Cleveland Clinic

Cleveland Clinic Laboratories

Technical Update • December 2023

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
5	Allergen, Honey Bee Components IgE												■
5	Allergen, Honey Bee IgE with Reflex to Components												■
5	Allergen, Paper Wasp Component IgE												■
5	Allergen, Paper Wasp IgE with Reflex to Component												■
5	Allergen, Total Venom Panel IgE with Reflex to Components												■
5	Allergen, Yellow Jacket (Common Wasp) Components IgE												■
5	Allergen, Yellow Jacket (Common Wasp) IgE with Reflex to Components												■
2	Amino Acids, Plasma w/ Consultation											■	
5	Ammonium, 24 hour, Urine												■
5	Ammonium, Random, Urine												■
5	Asparaginase Enzyme Activity												■
2–3	Candida & Trichomonas vaginalis, NAAT					■							
3	Chromogranin A						■	■	■	■	■	■	
5	COVID & Influenza A/B & RSV NAAT, Routine												■
3	Cryptococcus Ag Detection						■						
5	Drug Detection Panel, Umbilical Cord Tissue, with Marijuana Metabolite												■
3	Fungus Screen					■							
3–4	Hepatitis E Virus (HEV) Antibodies, IgG and IgM		■			■	■	■	■	■	■	■	

Test Update Page #		Order Code	Name Change	New Test	Test Discontinued	Special Information	Specimen Requirement	Component Change(s)	Methodology	Reference Range	Days Performed/Reported	Stability	CPT
6	Methylphenidate and Metabolite, Urine, Quantitative			■									
6	Mitragynine (Kratom), urine			■									
4	Mycoplasma pneumoniae PCR					■	■		■		■		
4	Phenytoin, Free						■	■					
4	Warfarin Sensitivity (CYP2C9, CYP2C cluster, CYP4F2, VKORC1) Genotyping						■						

