Cleveland Clinic

Cleveland Clinic Laboratories

Technical Update • September 2021

Cleveland Clinic Laboratories is dedicated to keeping you updated and informed about recent testing changes. This Technical Update is provided on a monthly basis to notify you of any changes to the tests in our catalog.

Recently changed tests are bolded, and they could include revisions to methodology, reference range, days performed, or CPT code. Deleted tests and new tests are listed separately. For your convenience, tests are listed alphabetically and order codes are provided.

To compare the new information with previous test information, refer to the online Test Directory at clevelandcliniclabs.com. Test information is updated in the online Test Directory on the Effective Date stated in the Technical Update. Please update your database as necessary.

For additional detail, contact Client Services at 216.444.5755 or 800.628.6816, or via email at clientservices@ccf.org.

Test Update Page #	Summary of Changes by Test Name	Order Code	Name Change	New Test	Test Discontinued	Special Information	Specimen Requirement	Component Change(s)	Methodology	Reference Range	Days Performed/Reported	Stability	CPT	Fee
3	Aldosterone										■			
3	Aldosterone/Direct Renin Ratio										■			
4–5	Bacterial Vaginosis Amplification			■										
5	Candida / Trichomonas Amplification			■										
3, 5	Hepatitis B Viral DNA, Ultra Quant					■	■					■		■
3, 5	Hepatitis C RNA by PCR						■					■		■
5	HIV 1 Drug Resistance by Next-Generation Sequencing												■	■
3	HIV Quant RNA by PCR					■	■					■		
3	Metanephrines, Urine 24 hour											■		
3	Metanephrines, Urine Random											■		
4	Nicotine and Cotinine, Serum							■						
4	Rapamune						■			■				
4	Thiopurine Metabolites by LC-MS/MS					■	■		■	■	■	■		

Update: Scheduled Test Changes On-Hold

With the recent delay in Cleveland Clinic's Beaker LIS implementation, test changes announced in previous Technical Updates are now on hold. These changes were to take place in August and September and are dependent on the go-live of the Beaker LIS.

Once a new Beaker go-live date has been identified, CCL will notify clients as soon as possible.

On-Hold: Changes to Test Build

- Complete Blood Count and Differential (CBCDIF)
- G-6-PD Quantitative (G6PDQT)
- Paroxysmal Nocturnal Hemoglobinuria (PNH) Panel by FCM (PNHPNL)
- Platelet Function Screen (PLTSCP)
- Prothrombin Time and PTT Elevation Diagnostic Panel (PTPTTE)
- Prothrombin Time Elevation Diagnostic Panel (PTEPNL)
- T-cell V Beta by Flow Cytometry (TVBETA)
- Urinalysis (with microscopic) with Culture if Indicated (UACII)
- Urinalysis Only (UA)
- Urinalysis with Microscopic (UAWMIC)

On-Hold: Test Discontinuations

- Acute Leukemia Markers (ACLUK2)
- Flow Cytometry Hold Sample (FLOHLD)
- HIV-1 Qualitative Test by PCR (HIV1QL)
- Lymphoma Markers, Tissue (BLYMPH)
- Peripheral Blood Low Grade Leuk Markers (PBLGLY)

