OCTOBER
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 has been confirmed to be highly sensitive and specific.

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 2: PreservCyt(ThinPrep)® and SurePath™ specimens

Effective October 17, 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 PreservCyt (Thinprep)® and SurePath™ specimens. There will be no changes to the collection devices for this phase of the transition. However, the following changes to methodologies are included.

Client Communication

	Current	New
Collection Device	PreservCyt (ThinPrep)® or SurePath™	PreservCyt (ThinPrep)® or SurePath™
Testing Platform	Hologic Aptima®	Roche COBAS® 6800/8800
Methodology	Transcription-Mediated Amplification and Hybrid Capture	Real-time Polymerase Chain Reaction (PCR)

As part of the transition, test 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. The following order codes will be affected by Phase 2 of the transition:

Test Code	Previous Name	New Name
4123	CT/NG, TMA, THINPREP	CT/NG, NAAT, THINPREP
5403	CHLAMYDIA, TMA, THINPREP	CHLAMYDIA, NAAT, THINPREP
5402	GONORRHEA, TMA, THINPREP	GONORRHEA, NAAT, THINPREP
5404	CT/NG, TMA, SUREPATH	CT/NG, NAAT, SUREPATH
5401	CHLAMYDIA, TMA, SUREPATH	CHLAMYDIA, NAAT, SUREPATH
5400	GONORRHEA, TMA, SUREPATH	GONORRHEA, NAAT, SUREPATH
3912	TRICHOMONAS, AMPLIFIED	TRICHOMONAS, NAAT
8167	PAP TEST,SUREPATH, IMAGED+HPV HR IF ASC + CT/NG, TMA + HSV I/II PCR	PAP TEST,SUREPATH, IMAGED+HPV HR IF ASC + CT/NG, NAAT + HSV I/II PCR
8144	PAP TEST, TP, IMAGED+HPV HR IF ASC/LSIL+CT/NG, TMA+HSV I/II+TRICH	PAP TEST, TP, IMAGED+HPV HR IF ASC/LSIL+CT/NG, NAAT+HSV I/II+TRICH

Collection Device Distribution

There will be no changes to the collection devices for this phase. PreservCyt (ThinPrep)® and SurePath® specimens should be collected per standard procedure.

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 PreservCyt (ThinPrep)®. CPL has verified these performance characteristics.

The performance characteristics for the Roche COBAS® CT/NG and Roche COBAS® TV test have been evaluated by CPL for SurePath™. Specimen types and sources that have not been specifically evaluated and approved by the FDA will include the following disclaimer on each report:

> *"The performance of this assay has not been specifically approved by the FDA for the Surepath collection device. The performance characteristics for these devices have been validated by Clinical Pathology Laboratories, Inc. CPL is authorized under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high complexity testing."*

Client Communication

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	Urine	4445	TRICHOMONAS, NAAT, MALE UR/SWAB	9/01/2022
1	Urine	3913	TRICH, FEMALE URINE, NAAT	9/01/2022
2	ThinPrep®	4123	CT/NG, AMPLIFIED, THINPREP	10/17/2022
2	ThinPrep®	5402	GONORRHEA, TMA, THINPREP	10/17/2022
2	ThinPrep®	5403	CHLAMYDIA, TMA, THINPREP	10/17/2022
2	ThinPrep®	3912	TRICHOMONAS, AMPLIFIED	10/17/2022
2	SurePath™	5404	CT/NG, TMA, SUREPATH	10/17/2022
2	SurePath™	5400	GONORRHEA, TMA, SUREPATH	10/17/2022
2	SurePath™	5401	CHLAMYDIA, TMA, SUREPATH	10/17/2022
2	SurePath™	3912	TRICHOMONAS, AMPLIFIED	10/17/2022
3	Swab	3755	CT/NG, RECTAL AND PHARYNGEAL	TBD*
3	Swab	3770	RECTAL CT/NG, PHARYNGEAL CT/NG	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	4445	TRICHOMONAS, NAAT, MALE UR/SWAB	TBD*
3	Swab	3911	TRICHOMONAS, SWAB, AMP	TBD*
3	Swab	3910	TRICH, VAGINAL SWAB	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.