70 YEARS OF DEDICATED SERVICE

PATHOLOGY LABORATORIES
A Sonic Healthcare Company

Client Communication

Molecular Testing Migration

Date Issued: June 21, 2019 **Effective: Monday, July 1, 2019**

Effective Monday, July 1, 2019, Pathology Laboratories, Inc. (PathLabs) will be transitioning Molecular Testing to ProMedica Laboratories (ProMedica PathLabs). This testing includes all Hologic Aptima® testing, Chlamydia trachomatis (CT), Neisseria gonorrhoeae (GC), Trichomonas vaginalis (TV), HPV testing (Roche Cobas® and Hologic Aptima) and HPV Genotyping. Also included in this transition will be the BD Affirm™ Test for bacterial vaginosis, which includes detection of Candida species, Gardnerella vaginalis and Trichomonas vaginalis by DNA.

In this transition, important points of interest are shown below:

Changes to Orderable Unit Codes

Updates to our database to accomplish this transition are shown within the charts beginning on page 3 of this communication.

Site Types

Body sites are required for all Hologic Aptima testing. Testing will be delayed or not initially performed, if not provided. An attempt will be made to contact clients to obtain the necessary information if not supplied with the original order.

Acceptable Site Types (Hologic Aptima)	**Test**
Endocervical, vaginal, and male urethral swab specimens	CT/GC
Female and Male urine specimens	
Cervical specimens in ThinPrep® vial	
Endocervical and vaginal swab specimens	TV
Cervical specimens in ThinPrep vial	
Cervical specimens in ThinPrep vial	HPV/ HPVGT

Unacceptable Site Types	**Test**	**Outcome**
Throat	CT/NG/TV/HPV	If submitted, we will attempt to find a reference laboratory to test the specimen.
Rectal		
Specimens from patients under the age of 14 years of age.		
Specimens which appear bloody or have a dark brown color.	Roche® HPV	Rejected

Supply Changes for Urine Trichomonas Testing

Urine specimens for Trichomonas testing will now be performed with the **Cepheid Xpert TV assay on the GeneXpert® Instrument System**. This new test, Trichomonas PCR, Urine, Unit Code 88201, utilizes automated real-time polymerase chain reaction (PCR) to detect Trichomonas vaginalis. The assay is intended for use with both female and male urines to aid in the diagnosis of trichomoniasis in symptomatic or asymptomatic patients.

A new collection device, A-50 Xpert® Urine Specimen Collection Kit, will be required.

Instructions for Collection

- **Prior to urine specimen collection, the patient should not have urinated for at least 1 hour and should not have cleansed the genital area (female patient) or the tip of the penis (male patient).**
- **Use only unpreserved, first-catch urine.**
- **Do not under or over fill the urine transport tubes, as this may affect assay performance.**
- **Minimum Volume = 7 mL**

Supply Ordering

Supplies are available through PathLabs' Supply Department for immediate distribution:

E-mail: supply@pathlabs.org | **Phone:** 419.255.4600, ext. 167 | **Fax:** 419.255.4636

70 YEARS OF DEDICATED SERVICE

PATHOLOGY LABORATORIES
A Sonic Healthcare Company

Specimen	Transport & Storage Temperature	Storage Time
Fill to the black dashed line on tube for the correct fill volume. Minimum Volume: 7 mL		
Female and Male Urine in Xpert Urine Transport Tube	Refrigerated	28 Days
	Room Temperature	14 Days
Unprocessed Urine Specimen in Sterile Container (Male & Female)	Refrigerated	4 Days

As we transition our Molecular Testing to our ProMedica partner laboratory, PathLabs will be making updates and modifications to our database, as more fully described in this disclosure. All established and corresponding reference ranges for any testing performed by the ProMedica Laboratories will be noted on the patient reports. As previously communicated, we will also adopt their critical value ranges as approved by our joint Medical Director. Please review the information and make changes as applicable to your practice/facility.

Orderable Code	Test Name	Retired Test Codes	Replacement Code	Replacement Test Codes	Revised Result Field	Specimen Requirements Handling Instructions	Expected Turnaround	Reference Ranges	CPT Change	Other	Page No.
1995	CHLAMYDIA/N. GONORRHOEAE / T. VAGINALIS, AMPLIFIED PROBE (UR)				✓						2, 3
88201	TRICHOMONAS PCR, URINE								NEW		2, 3
38517	HPV HIGH RISK (THINPREP)				✓						2, 3
38531	HPV-HR BY TMA, REFLEX 16 AND 18/45				✓						2, 3
38958	HPV-HR BY TMA				✓						2, 3
385310	HPV 16 AND 18/45 GENOTYPES BY TMA (reflex only test)				✓						2, 3

70 YEARS OF DEDICATED SERVICE

PATHOLOGY LABORATORIES
A Sonic Healthcare Company

Replacement Test Codes

		EMR Interface Mapping		Other				
Orderable Code	**Test Name**	**Result Code**	**Result Name** (Test Components)	**AOE**	**Reportable**	**LOINC**	**UOM**	**CPT**
1995	CHLAMYDIA /	18741	SOURCE	Y	Y	31208-2		
	N. GONORRHOEAE /	990260	CHLAM TRACHOMATIS rRNA	N	Y	21613-5		87491
	T. VAGINALIS,	990261	NEISS GONORRHOEAE rRNA	N	Y	24111-7		87591
	AMPLIFIED PROBE (UR)	882011	SOURCE	Y	Y	31208-2		
		882012	TRICHOMONAS PCR	N	Y	69937-1		87661
88201	TRICHOMONAS	882011	SOURCE	Y	Y	31208-2		
	PCR, URINE	882012	TRICHOMONAS PCR	N	Y	69937-1		87661
38517	HPV HIGH RISK	385173	HPV SPECIMEN TYPE	Y	Y	31208-2		
	(THINPREP)	385171	HPV 16	N	Y	77399-4		87624
		385172	HPV 18	N	Y	77400-0		
		385170	OTHER HR HPV GENOTYPES	N	Y	71431-1		
38531	HPV-HR BY TMA,	385310	SOURCE	Y	Y	31208-2		
	REFLEX 16 AND 18/45	38531	HPV HIGH RISK	N	Y	6514-4		87624
38958	HPV-HR BY TMA	385310	SOURCE	Y	Y	31208-2		
		38958	HPV HIGH RISK	N	Y	6514-4		87624
385310	HPV 16 AND 18/45	385310	SOURCE	Y	Y	31208-2		
	GENOTYPES BY TMA	3853100	HPV 16	N	Y	59263-4		87625
	(Reflex Test Only)	3853101	HPV 18/45	N	Y	59264-2		

Note: CPT codes are provided for information only and are based on PathLabs' current understanding of Medicare rules and carrier instructions and in accordance with the current issue of Physicians Current Procedural Terminology published by the American Medical Association. Medicare coding may differ from coding used by other third party payers. Questions regarding coding should be confirmed with the payer being billed. PathLabs cannot accept responsibility for the reimbursement clients may or may not receive based on the procedure codes provided.

Our on-line Test Directory will be updated for these changes beginning Monday, July 1, 2019.

Please review the information and make changes as applicable to your practice/facility. If you have any questions, please contact our Client Service Department at 419.255.4600 or toll-free at 800.281.8804, your Account Executive, or Dr. Nicole Hubbard, Medical Director of Infectious Disease Pathology, available through ProMedica Laboratories' Customer Service at 888.471.4134.

We are excited for this transition and the ability to enhance our service offering with new and improved technology available through the combined efforts of ProMedica PathLabs.

Thank you for supporting Pathology Laboratories.