Test Changes

Test Name	Order Code	Change	Effective Date
Aldosterone	ALDO	**Days Performed:** **Monday through Friday**	9/7/21
Aldosterone/Direct Renin Ratio	ALDREN	**Days Performed:** **Monday through Friday**	9/7/21
Hepatitis B Viral DNA, Ultra Quant	HBVDNU	**Special Information:** The quantitative range of this assay is **10 IU/mL to 1,000,000,000 IU/mL.** Elevated levels of hemoglobin at concentrations of 500 mg/dl may interfere with the quantitation. Rare mutations in the highly conserved region of the viral genome may cause under-quantitation or failure to detect the virus. **Specimen Requirement:** 2 mL serum from serum separator tube (SST gold); Minimum 1.5 mL; Refrigerated Separate plasma from red cells within 24 hours of collection. **Sterile aliquot tubes must be used. Sample must be aliquoted first if sample is to be frozen.** OR 2 mL plasma from EDTA PPT (white) tube; Minimum 1.5 mL; Refrigerated Separate plasma from red cells within 24 hours of collection. **If aliquoting is necessary, sterile aliquot tubes must be used. Sample must be aliquoted first if sample is to be frozen.** **OR 2 mL plasma from EDTA (lavender) tube; Minimum 1.5 mL Refrigerated** **Separate plasma from red cells within 24 hours of collection.** **Sterile aliquot tubes must be used. Sample must be aliquoted first if sample is to be frozen.** **Stability:** Ambient: **24 hours** Refrigerated: **6 days** Frozen: **12 weeks at less than -18 degrees**	effective immediately
Hepatitis C RNA by PCR	HCQPCR	**Specimen Requirement:** 3 mL plasma from EDTA PPT (white) tube; Refrigerated Centrifuge within 24 hours of collection. **Sample must be aliquoted first if sample is to be frozen.** OR 3 mL serum from serum separator (SST Gold) tube; Refrigerated Centrifuge within 24 hours of collection. **Sample must be aliquoted first if sample is to be frozen.** **Stability:** Ambient**: 24 hours** Refrigerated**: 6 days** Frozen**: 12 weeks**	effective immediately
HIV Quant RNA by PCR	HIVRNA	**Special Information:** **Specimens must be collected and transported using the Aptima Multitest Swab Specimen Collection Kit. Any other transport system is unacceptable. Vaginal specimens are the only acceptable specimen type. This test is for use in women with symptoms of vaginitis. Other tests for the evaluation of vaginitis are available on vaginal fluid or vaginal swab specimens. If only bacterial vaginosis is suspected, then the Bacterial Vaginosis Scored Gram Stain (BVSTN) should be ordered. It should be noted that molecular diagnostic methods have significantly higher cost to patient charges than other methods.** **Specimen Requirement:** 3 mL plasma from EDTA PPT (white top) tube; Refrigerated Centrifuge within 24 hours of collection**. Sample must be aliquoted first if sample is to be frozen.** **Stability:** Ambient: 24 hours Refrigerated: 6 days **Frozen: 6 months (cannot be frozen PPT tube)**	effective immediately
Metanephrines, Urine 24 hour	UMETAN	**Stability:** Ambient: **7 days** Refrigerated: 2 weeks Frozen**:** 1 month (one free thaw cycle allowed)	10/12/21
Metanephrines, Urine Random	UMETRA	**Stability:** Ambient: **7 days** Refrigerated: 2 weeks Frozen**:** 1 month	10/12/21

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Nicotine and Cotinine, Serum	NICOT	**Includes:** **Nicotine (NIC) and Cotinine (COT).** **Nornicotine (NORNIC) is being removed from the panel.**	10/5/21
Rapamune	RAPAM	**Specimen Requirement:** 2.5 mL whole blood from EDTA (lavender) tube; Refrigerated **Collect immediately prior to next dose.** **Reference Range:** **4.0–12.0 ng/mL**	10/5/21
Thiopurine Metabolites by LC-MS/MS	THIMET	**Special Information:** **Grossly hemolyzed, lipemic, icteric and clotted specimens will be rejected.** **This test is New York DOH approved.** **Clinical Information:** **This test is primarily used to verify compliance, optimize therapy, and identify elevated metabolite concentrations that may result in toxicity after initiation of thiopurine drug therapy for the treatment of inflammatory bowel disease. Recommended time points for monitoring include: 4 weeks after starting treatment to verify patient compliance and look for early risk of toxicity; 12 to 16 weeks after starting therapy when 6-thioguanine nucleotides have reached steady-state; and annually. It may also be ordered in patients who do not respond to therapy as expected or as needed for dose changes, flare-ups, signs of toxicity, or suspicion of noncompliance. The test will measure 6-methylmercaptopurine (6-MMP) and 6-thioguanine nucleotides (6-TGN) in erythrocytes. Target 6-thioguanine (6-TGN) concentrations are 235 to 450 pmol/8x10(8) RBC with lower levels suggesting suboptimal dosing and higher levels associated with increased risk of myelotoxicity and leukopenia. High 6-methylmercaptopurine (6-MMP) levels (greater than 5700 pmol/8x10[8] RBC) suggest an increased risk for hepatotoxicity and potentially "thiopurine hypermethylation."** **Specimen Requirement:** **3 mL whole blood in EDTA (Lavender) tube; Minimum 1.5 mL; Refrigerated** **Separate specimens must be submitted when multiple tests are ordered.** **Stability:** Ambient: **24 hours** Refrigerated: **8 days** Frozen: Unacceptable **Methodology: Quantitative Liquid Chromatography - Tandem Mass Spectrometry** **Days Performed: Monday through Saturday** **Reported: 1–5 days**	10/25/21

