



Client Communication

Cytology and Molecular Testing Updates

Effective March 2, 2023

Notification Date:
June 1, 2023

Effective Date:
June 12, 2023

NOTE: All changes are shown in red for easy reference.

Pathology Laboratories, Inc. (PathLabs) is pleased to announce we will bring HPV, Pap, and STD (Sexually Transmitted Disease) Swab testing for *Chlamydia trachomatis* (CT), *Neisseria gonorrhoea* (NG), and *Trichomonas vaginalis* (TV) in-house, effective Thursday, March 2, 2023.

As a result of internalizing this testing, PathLabs is in the process of updating our HPV, Pap, and STD Swab tests; specifically, to accommodate an expanded test menu, introduce a new methodology for molecular testing, convey decreased analytic times, present a new collection device for the Roche platform, and initiate EMR code changes.

As of June 12th, we are converting to a new Cytology/Histology Requisition (version 05/2023), shown at the end of this publication, to be used for ordering Cytology, Histology and Molecular testing. PathLabs' sales team and supply department will be distributing the new requisition beginning next week.

All testing updates are disclosed in the context of this publication and provided in further detail in the charts below. All changes are marked in bright blue.

The test updates include changes for certain tests in the following areas:

- Expanded Test Menu
- Methodology
- Analytic Time
- Collection Devices
- CPT Codes
- EMR Mapping/LOINC Codes
- Inactivated Codes



Expanded Test Menu

Effective **March 2, 2023**, PathLabs will expand its internal test menu for Cytology and Molecular testing on ThinPrep and Swab specimens to **two (2) platforms as specified**:

Roche COBAS® 6800 Real-Time Polymerase Chain Reaction (PCR): NEW

The **NEW Roche COBAS® 6800** instrumentation is offered in conjunction with Sonic Healthcare USA, Inc.'s (Sonic) expansion to the Roche platform for a comprehensive approach to Women's Health testing. Sonic has validated the Roche platform and has deemed it to be the "preferred method" due to its ability to increase process uniformity and reduce instrument redundancy.

Hologic Aptima® Transcription-Mediated Amplification (TMA): Currently Available Through our internalization initiative, PathLabs will continue to offer the "currently available" Hologic Aptima® platform without change.

Due to this platform driven test menu expansion, there will be changes to the codes specific to the method performed for the testing as further described below in this publication.

Methodology Updates

Pap testing will be internalized, offering significantly decreased turnaround time, benefitting clinicians and patients. Pap testing will continue to be performed using state-of-the-art computer-guided imaging.

(Please see Client Communication released in October 2022 for information on the Pap testing methodology.)

The HPV and STD testing will be available to be performed on the **Roche COBAS® 6800** or the **Hologic Aptima®** platforms for both ThinPrep and Swab specimens.

| Platform | Methodology |
|-------------------|--|
| Roche COBAS® 6800 | Real-Time Polymerase Chain Reaction (PCR) |
| Hologic Aptima® | Transcription-Mediated Amplification (TMA) |

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Our Sonic affiliate, Clinical Pathology Laboratories (CPL), 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 confirmed as a highly sensitive and specific assay.
- The stability and handling of fresh and transferred urine with both systems are equivalent.

Analytic Time

| Test | New (Reduced) | Current |
|-----------------|---------------|-----------|
| HPV | 1-2 Days | 2-5 Days |
| Pap | 3-5 Days | 7-10 Days |
| Roche COBAS® | 1-2 Days | N/A |
| Hologic Aptima® | 1-2 Days | 2-3 Days |

Collection Device Updates

Each methodology has a unique collection device for swab testing as noted in the chart below:

| | NEW "Preferred" Testing Platform | "Currently Available" Testing Platform |
|-------------------|---|--|
| Collection Device | Roche COBAS® PCR Swab Kit | Hologic® Aptima Swab Collection Kit |
| |  |  |
| Platform | Roche COBAS® 6800 | Hologic Aptima® |
| Methodology | Real-time Polymerase Chain Reaction (PCR) | Transcription-Mediated Amplification (TMA) |

CPT Code

The CPT codes for testing are unchanged.

