Client Update

BioReference® | GenPath®

Test Name	Test Code	Effective Date
Allergen Curry (rf281) **Allergen Hops (rf324)** **Allergen Cardamon (rf267)**	**2356-4** **A333-7** **2308-5**	**Immediately**

Allergen Curry (2356-4), Hops (A333-7), and Cardamon (2308-5) have been discontinued by the manufacturer. No alternative testing is available at this time.

Test Name	Test Code	Effective Date
KAPPA LIGHT CHAIN, Urine, Random	**R162-9**	**Immediately**

KAPPA LIGHT CHAIN, Urine, Random (R162-9) will be retired. The recommended alternate test is URINE FREE KAPPA+LAMBDA (L592-5)

	Previous Test Information	New Test Information
Primary Container	Urine	Urine
Minimum Volume	0.5mL	10.00
Turn Around Time*	6 Days	3 Days
Transportation Temp	Refrigerate	Refrigerate
Stability	7 days Refrigerate, 14 days Frozen	21 days Refrigerate, 180 days Frozen
Methodology	Nephelometry	Immunoturbidimetric
Reference Range	<=32.90 mg/L	Please see Profile Components
Collection Instructions	Random urine collected in a plastic leak-proof container, no preservative.	Submit urine specimen without preservatives
Profile Components	N/A	Kappa/Lambda Urine Ratio Not Estab. Free Kappa Urine <32.91 mg/L Free Lambda Urine <3.80 mg/L
CPT Code(s)**	83883	83521x2
Clinical Utility (If applicable)	N/A	The measurement of free light chains is used in the diagnosis and monitoring of multiple myeloma, lymphocytic neoplasms, waldenstrom's macroglobulinaemia, AL amyloidosis light chain deposition disease and connective tissue diseases such as systemic lupus erythematosus (SLE) in conjunction with other laboratory and clinical findings.

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Test Name	Test Code	Effective Date
HIV-1 Genotyping Assay (≥500 copies/mL viral load)	**M396-0**	**Immediately**

In addition to our M392-9 panel which will run the HIV-1 viral load and will reflex to the appropriate HIV Genotype depending on the result (From <20 to >1000 copies/ml), we are pleased to launch the **new panel M396-0.**

This panel will run the HIV-1 Viral load and will also automatically reflex to either the HIV-1 Genotype (TN88-5) when the viral load is greater than or equal to 1000 copies/ml or the HIV-1 Genotype (TQ70-7) when the viral load is >500 but <1000 copies/ml. The components of both TN88-5 and TQ70-7 are the same. This will not reflex to a Genosure Archive genotype if the HIV-1 viral load is ≤ 500 copies/ml.

NOTE: If a genotype is required for a low or undetectable viral load, a second frozen sample should be submitted for the Genosure Archive Assay (J001-9). If a second frozen was sent in with the original request, the add-on of J001-9 must be done within 5 days of the HIV-1 viral load result.

	New Test Information
Primary Container	2 EDTA lavender top - (Aliquoted Plasma)
Minimum Volume	0.8ml
Turn Around Time*	12 days
Transportation Temp	0-4 degrees C
Stability	14 days
Methodology	Next generation sequencing (NGS)
Collection Instructions	Gently invert lavender top 8-10 times. Store tubes in upright position for up to 2 hours prior to centrifugation. Centrifuge at 1900 x g for 10 minutes at 2-8 degrees C. Transfer to plastic transfer tube and label with date/time collected, EDTA PLASMA and patient's name and freeze
Reference Range	Susceptible
Profile Components	Protease, reverse transcriptase (NRTI and NNRTI), and integrase regions
CPT Code(s)**	0219U
Clinical Utility (If applicable)	Management of HIV-1 infection. Identifies drug resistance to HIV-1 protease, reverse transcriptase and integrase regions of POL gene.

Test Name	Test Code	Effective Date
CD19 By Immunohistochemistry	**TQ96-2 (With Interp)** **TQ97-0 (Tech Only)**	**Immediately**

BioReference/GenPath Oncology is pleased to offer CD19, a pan B-cell target for immunotherapies for several types of lymphoma, including DLBCL.