Test Changes

Test Name	Order Code	Change	Effective Date
Amino Acids, Plasma w/ Consultation	PAABI	**Stability:** Ambient: Unacceptable Refrigerated: 24 hours, **after separation from cells** Frozen: 2 weeks, **after separation from cells**	effective immediately
Candida & Trichomonas vaginalis, NAAT	CVTV	**Special Information:** Microbiology Preanalytic Guidance: http://portals.ccf.org/plmi/Laboratory-Medicine/Microbiology-Specimen-Collection-Transport-Information. The specimen must be a vaginal swab collected and transported using the Aptima Multitest Swab Specimen Collection Kit. Up to two tests can be run on a single Aptima Multitest Swab specimen (ie. GCCT+CVTV or CVTV+BVAMP)–if specimen sources have been correctly selected, the shared tests will print on the same label. Do not place more than one label on a single collection tube. Specimens collected from a non-vaginal source, with an inappropriate or expired collection device, or containing >1 swab may be rejected. Related alternative orders: 1. TRVAMP: in-house Trichomonas vaginalis standalone NAAT (use when complicated vulvovaginal candidiasis is not on the differential). 2. CANSTN: in-house vaginal smear for yeast (use when diagnosing uncomplicated vulvovaginal candidiasis). 3. BVCNSM: in-house vaginal smear gram stain for bacterial vaginosis diagnosis by Nugent score and microscopic exam for yeast (use when both BV and uncomplicated vulvovaginal candidiasis are on the differential). 4. FUNGSC: in-house fungal culture for yeast (use for diagnosis of candida vaginitis in cases where wet mount is negative but disease is still suspected, and/or complicated vulvovaginal candidiasis is suspected). **Note that the Aptima Multitest Swab Specimen cannot be used to add-on FUNGSC. Please refer to FUNGSC test directory entry for specimen collection requirements and details.** **Clinical Information:** Vaginitis syndrome is characterized by a spectrum of conditions including vaginal and vulvar irritation, odor, discharge and pruritus. Causes of vaginitis include mechanical and chemical factors (feminine hygiene products, contraceptive materials, etc.) as well as infectious agents. Up to 90% of infectious vaginitis cases are caused by bacterial vaginosis (BV), vulvovaginal candidiasis (candida vaginitis, CV) and trichomoniasis (Trichomonas vaginalis, TV). BV has been diagnosed in 22-50% of symptomatic patients, CV in 17-39%, and TV in 4-35%. The Aptima CV/TV assay is an FDA-cleared in vitro nucleic acid amplification test (NAAT) for the detection of RNA from microorganisms associated with vulvovaginal candidiasis and trichomoniasis. *(continued on page 3)*	effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Candida & Trichomonas vaginalis, NAAT *(continued from page 2)*	CVTV	**Clinical Information (continued):** 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 patients with a clinical presentation consistent with vaginitis or vulvovaginitis. CV and TV may be detected by microscopy, culture, and nucleic acid using specimens collected with vaginal swabs. Use of this NAAT should be reserved diagnosis of complicated vulvovaginal candidiasis where identification of Candida glabrata (not easily recognized on microscopy due to lack of pseudohyphae/ hyphae, increased azole resistance) may be important. Trichomonas only testing by NAAT is available as a stand-alone test (order code TRVAMP) when complicated vulvovaginal candidiasis is not on the differential. **Fungal culture is available as a stand-alone test (order code FUNGSC) and is the test of choice when trying to recover a fungal isolate for potential susceptibility testing. FUNGSC cannot be added onto the Aptima Multitest Swab Specimen – please refer to FUNGSC test directory entry for specimen collection requirements and details.**	effective immediately
Chromogranin A	CHROMA	**For interface clients only–Test build may need to be modified** **Special Information:** Plasma is not acceptable. Grossly hemolyzed samples will be rejected. The Chromogranin A test is performed using the **B·R·A·H·M·S CgA II KRYPTOR** method. Results obtained with different assay methods or kits cannot be used interchangeably. **Clinical Limitation:** *information has been removed* **Specimen Requirement:** 1 mL serum from serum separator (Gold) tube; **Frozen; Within 2 hours of collection, centrifuge and transfer serum to CCL transport tube and freeze.** *OR* 1 mL serum from no additive (Red) tube; **Frozen; Within 2 hours of collection, centrifuge and transfer serum to CCL transport tube and freeze.** **Stability:** Ambient: **48 hours** Refrigerated: **48 hours** Frozen: **30 days** **Methodology: Immunofluorescence** **Reference Range: <187** ng/mL **Days Performed:** Mon, Thu 7:00 am **Reported:** 7 days	effective immediately
Cryptococcus Ag Detection	CAD	**Specimen Requirement:** 2 mL cerebrospinal fluid (CSF) in sterile container; Transport recommendations: Refrigerated: 72 hrs, Frozen; indefinitely. *OR* **1-2** mL serum from serum separator (Gold) tube; **Refrigerated; Serum should be separated from cells ASAP after collection by centrifuging.** Transport recommendations: Refrigerated: 72 hrs, Frozen; indefinitely.	effective immediately
Fungus Screen	FUNGSC	**Special Information:** The Fungal Screen is designed to detect rapidly growing yeast. For slower growing yeasts and molds, order a Fungal Culture (order code FCUL). If culture is positive, limited identification is performed from nonsterile sites. Full identification is performed from sterile sites with an additional charge. Identification CPT codes that may apply include: 87106, 87107, 87153. Antimicrobial susceptibilities are performed on sterile sites, and CPT code 87186 would apply. **Susceptibility testing on isolates recovered from non-sterile sites (ie. genital) must be separately requested when clinically needed. This can be requested by calling lab client services.**	effective immediately
Hepatitis E Virus (HEV) Antibodies, IgG and IgM	HEPE	**For interface clients only–Test build may need to be modified** **Name:** Previously Hepatitis E Virus IgG & IgM Abs **Special Information: This test is New York DOH approved.** **Clinical Information:** *clinical information has been removed* **Specimen Requirement:** 0.5 mL serum from serum separator (Gold) tube; **Refrigerated; Separate serum from cells within 2 hours of collection and transfer to standard aliquot tube.** *(continued on page 4)*	1/6/24