Updated Order Codes - EMR Mapping

The listing provided below, alphabetized by specimen type and test, contains specific information as to the modifications. All changes are marked as **bright blue**.

Swab Specimen Types STD ROCHE Swabs

| Order Code | Reporting Title | Result Code | Description | CPT |
|------------|--|-------------|----------------------------|-------|
| 99034 | CHLAMYDIA, NAAT, ROCHE, SWAB | 990341 | CHLAMYDIA, NAAT, SWAB | 87491 |
| 1980 | CHLAMYDIA/N. GONORRHEA/T. VAGINALIS, NAAT, ROCHE, SWAB | 990341 | CHLAMYDIA, NAAT, SWAB | 87491 |
| | | 990351 | GONORRHEA, NAAT, SWAB | 87591 |
| 1983 | CHLAMYDIA/N.GONORRHEA, NAAT, ROCHE, SWAB | 201411 | TRICHOMONAS,NAAT, VAG SWAB | 87661 |
| | | 990341 | CHLAMYDIA, NAAT, SWAB | 87491 |
| 99035 | GONORRHEA, NAAT, ROCHE, SWAB | 990351 | GONORRHEA, NAAT, SWAB | 87591 |
| | | 201411 | TRICHOMONAS,NAAT, VAG SWAB | 87661 |

STD APTIMA Swabs (Vaginal Swabs Only)

| Order Code | Reporting Title | Result Code | Description | CPT | LOINC |
|------------|---|---------------------------------|---------------------------|-----------------------|---------|
| 38899 | BACTERIAL VAGINOSIS, NAAT, APTIMA, SW | 388991 | BACTERIAL VAGINOSIS, NAAT | 81513 | 94420-7 |
| 38896 | CANDIDA SPP, NAAT, APTIMA, SWAB | 388961 | CANDIDA GLABRATA | 87481 | 94421-5 |
| | | 388962 | CANDIDA SPP | 87481 | 47000-5 |
| 38905 | CANDIDA VAGINITIS/TRICHOMONAS VAGINALIS, NAAT, APTIMA, SWAB | 388961 | CANDIDA GLABRATA | 87481 | 94421-5 |
| | | 388962 | CANDIDA SPP | 87481 | 47000-5 |
| | | 3890500 - TRICHOMONAS VAGINALIS | 389051 | TRICHOMONAS VAGINALIS | 87661 |
| 99016 | CHLAMYDIA, NAAT, APTIMA, SWAB | 990250 | CHLAMYDIA, NAAT, SWAB | 87491 | |
| | | | OTHER TEST CODES REMOVED | | |
| 1997 | CHLAMYDIA/N. GONORRHEA, NAAT, APTIMA, SWAB | 990250 | CHLAMYDIA, NAAT, SWAB | 87491 | |
| | | 990251 | GONORRHEA, NAAT, SWAB | 87591 | |
| | | | OTHER TEST CODES REMOVED | | |

STD APTIMA Swabs (Vaginal Swabs Only) (continued)

| Order Code | Reporting Title | Result Code | Description | CPT | LOINC |
|---|---|-------------------|---|------------------|------------------|
| 1994 | CHLAMYDIA/N. GONORRHEA/T. VAGINALIS, NAAT, APTIMA, ENDOCX SWAB | 990250 | CHLAMYDIA, NAAT, SWAB | 87491 | 87491 |
| | | 990251 | GONORRHEA, NAAT, SWAB | 87591 | 87591 |
| | | 200701 | TRICHOMONAS, NAAT, ENDOCX SWAB | 87661 | 87661 |
| | | | OTHER TEST CODES REMOVED | | |
| NOTE: Replacement code for 1994 is Order Code 1980, page 4. | | | | | |
| | | 990250 | CHLAMYDIA, NAAT, SWAB | 87491 | |
| | | 990250 | CHLAMYDIA, NAAT, SWAB | 87491 | |
| 2009 | CHLAMYDIA/N. GONORRHEA/T. VAGINALIS, NAAT, APTIMA, VAGINAL SWAB | 990251 | GONORRHEA, NAAT, SWAB | 87591 | |
| | | 200601 | TRICHOMONAS, NAAT, VAG SWAB | 87661 | |
| | | | OTHER TEST CODES REMOVED | | |
| 99017 | GONORRHEA, NAAT, APTIMA, SWAB | 990251 | GONORRHEA, NAAT, SWAB | 87591 | |
| | | | OTHER TEST CODES REMOVED | | |
| 38895 | M. GENITALIUM, NAAT, APTIMA SWAB | 388951 | MYCOPLASMA, NAAT, SWAB | 87563 | 69935-5 |
| 2007 | TRICHOMONAS, NAAT, APTIMA, ENDOCX SWAB | 200701 | TRICHOMONAS, NAAT, ENDOCX SWAB | 87661 | |
| NOTE: Replacement code for 2007 is Order Code 2014, page 4. | | | | | |
| 2006 | TRICHOMONAS, NAAT, APTIMA, VAG SWAB | 200601 | TRICHOMONAS, NAAT, VAG SWAB | 87661 | |

