptima) 	COBAS® PCR media Dual Swab Kit collection devices 
Testing Platform	Hologic Aptima®	Roche COBAS® 6800/8800
Methodology	Transcription-Mediated Amplification and Target Capture	Real-time Polymerase Chain Reaction (PCR)

Important Note: During and after the transition, if CPL receives Aptima collection devices they will continue to be run on the Hologic platform without delays to testing. Please contact your local CPL facilities for supplies. For more information about this transition, your CPL Account Representative is briefed and prepared to address your questions or concerns.

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Important Note: Effective 1/9/2023, CPL will accept Roche COBAS® PCR media Dual-Swab for Bacterial Vaginosis by PCR (Order code 3920) and Candida by PCR (Order code 3914) in addition to the currently accepted Hologic Aptima, Eswab, or liquid-based cytology collection devices.

The following order codes will be affected by Phase 3 of the transition:

Test Code	Current Test Name	New Test Name	Methodology and collection device change
3755	C. TRACHOMATIS/N. GONORRHOEAE, RECTAL AND PHARYNGEAL	—	✓
3770	C. TRACHOMATIS/N. GONORRHOEAE, RECTAL/PHARYNGEAL	—	✓
3771	C. TRACHOMATIS, RECTAL/PHARYNGEAL	—	✓
3772	N. GONORRHOEAE, RECTAL/PHARYNGEAL	—	✓
5249	CT/NG, TMA, SIMPLESWAB	CT/NG, NAAT, SWAB	✓
5398	CHLAMYDIA, TMA, SIMPLESWAB	CHLAMYDIA, NAAT, SWAB	✓
5396	GONORRHEA, TMA, SIMPLESWAB	GONORRHEA, NAAT, SWAB	✓
4445	TRICHOMONAS, NAAT, MALE UR/SWAB	—	✓
3911	TRICHOMONAS, SWAB, AMP	TRICHOMONAS, NAAT, CERVICAL SWAB	✓
3910	TRICHOMONAS, SIMPLESWAB	TRICHOMONAS, NAAT, VAGINAL SWAB	✓

Distribution

Your CPL Account Representative will provide supplies to include the new collection devices as previously. There will be no change in the ordering or distribution process.

As a reminder, CPL has previously implemented the following changes related to molecular testing:

Phase 1: Urine

Effective September 1, 2022. See previously published client communication https://www.cpllabs.com/wh-testing-roche-cobas.

Phase 2: ThinPrep® and SurePath™

Effective October 17, 2022. See previously published client communication https://www.cpllabs.com/wh-testing-roche-cobas-ph2.

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FDA Approved/Cleared Status

The performance characteristics for the Roche COBAS® CT/NG and TV test have been evaluated and approved by the FDA for COBAS® PCR Dual-Swab collection devices from endocervical, vaginal, anorectal, and oropharyngeal sources for CT/NG and endocervical and vaginal sources for TV. CPL has verified these performance characteristics.

CT/NG and TV tests from male penile urethral/meatal swabs using the COBAS® PCR media Dual-Swab collection devices will be performed using a laboratory-developed test based on Roche COBAS® CT/NG and TV method. As a laboratory-developed assay, this testing will include an LDT disclaimer Indicating that the performance characteristics of the assay have been validated by the performing laboratory as authorized for high complexity laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Please review your report for specific method notes.

Please contact your CPL Account Representative should you have any questions regarding these changes.

References:
1. cobas CT/NG Qualitative nucleic acid test for use on the cobas 6800/8800 Systems. Package Insert. Roche Diagnostics. 07998007001-04EN.
2. cobas TV/MG Qualitative nucleic acid test for use on the cobas 6800/8800 Systems. Package Insert. Roche Diagnostics. 08308535001-03EN.