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Hepatitis E Virus (HEV) Antibodies, IgG and IgM *(continued from page 3)*		**Specimen Requirement (continued):** *OR* **0.5 mL plasma from EDTA (Lavender) tube; Refrigerated; Separate plasma from cells within 2 hours of collection and transfer to standard aliquot tube.** **Stability:** Ambient: **After separation from cells: Unacceptable** Refrigerated: **After separation from cells:** 2 weeks Frozen: **After separation from cells: Indefinitely (avoid repeated freeze/thaw cycles)** **Methodology: Qualitative Enzyme-linked Immunosorbent Assay** **Reference Range:** Hepatitis E IgG Abs: **Negative** Hepatitis E IgM Abs: **Negative** **Days Performed: Tue,** Thu**, Sat** **Reported: 2–6** days	
Mycoplasma pneumoniae PCR	MYCPCR	**Special Information: Specimen source required. Urine specimens will be rejected. This test is New York state approved.** **Clinical Information: This test is useful to detect M. pneumoniae bacteria.** **Specimen Requirement:** 2 mL sputum in sterile container; Frozen *OR* 1 mL cerebrospinal fluid (CSF) in sterile container; Frozen *OR* **respiratory swab in Viral Transport Media; Frozen** *OR* 2 mL pleural fluid in sterile container; Frozen *OR* 2 mL tracheal aspirate in sterile container; Frozen *OR* 2 mL bronch (BAL) in sterile container; Frozen *OR* 2 mL bronch brushing(s) in sterile container; Frozen **Stability:** Ambient: **24 hours** Refrigerated: 5 days Frozen: 1 year **Methodology: Qualitative Polymerase Chain Reaction** **Reported:** 2–**5** days	effective immediately
Phenytoin, Free	PHTFR	**Special Information:** Do not collect in a gel separator tube. Draw once steady state is achieved. **Usual sampling time varies dependent upon desired measurement of peak or trough.** **Clinical Limitation: Due to the observed cross-reactivity of the assay to fosphenytoin, it is recommended that samples for serum phenytoin measurements be collected at least 2 hours after an intravenous dose of fosphenytoin and at least 4 hours after an intramuscular dose.** **Clinical Information: Phenytoin is highly protein bound, and only the free (unbound) fraction is pharmacologically active. The free fraction may be increased, for instance, due to interaction with other highly protein-bound drugs, or in patients with albumin deficiency, anemia, uremia or with hepatic or renal insufficiency, resulting in an increased effect at the same total drug concentration as in plasma of normal patients. Monitoring the free phenytoin concentration can be useful in response to these altered disposition states, especially, in case the clinical picture of the patient does not correlate well with the total serum/plasma phenytoin concentration.** **Specimen Requirement:** 2 mL serum from no additive (Red) tube; Refrigerated; Do not collect in a gel separator tube. Centrifuge and transfer serum to a CCL tube and refrigerate. **Do not share tube with another test.** **Stability:** Ambient: After separation from cells: 7 days Refrigerated: After separation from cells: 7 days Frozen: After separation from cells: **16 weeks**	1/16/24
Warfarin Sensitivity (CYP2C9, CYP2C cluster, CYP4F2, VKORC1) Genotyping	WRFSEN	**Special Information:** Plasma, serum and frozen specimens in glass collection tubes will be rejected. Whole blood is the preferred specimen. This test is New York DOH approved. **Specimen Requirement:** 3 mL whole blood in EDTA (Lavender) tube; Refrigerated *OR* 3 mL whole blood in Acid Citric Dextrose (ACD) A or B (Yellow) tube; Refrigerated **Note:** *saliva specimen has been removed*	effective immediately