ThinPrep Specimen Types ROCHE HPV

| Order Code | Reporting Title | Result Code | Description | CPT |
|------------|--------------------------|-------------|------------------------|-------|
| | | 385174 | HPV INTERPRETATION | 87624 |
| 38517 | HPV HIGH RISK (THINPREP) | 385171 | HPV 16 | |
| | | 385172 | HPV 18 | |
| | | 385170 | OTHER HR HPV GENOTYPES | |

APTIMA HPV

| Order Code | Reporting Title | Result Code | Description | CPT |
|------------|------------------------------------|-------------|---------------|-------|
| | | 38531 | HPV HIGH RISK | 87624 |
| 38531 | HPV-HR BY TMA, REFLEX 16 AND 18/45 | 3853100 | HPV 16 | |
| | | 3853101 | HPV 18/45 | |

Reflexive HPV - Conditional

| Order Code | Reporting Title | Result Code | Description | CPT |
|------------|--------------------------------|-------------|--------------------|-----|
| 373460 | ROCHE HPV IF ASC-US, THINPREP | 3734600 | REFLEX HPV REQUEST | N/A |
| 373469 | APTIMA HPV IF ASC-US, THINPREP | 3734600 | REFLEX HPV REQUEST | N/A |

PAP

| Order Code | Reporting Title | Result Code | Description | CPT |
|------------|--------------------------------|-------------|-----------------------------|-------|
| 51006 | PAP, THINPREP W/ IMAGING, DIAG | 510060 | PAP, THIN PREP WITH IMAGING | 88175 |
| | | 14100 | LMP: | |
| | | 14102 | SOURCE: | |
| | | | OTHER TEST CODES REMOVED | |

STD ROCHE ThinPrep

| Order Code | Reporting Title | Result Code | Description | CPT |
|------------|---|-------------|-----------------------------|-------|
| 99032 | CHLAMYDIA, NAAT, ROCHE, THINPREP | 990321 | CHLAMYDIA, NAAT, THINPREP | 87491 |
| 1990 | CHLAMYDIA/N. GONORRHEA, NAAT, ROCHE, THINPREP | 990321 | CHLAMYDIA, NAAT, THINPREP | 87491 |
| | | 990331 | GONORRHEA, NAAT, THINPREP | 87591 |
| 1989 | CHLAMYDIA/N. GONORRHEA/TRICHOMONAS, NAAT, ROCHE, THINPREP | 990321 | CHLAMYDIA, NAAT, THINPREP | 87491 |
| | | 990331 | GONORRHEA, NAAT, THINPREP | 87591 |
| | | 201110 | TRICHOMONAS, NAAT, THINPREP | 87661 |
| 99033 | GONORRHEA, NAAT, ROCHE, THINPREP | 990331 | GONORRHEA, NAAT, THINPREP | 87591 |
| 2011 | TRICHOMONAS, NAAT, ROCHE, THINPREP | 201110 | TRICHOMONAS, NAAT, THINPREP | 87661 |

