SEPTEMBER
2022

CLINICAL PATHOLOGY LABORATORIES
A Sonic Healthcare Clinical Laboratory

Roche Transition: Women's Health Testing

As part of our comprehensive plan for Women's Health testing, CPL will be transitioning *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (NG) and *Trichomonas vaginalis* (TV) testing to the Roche COBAS® 6800/8800 platform. The transition will take place in several phases based on specimen type:

- **Phase 1:** Urine specimens
- **Phase 2:** Liquid-based Pap specimens (Thinprep® and Surepath™)
- **Phase 3:** Swab specimens

The laboratory has validated the Roche platform and determined that:

- The Roche® and Hologic® methods are both FDA-approved nucleic-acid amplification technologies (NAAT).
    - The Roche® method is qualitative real-time polymerase chain reaction (PCR).
    - The Hologic® method is qualitative target capture and Transcription-Mediated Amplification assay (TMA).
- The Roche® and Hologic® methods are analytically equivalent according to CDC and CPL evaluations.
- The Roche® method confirms as a highly sensitive and specific assay.
- The stability and handling of fresh and transferred urine with both systems are equivalent so client impact is expected to be negligible.

CPL will make every effort to assure that this transition causes no disruption of service. We believe that this transition will improve the pre-analytical and analytical processes by increasing process uniformity and instrumentation redundancy.

Phase 1: Urine Specimens

Effective September 1, 2022, 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 urine specimens. This transition phase will include the following changes to methodologies and collection devices.

Client Communication

	Current	New
Collection Device	Aptima® Urine (Yellow Aptima)	COBAS® PCR Urine Kit collection devices
Testing Platform	Hologic Aptima®	Roche COBAS® 6800/8800
Methodology	Transcription-Mediated Amplification and Hybrid Capture	Real-time Polymerase Chain Reaction (PCR)

Order codes and test names will remain the same for the test affected in this phase. The following order codes will be affected by Phase 1 of the transition:

Order Code	Name	Order Code	Name
4335	CT/NG, NAAT, URINE	4445	TRICHOMONAS, NAAT, MALE UR/SWAB
5397	GONORRHEA, NAAT, URINE	3913	TRICHOMONAS, NAAT, URINE
5399	CHLAMYDIA, NAAT, URINE		

Collection Device Distribution

Beginning in September distribution will begin transitioning from Aptima® Urine (Yellow Aptima) collection devices to COBAS® PCR Urine Kit collection devices. Clients will no longer be supplied with Aptima® Urine (Yellow Aptima) collection devices after current inventory is depleted, and orders for urine collection kits will be fulfilled with COBAS® PCR Urine Kits.

During the transition, Aptima® Urine (Yellow Aptima) collection devices will continue to be run on the Hologic® platform, and Roche COBAS® PCR Urine Kit collection devices will be run on the Roche COBAS® platform without delays to testing.

Please contact your local CPL facility for supplies. There will be no change in the ordering or distribution process.

FDA Approved Status

The performance characteristics for the Roche COBAS® CT/NG and TV test have been evaluated and approved by the FDA for COBAS® PCR Urine Kit in male and female patients. CPL has verified these performance characteristics.

Client Communication

CPT Code

The CPT codes for testing for *Chlamydia trachomatis, Neisseria gonorrhoeae* and *Trichomonas vaginalis* are unchanged.

Phased Approach

The transition will take place in several phases to accommodate the logistics of collection device distribution. Further communications will be published for the beginning and end of each transition phase. See the effective dates for the beginning of each phase in the chart below:

Phase	Specimen Type	Order Code	Name	Effective Date
1	Urine	4335	CT/NG, NAAT, URINE	9/01/2022
1	Urine	5397	GONORRHEA, NAAT, URINE	9/01/2022
1	Urine	5399	CHLAMYDIA, NAAT, URINE	9/01/2022
1	Swab	4445	TRICHOMONAS, NAAT, MALE UR/SWAB	9/01/2022
1	Urine	3913	TRICHOMONAS, NAAT, URINE	9/01/2022
2	ThinPrep®	4123	CT/NG, TMA, THINPREP	TBD*
2	ThinPrep®	5402	GONORRHEA, TMA, THINPREP	TBD*
2	ThinPrep®	5403	CHLAMYDIA, TMA, THINPREP	TBD*
2	ThinPrep®	3912	TRICHOMONAS, AMPLIFIED	TBD*
2	SurePath™	5404	CT/NG, TMA, SUREPATH	TBD*
2	SurePath™	5400	GONORRHEA, TMA, SUREPATH	TBD*
2	SurePath™	5401	CHLAMYDIA, TMA, SUREPATH	TBD*
2	SurePath™	3912	TRICHOMONAS, AMPLIFIED	TBD*
3	Swab	3755	C. TRACHOMATIS/N. GONORRHOEAE, RECTAL AND PHARYNGEAL	TBD*
3	Swab	3770	C. TRACHOMATIS/N. GONORRHOEAE, RECTAL/PHARYNGEAL	TBD*
3	Swab	5249	CT/NG, TMA, SIMPLESWAB	TBD*
3	Swab	5398	CHLAMYDIA, TMA, SIMPLESWAB	TBD*
3	Swab	5396	GONORRHEA, TMA, SIMPLESWAB	TBD*
3	Swab	3911	TRICHOMONAS, SWAB, AMP	TBD*
3	Swab	3910	TRICHOMONAS, SIMPLESWAB	TBD*

* TBD = To Be Determined

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

References

COBAS® CT/NG Qualitative nucleic acid test for use on the COBAS® 6800/8800 Systems. Package Insert. Roche Diagnostics®. 07998007001-04EN.

COBAS® TV/MG Qualitative nucleic acid test for use on the COBAS® 6800/8800 Systems. Package Insert. Roche Diagnostics®. 08308535001-03EN.

https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6302a1.htm