New Tests

Test Name	Order Code	Change	Effective Date
Allergen, Honey Bee Components IgE	HBEECP	**Note: New test was announced in the October update, but financial information was not available at that time** **CPT:** 86008x5	effective immediately
Allergen, Honey Bee IgE with Reflex to Components	HBEERF	**Note: New test was announced in the October update, but financial information was not available at that time** **CPT:** 86003	effective immediately
Allergen, Paper Wasp Component IgE	PWSPCP	**Note: New test was announced in the October update, but financial information was not available at that time** **CPT:** 86008	effective immediately
Allergen, Paper Wasp IgE with Reflex to Component	PWSPRF	**Note: New test was announced in the October update, but financial information was not available at that time** **CPT:** 86003	effective immediately
Allergen, Total Venom Panel IgE with Reflex to Components	VENOMS	**Note: New test was announced in the October update, but financial information was not available at that time** **CPT:** 86003x3	effective immediately
Allergen, Yellow Jacket (Common Wasp) Components IgE	YJAKCP	**Note: New test was announced in the October update, but financial information was not available at that time** **CPT:** 86008x2	effective immediately
Allergen, Yellow Jacket (Common Wasp) IgE with Reflex to Components	YJAKRF	**Note: New test was announced in the October update, but financial information was not available at that time** **CPT:** 86003	effective immediately
Ammonium, 24 hour, Urine	UNH424	**Note: New test was announced in the November update, but financial information was not available at that time** **CPT:** 82140	effective immediately
Ammonium, Random, Urine	UNH4RDM	**Note: New test was announced in the November update, but financial information was not available at that time** **CPT:** 82140	effective immediately
Asparaginase Enzyme Activity	ASNASE	**Note: New test was announced in the November update, but financial information was not available at that time** **CPT:** 82657	effective immediately
COVID & Influenza A/B & RSV NAAT, Routine	CVFLRS	**Note: New test was announced in the October update, but financial information was not available at that time** **CPT:** 87637	effective immediately
Drug Detection Panel, Umbilical Cord Tissue, with Marijuana Metabolite	DTOFMP	**Note: New test was announced in the November update, but financial information was not available at that time** **CPT:** 80326; 80347; 80364; 80355; 80349; Alt code G0481	effective immediately

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Methylphenidate and Metabolite, Urine, Quantitative	URTALN	**Includes:** Methylphenidate Ritalinic acid **Special Information:** This test is New York DOH approved. **Clinical Information:** This test is useful for general testing in contexts of compliance and/or abuse. **Specimen Requirement:** 2 mL random urine in clean container (No preservatives); Minimum 1 mL; Refrigerated **Stability:** Ambient: Unacceptable Refrigerated: 3 weeks Frozen: 3 months **Methodology:** Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) **Reference Range:** Methylphenidate, Urn, Quant: <10.0 ng/mL Ritalinic acid, Urn, Quant: <50.0 ng/mL **Days Performed:** Mon, Thu, Sat **Reported:** 2–8 days **CPT:** 80360; Alt code G0480	12/12/23
Mitragynine (Kratom), urine	UKRTOM	**Includes:** Kratom, Screen **Special Information:** If screen is positive, confirmation will be performed at additional cost. **Clinical Information:** This test is useful to detect presence of the kratom alkaloid mitragynine, a mood-altering opioid receptor agonist which has both stimulant and opioid effects. **Specimen Requirement:** 10 mL random urine in clean container (No preservatives); Minimum 1 mL; Frozen **Stability:** Ambient: 72 hours Refrigerated: 2 weeks Frozen: 6 months **Methodology:** Qualitative Immunoassay **Reference Range:** Negative **Days Performed:** Varies **Reported:** 7–10 days **CPT:** 80307	12/12/23