STD APTIMA ThinPrep

| Order Code | Reporting Title | Result Code | Description | CPT |
|------------|--|-------------|---|-------|
| 38774 | BACTERIAL VAGINOSIS BY PCR (NOTE A) (Formerly named Bacterial Vaginosis SimpleSwab® by PCR) | | | |
| 38775 | CANDIDA BY PCR (NOTE A) (Formerly named Candida SimpleSwab® by PCR) | | | |
| 99018 | CHLAMYDIA, NAAT, APTIMA, THINPREP | 990260 | CHLAMYDIA, NAAT, THINPREP | 87491 |
| | | 990260 | CHLAMYDIA, NAAT, THINPREP | 87491 |
| 1993 | CHLAMYDIA/N. GONORRHEA/T. VAGINALIS, NAAT, APTIMA, THINPREP | 990261 | GONORRHEA, NAAT, THINPREP | 87591 |
| | | 88200 | TRICHOMONAS, NAAT, THINPREP OTHER TEST CODES REMOVED | 87661 |
| 1996 | CHLAMYDIA/N. GONORRHEA, NAAT, APTIMA, THINPREP | 990260 | CHLAMYDIA, NAAT, THINPREP | 87491 |
| | | 990261 | GONORRHEA, NAAT, THINPREP | 87591 |
| 99019 | GONORRHEA, NAAT, APTIMA, THINPREP | 990261 | GONORRHEA, NAAT, THINPREP | 87591 |
| 88200 | TRICHOMONAS, NAAT, APTIMA, THINPREP | 88200 | TRICHOMONAS, NAAT, THINPREP OTHER TEST CODES REMOVED | 87661 |

NOTE A: Primary collection changing from SimpleSwab® to ThinPrep® Aptima. All Result Codes remain constant.

Client Communication

Requisition Related Order Codes

| Order Code | Reporting Title |
|------------------|---|
| | HSV |
| 38791 | HSV 1/2, AMPLIFIED |
| | SIMPLESWAB See complete offering of tests on page 9. |
| 38774 | BACTERIAL VAGINOSIS, SIMPLESWAB, BY PCR |
| 38775 | CANDIDA, SIMPLESWAB, BY PCR |
| 38792 | SIMPLESWAB COMPREHENSIVE PANEL |
| | SUREPATH |
| 37894 | CHLAMYDIA, NAAT, SurePath |
| 38847 | CT/NG |
| 37893 | GONORRHEA, NAAT, SurePath |
| 38519 | HR HPV |
| 38521 | HR HPV IF ASCUS(21+) |
| 37885 | PAP |
| | URINE STD |
| 1999 | CHLAMYDIA/N. GONORRHEA, NAAT, URINE |
| 1995 | CHLAMYDIA/N. GONORRHEA/T. VAGINALIS, NAAT, URINE |

NOTE:

The new Cytology/Histology/Molecular requisition is disclosed on page 9 of this publication. These order codes are offered and appear in new sections of the stated requisition.

Inactivated Order Codes

| Order Code | Reporting Title | Order Code |
|------------|--|------------|
| 3734612 | APTIMA HPV IF NEG OR ASCUS(TP)-E | N/A |
| 3734613 | APTIMA HPV IF UNSAT/ASCUS OR ABOVE | N/A |
| 38777 | CHLAMYDIA, NAAT, SWAB | 99016 |
| 1994 | CHLAMYDIA/N. GONORRHEA/T. VAGINALIS, NAAT, APTIMA, ENDOCX SWAB | 1980 |
| 2008 | CHLAMYDIA/N. GONORRHEA/T. VAGINALIS, NAAT, MALE | 1995 |
| 38778 | GONORRHEA, NAAT, SWAB | 99017 |
| 376302 | HIGH RISK HPV, AMPLIFIED | N/A |
| 38518 | HPV HIGH RISK (THINPREP) | 38517 |
| 373468 | HPV IF NEGATIVE OR ASCUS(TP),E-ORD | N/A |
| 3734614 | HPV IF UNSAT/ASCUS OR ABOVE(TP) | N/A |
| 373462 | HPV REGARDLESS OF PAP(TP),E-ORDERS | N/A |
| 38958 | HPV-HR BY TMA | N/A |
| 2002 | TRICHOMONAS, NAAT, MALE SWAB | 2001 |
| 38776 | TRICHOMONAS,NAAT,VAG SWAB | 2006 |
| 2007 | TRICHOMONAS, NAAT, APTIMA, ENDOCX SWAB | 2014 |

NOTE:

The specified order codes will be inactivated. Replacement codes are identified if available.