	New Test Information
Primary Container	BLK - Formalin-fixed, Paraffin-embedded Tissue
Turn Around Time*	Two days

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Transportation Temp	Room Temperature. Ship block with cold pack during warm weather
Methodology	Immunohistochemistry
Collection Instructions	BLK: This comes in block form from a client with a surgical number imprint
CPT Code(s)**	88341x1
Clinical Utility (If applicable)	A B-cell biomarker for several types of lymphoma, including DLBCL

Test Name	Test Code	Effective Date
Hologic Aptima Candida (CV)	**M403-4**	**Immediately**

We are pleased to launch Hologic Aptima Candida (M403-4), an *FDA-approved assay for the detection of* both Candida Species and Candida Glabrata when collected in Hologic Aptima Multitest Swabs.

The Aptima® CV assay is an *in vitro* nucleic acid amplification test for the detection of RNA from microorganisms associated with vulvovaginal candidiasis. The assay utilizes real time transcription-mediated amplification (TMA) to detect and qualitatively report (i.e. Detected, Not Detected or Invalid) results for the following organisms:

- *Candida species group (C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis) - TL77-2*
- *Candida glabrata – TL78-0*

The assay differentiates between Candida glabrata and the Candida species group (C spp) by targeting the RNA component of RNAse P ribonucleoprotein; the assay does not differentiate among C spp. The assay is intended to aid in the diagnosis of vulvovaginal candidiasis on the automated Panther® system using clinician-collected and patient-collected vaginal swab specimens with a clinical presentation consistent with vaginitis or vulvovaginitis.

	New Test Information
Primary Container	Aptima Multitest Swabs
Turn Around Time*	3 days
Transportation Temp	15-30 degrees C {60-85 degrees F)
Stability	21 days
Methodology	Real time transcription-mediated amplification {TMA)
Reference Range	Not Detected
Collection Instructions****	Using the Aptima Multitest swab: • Physician Collection (collected within a health care facility) carefully insert the swab into the vagina about 2 inches (S cm) past the introitus and **gently rotate the swab clockwise** for 10 to 30 seconds. Make sure the swab touches the walls of the vagina so that moisture is absorbed by the swab and then withdraw the swab without touching the skin. • Patient Self Collection (within a health care facility) carefully insert the swab into the vagina about 2 inches (5 cm) inside the opening of the vagina and **gently rotate the swab clockwise** for 10 to 30 seconds. Make sure the swab touches the walls of the vagina so that moisture is absorbed.
CPT Code(s)**	87487
Profile Components	TL-77-2, TL-78-0
Clinical Utility (If applicable)	The assay is intended to aid in the diagnosis of vulvovaginal candidiasis

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Test Name	Test Code	Effective Date
Hologic Aptima BV	**TL79-8**	**Immediately**

We are pleased to launch Hologic Aptima BV (TL79-8), an *FDA-approved assay for the detection* of Bacterial Vaginosis (BV) when collected in Hologic Aptima Multitest Swabs.

The Aptima·BV assay is an *in vitro* nucleic acid amplification test that utilizes real time transcription-mediated amplification (TMA) for detection of ribosomal RNA from bacteria associated with bacterial vaginosis (BV). This includes *Lactobacillus (L. gasseri, L.crispatus, and L. jensenii*), Gardnerella vaginalis, and Atopobium vaginae.

The assay reports a single qualitative result (i.e. Detected, Not Detected, or Invalid) for BV and does not report results for individual organisms. The assay is intended to aid in the diagnosis of BV on patient-collected Aptima vaginal swab specimens with a clinical presentation consistent with vaginitis and/or vaginosis.

	New Test Information
Primary Container	Aptima Multitest Swabs
Turn Around Time*	3 days
Transportation Temp	15-30 degrees C {60-85 degrees F)
Stability	21 days
Methodology	Real time transcription-mediated amplification {TMA)
Reference Range	Not Detected
Collection Instructions****	Using the Aptima Multitest swab: • Physician Collection (collected within a health care facility) carefully insert the swab into the vagina about 2 inches (S cm) past the introitus and **gently rotate the swab clockwise** for 10 to 30 seconds. Make sure the swab touches the walls of the vagina so that moisture is absorbed by the swab and then withdraw the swab without touching the skin. • Patient Self Collection (within a health care facility)carefully insert the swab into the vagina about 2 inches (5 cm) inside the opening of the vagina and **gently rotate the swab clockwise** for 10 to 30 seconds. Make sure the swab touches the walls of the vagina so that moisture is absorbed.
CPT Code(s)**	81513
Clinical Utility (If applicable)	The assay is intended to aid in the diagnosis of BV