New Tests

Test Name	Order Code	Change	Effective Date
Bacterial Vaginosis Amplification	**BVAMP**	**Special Information:** **Specimens must be collected and transported using the Aptima Multitest Swab Specimen Collection Kit. Any other transport system is unacceptable. Vaginal specimens are the only acceptable specimen type. This test is for use in women with symptoms of vaginitis. Other tests for the evaluation of vaginitis are available on vaginal fluid or vaginal swab specimens. If only bacterial vaginosis is suspected, then the Bacterial Vaginosis Scored Gram Stain (BVSTN) should be ordered. It should be noted that molecular diagnostic methods have significantly higher cost to patient charges than other methods.** **Clinical Information:** **The Aptima® BV assay is an in vitro nucleic acid amplification test that utilizes real time transcription-mediated amplification (TMA) for detection and quantitation of ribosomal RNA from bacteria associated with bacterial vaginosis (BV), including Lactobacillus (L. gasseri, L. crispatus, and L. jensenii), Gardnerella vaginalis, and Atopobium vaginae. The assay reports a qualitative result for BV and does not report results for individual organisms. The assay is intended to aid in the diagnosis of BV on the automated Panther® system using clinician-collected and patient-collected vaginal swab specimens from females with a clinical presentation consistent with vaginitis and/or vaginosis.** *(continued on page 4)*	10/7/2021

New Tests (Continued)

Test Name	Order Code	Change	Effective Date
Bacterial Vaginosis Amplification *(continued from page 3)*		**Specimen Requirement:** **Swab, genital; Aptima Multitest Collection Kit; Ambient** **Only the Aptima Multitest Swab Specimen Collection Kit is acceptable.** **Stability:** Ambient: **30 days at 15 degrees C to 30 degrees C** Refrigerated: **30 days at 2 degrees C to 8 degrees C** Frozen: **90 days at -20 degreec C to -70 degrees C** **Methodology: Transcription-Mediated Amplification** **Reference Range: Negative** **Days Performed: Varies, Mon–Fri 7:00 am–11:00 pm** **Reported: 2–3 days**	
Candida / Trichomonas Amplification	CVTV	**Special Information:** **Specimens must be collected and transported using the Aptima Multitest Swab Specimen Collection Kit. Any other transport system is unacceptable. Vaginal specimens are the only acceptable specimen type. This test is for use in women with symptoms of vaginitis or vulvovaginitis.** **Clinical Information:** **The Aptima® CV/TV assay is an in vitro nucleic acid amplification test for the detection of RNA from microorganisms associated with vulvovaginal candidiasis and trichomoniasis. The assay utilizes real time transcription-mediated amplification (TMA) to detect and qualitatively report results for the following organisms: • Candida species group (C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis) • Candida glabrata • Trichomonas vaginalis 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. For Trichomonas vaginalis, the assay targets ribosomal RNA (rRNA) and differentiates the result from results for Candida glabrata and C spp. The assay is intended to aid in the diagnosis of vulvovaginal candidiasis and trichomoniasis on the automated Panther® system using clinician-collected and patient-collected vaginal swab specimens from females with a clinical presentation consistent with vaginitis or vulvovaginitis.** **Specimen Requirement:** **Swab, genital; Aptima Multitest Collection Kit; Ambient** **Only the Aptima Multitest Swab Specimen Collection Kit is acceptable.** **Stability:** Ambient: **30 days at 15 degrees C to 30 degrees C** Refrigerated: **30 days at 2 degrees C to 8 degrees C** Frozen: **90 days at -20 degreec C to -70 degrees C** **Methodology: Transcription-Mediated Amplification** **Reference Range: Negative** **Days Performed: Varies, Mon–Fri 7:00 am–11:00 pm** **Reported: 2–3 days**	10/10/21
HIV 1 Drug Resistance by Next-Generation Sequencing	HIVNGS	**Note: This test was previously announced in the August Technical Update.** **CPT: 87900 (x1), 87901 (x1), 87906 (x1)** **Price: $1019.00**	effectively immediately

Fee Reductions

Test Name	Order Code	List Fee	CPT Code	Effective Date
Hepatitis B Viral DNA, Ultra Quant	HBVDNU	$378.00	87517	effective immediately
Hepatitis C RNA by PCR	HCQPCR	$366.00	87522	effective immediately