Client Communication

Our online test directory will be updated to reflect this information on **June 12, 2023**.

This Client Communication will be posted to our website for reference.

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 419.255.4601/800.281.8804 or your account executive. Thank you.

NOTE: CPT codes are provided for information only, and are based on Pathology Laboratories' current understanding of Medicare rules and carrier instructions and in accordance with the current issue of physicians current procedural terminology (CPT), 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. Pathology Laboratories cannot accept responsibility for the reimbursement clients may or may not receive based on the procedure codes provided.

Cytology, Histology & Molecular Requisition

Version 05/2023 Effective June 12, 2023



PATHOLOGY LABORATORIES
A Sonic Healthcare Clinical Laboratory

1946 N. 13th St.,
Toledo, Ohio 43604
Customer Service
419-255-4601
800-281-8804

Patient Name (Last) _____ (First) _____ (MI) _____

Patient SS#/ID# _____ **(IMPORTANT)**

Patient Address _____

City, State, Zip _____

Date of Birth (IMPORTANT) _____ **Sex** _____ **Race** _____ **Phone #** _____
() () ()

Responsible Party (if other than Patient) _____

DATE OF SERVICE _____

DIAGNOSIS CODES

DIAGNOSIS CODES REQUIRED

PATIENT HISTORY

DATE OF LAST MENSTRUAL PERIOD _____

Pregnancy Postpartum Postmenopausal PMP bleeding

Hysterectomy Hysterectomy, Supracervical HRT DES Exposure

Birth Control: Oral IUD Other _____

CLINICAL INFORMATION
(Please list previous atypical cytology, surgeries or procedures, personal Hx of cancer, pertinent examination findings, etc.)

SOURCE Vaginal Cervical Endocervical **(Required)**

GYN CYTOLOGY TESTING

Pap tests are subject to an additional charge if a review is performed by a pathologist.

Age-based ACOG Screening Recommendations

ThinPrep® Pap w/Imaging & Roche High Risk (HR) HPV (DNA)

PAP (51006)

PAP, reflex HR HPV if ASCUS (ages 21 and over) (51006/373460)

PAP and HR HPV (cotesting ages 30-65) (51006/38517)

PAP, reflex HR HPV if ASCUS, CT/NG (w/STI risks) (51006/373460/1990)

ThinPrep® Pap w/Imaging & Aptima High Risk (HR) HPV (mRNA) w/Reflex to Genotype

PAP (51006)

PAP, reflex HR HPV if ASCUS (ages 21 and over) (51006/373469)

PAP and HR HPV (cotesting ages 30-65) (51006/38531)

PAP, reflex HR HPV if ASCUS, CT/NG (w/STI risks) (51006/373469/1996)

Sure Path™ Pap w/Imaging & Roche High Risk (HR) HPV (DNA)

PAP (37885)

PAP, reflex HR HPV if ASCUS (ages 21 and over) (37885/38521)

PAP and HR HPV (cotesting ages 30-65) (37885/38519)

PAP, reflex HR HPV if ASCUS, CT/NG (w/STI risks) (37885/38521/38847)

HSV TESTING

HSV Testing (Out of Vial: Roche Only OR SimpleSwab™ Orange Aptima)
38791 Source of Specimen: _____