Test Name	Test Code	Effective Date
Cystic Fibrosis 40 (CF 40)	**J435-9**	**8/9/2024**

Effective August 9th, Cystic Fibrosis 40 (J435-9) will be retired. Cystic Fibrosis carrier screening will still be available under Expanded Cystic Fibrosis (J434-2). Expanded CF uses the same NGS platform, sample requirements, turnaround time, and CPT codes as CF 40. However, CF 40 (J435-9) includes only 40 variants in the CFTR gene compared to Expanded CF (J434-2) which includes over 200 variants, providing a better detection rate for your patients.

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CF 40 (J435-9) is also included in CF, Fragile X, and SMA carrier screening panel (2115-4). As of August 9th, we will no longer offer this specific panel combination. Instead Expanded CF, Fragile X and SMA carrier screening (P150-6) will be available to best serve your patients.

If you currently order cystic fibrosis carrier screening using one of the CF40 test codes, please switch from test code J435 to J434 and/or from test code 2115 to P150. If Cystic Fibrosis 40 is ordered after August 9th, the test codes will be automatically flipped to Expanded Cystic Fibrosis.

Test Name	Test Code	Effective Date
Chlamydia and Gonorrhea, DNA, PCR Roche Swab	**L583-4**	**Immediately**

Cobas Chlamydia (CT) and Gonorrhea (GC) assay that utilizes real-time polymerase chain reaction (PCR), for the direct detection of Chlamydia trachomatis (CT) and/or Neisseria gonorrhoeae (NG) DNA in male and female urine, clinician- instructed self-collected vaginal swab specimens (collected in a clinical setting), and clinician-collected vaginal swab specimens, endocervical swab specimens all collected in cobas® PCR Media (Roche Molecular Systems, Inc.)

	New Test Information
Primary Container	Roche Collection Swab
Turn Around Time*	3 days
Transportation Temp	2-30 degrees C {60-85 degrees F)
Stability	21 days
Methodology	Real time Polymerase Chain Reaction
Reference Range	Not Detected
Profile Components	T832-5, T833-3
CPT Code(s)**	87491, 87591

Test Name	Test Code	Effective Date
Chlamydia/Gonorrhea, DNA, PCR Roche Anorectal Swab	**M410-9**	**Immediately**

Cobas Chlamydia (CT) and Gonorrhea (GC) assay that utilizes real-time polymerase chain reaction (PCR), for the direct detection of Chlamydia trachomatis (CT) and/or Neisseria gonorrhoeae (NG) DNA in clinician-collected anorectal swab specimens all collected in Cobas® PCR Media (Roche Molecular Systems, Inc.) tubes.

	New Test Information
Primary Container	Roche Collection Swab
Turn Around Time*	3 days
Transportation Temp	2-30 degrees C {60-85 degrees F)
Stability	21 days
Methodology	Real time Polymerase Chain Reaction
Reference Range	Not Detected
Profile Components	TQ73-1, TQ74-9

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CPT Code(s)**	87491, 87591

Test Name	Test Code	Effective Date
Chlamydia/Gonorrhea, DNA, PCR Roche Oropharyngeal Swab	**M409-1**	**Immediately**

Cobas Chlamydia (CT) and Gonorrhea (GC) assay that utilizes real-time polymerase chain reaction (PCR), for the direct detection of Chlamydia trachomatis (CT) and/or Neisseria gonorrhoeae (NG) DNA in clinician-collected oropharyngeal swab specimens all collected in cobas® PCR Media (Roche Molecular Systems, Inc.) tubes.

	New Test Information
Primary Container	Roche Collection Swab
Turn Around Time*	3 days
Transportation Temp	2-30 degrees C {60-85 degrees F)
Stability	21 days
Methodology	Real time Polymerase Chain Reaction
Reference Range	Not Detected
Profile Components	TQ71-5, TQ73-1
CPT Code(s)**	87491, 87591

Questions? Please contact your Account Executive or Customer Service directly.

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