MOLECULAR TESTING

OUT OF VIAL TESTING:

| | | |
|--|--|---|
| ThinPrep® - Roche | ThinPrep® - Aptima | SurePath™ - Roche |
| <input type="checkbox"/> CT/NG 1990 | <input type="checkbox"/> Bacterial Vaginosis 38774 | <input type="checkbox"/> CT/NG 38847 |
| <input type="checkbox"/> CT/NG/TV 1989 | <input type="checkbox"/> Candidiasis 38775 | <input type="checkbox"/> Chlamydia (CT) 37894 |
| <input type="checkbox"/> Chlamydia (CT) 99032 | <input type="checkbox"/> CT/NG 1996 | <input type="checkbox"/> Gonorrhea (NG) 37893 |
| <input type="checkbox"/> Gonorrhea (NG) 99033 | <input type="checkbox"/> CT/NG/TV 1993 | <input type="checkbox"/> HR HPV 38519 |
| <input type="checkbox"/> Trichomonas (TV) 2011 | <input type="checkbox"/> Chlamydia (CT) 99018 | |
| <input type="checkbox"/> HR HPV 38517 | <input type="checkbox"/> Gonorrhea (NG) 99019 | |
| | <input type="checkbox"/> Trichomonas (TV) 88200 | |
| | <input type="checkbox"/> HR HPV 38531 | |

SWAB TESTING:

COBAS® PCR Media Dual Swab Kit (Roche Swab)

| | | |
|---|--|---|
| <input type="checkbox"/> CT/NG NAAT 1983 | <input type="checkbox"/> Bacterial Vaginosis 38899 | <input type="checkbox"/> Chlamydia (CT) 99016 |
| <input type="checkbox"/> CT/NG/TV NAAT 1980 | <input type="checkbox"/> Candida spp 38896 | <input type="checkbox"/> Gonorrhea (NG) 99017 |
| <input type="checkbox"/> Chlamydia (CT) NAAT 99034 | <input type="checkbox"/> Candida vaginitis / Trichomonas vaginalis 38905 | <input type="checkbox"/> Mycoplasma genitalium (Mgen) 38895 |
| <input type="checkbox"/> Gonorrhea (NG) NAAT 99035 | <input type="checkbox"/> CT/NG 1997 | <input type="checkbox"/> Trichomonas (TV) NAAT 2006 |
| <input type="checkbox"/> Trichomonas (TV) NAAT 2014 | <input type="checkbox"/> CT/NG/TV 2009 | |

NON-GYN CYTOLOGY TESTING

Routine Non-Gyn Cytology (CytoLyt™ Fixative) Source of Specimen: _____

Fine Needle Aspiration for Cytology (CytoLyt™ Fixative) Site: _____

Additional Studies (Fresh Specimen Only): Aerobic/Anaerobic Culture Flow Cytometry Other _____

BILL TO: Phys.Ofc./Client Insurance Self Pay

PHYSICIAN AND ADDRESS (PLEASE PRINT)

PHYSICIAN NOTICE

When ordering laboratory services for which Medicare reimbursement will be sought, physicians (or other practitioners authorized by law to order tests) should only order tests that are medically necessary for the diagnosis or treatment of a patient, rather than for screening purposes. Non-covered screening tests must be billed to the patient.

ATTACHMENTS:

Insurance Info. Medicare # _____

ABN _____

Other _____ Other Insurance# _____

DATE OF SURGERY:

Specimen Source: _____
(If Endometrium, please indicate LMP and + Hormonal Therapy)

Breast Biopsies:
Time excised: _____ Time placed in formalin: _____

Physician/Practitioner X _____ **SIGNATURE (REQUIRED)**

DATE OF SURGERY:

Specimen Source: _____
(If Endometrium, please indicate LMP and + Hormonal Therapy)

Breast Biopsies:
Time excised: _____ Time placed in formalin: _____

CERVIX (if applicable)
12:00

MICROBIOLOGY (Genitourinary)

Susceptibility

Antibiotic Therapy Yes No

85050 Genital Culture

86075 Group B Strep Screen

86076 Group B Screen, Susceptibility

37493 Chlamydia Culture

1999 Chlamydia/NG, NAAT, Urine

1995 Chlamydia/NG/Trich, NAAT, Urine

87050 Gonorrhea Screen

95010 Herpes Culture

85052 Vag. Pathogens (Affirm™ VP III)

Other: _____

Site: _____ **(Required)**

LAB USE ONLY

PLACE BAR CODE LABEL HERE

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