Cleveland Clinic

Cleveland Clinic Laboratories

Technical Update • September 2024

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 Laboratory Customer Service 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
2	17-Hydroxyprogesterone, Urine										■		
2	Antidepressant Panel, Urine (Quantitative)		■				■				■		
2	Baclofen						■				■	■	■
2	Bacterial Vaginosis NAAT		■					■					
2	Biotin (Vitamin B7)		■										
2	Candida/Trichomonas NAAT		■					■					
7	Celiac Gluten Free Panel				■								
6	Chitotriosidase Assay			■									
2	CO_2									■			
3	Cold Agglutinins					■							
3	Cyanide, Blood										■		
6	FLT3 ITD MRD Assay			■									
3	Fluvoxamine, Serum and Plasma										■		
3–4	Gonorrhea/Chlamydia NAAT		■			■		■					
6	HEX4, urine			■									
4	Melanocyte Stimulation Hormone, Alpha (a-MSH)						■				■		
4	Mycoplasma genitalium NAAT		■					■					
7	Oxysterols, Plasma			■									
4	Selenium Blood					■							
5	Sulfonylurea Hypoglycemics						■				■		■

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
5	Synthetic Glucocorticoid Screen, Urine					■		■			■	■	■
5	Syphilis Treponemal with reflex		■										
5	Trichomonas vaginalis NAAT		■			■		■					

Test Changes

Test Name	Order Code	Change	Effective Date
17-Hydroxyprogesterone, Urine	U17OHP	**Reported:** 8–**14** days	effective immediately
Antidepressant Panel, Urine (Quantitative)	UTCAQT	**Name:** Previously Antidepressant Panel Quantitative, Urine **Specimen Requirement:** 2 mL random urine from clean container; Refrigerated; Transfer 2 mL urine to standard aliquot tube. **Separate specimens must be submitted when multiple tests are ordered.** **Reported: 9–12** days	effective immediately
Baclofen	BACLOF	**Specimen Requirement:** 1 mL serum from no additive (Red) tube; Refrigerated; Do not use serum separator tubes. Separate serum from cells within 2 hours of collection and transfer into standard aliquot tube. **Separate specimens must be submitted when multiple tests are ordered.** *OR* 1 mL plasma from EDTA (Lavender); Refrigerated; Do not use separator tubes. Separate plasma from cells within 2 hours of collection and transfer into standard aliquot tube. **Separate specimens must be submitted when multiple tests are ordered.** **Stability:** Ambient: 2 weeks Refrigerated: 2 weeks Frozen: **4** months **Reported: 9–12** days **CPT:** 80369/**G0480**	effective immediately
Bacterial Vaginosis NAAT	BVAMP	**For interface clients only–Test build may need to be modified** **Name:** Previously Bacterial Vaginosis (BV), NAAT **Reference Range:** Bacterial vaginosis: Not detected	11/19/24
Biotin (Vitamin B7)	VITB7	**Name:** Previously Vitamin B7 (Biotin)	effective immediately
Candida/Trichomonas NAAT	CVTV	**For interface clients only–Test build may need to be modified** **Name:** Previously Candida & Trichomonas vaginalis, NAAT **Reference Range:** Candida species group **RNA**: Not detected Candida glabrata **RNA**: Not detected Trichomonas vaginalis **RNA**: Not detected	11/19/24
CO_2	CO2	**Reference Range:** 22–30 mmol/L **Critical: < 10 mmol/L**	9/12/24

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Cold Agglutinins	COLD	**Specimen Requirement:** 3 mL serum from no additive (Red) tube; Collection Ambient; **Transport Refrigerated; 1. Pre-warm tube(s) to 37°C in a water bath, incubator, or in a cup with heal warmers. 2. Immediately after collection, incubate the clotting blood for 90 minutes in a 37°C water bath, incubator, or in a cup with heel warmers. 3. Centrifuge tube(s) for 5 minutes at 3,000 rpm at room temperature 4. Remove the serum using a polystyrene transfer pipette and place into a labelled plastic tube. If needed repeat step 3 to remove extraneous red blood cells.**	10/15/24
Cyanide, Blood	CYANID	**Reported: 11–15** days	effective immediately
Fluvoxamine, Serum and Plasma	FLUVOX	**Specimen Requirement:** 1 mL serum from no additive (Red) tube; Refrigerated; Do not use serum separator tubes. Separate serum from cells ASAP or within 2 hours of collection and transfer to standard aliquot tube. Separate specimens must be submitted when multiple tests are ordered. *OR* 1 mL plasma from EDTA (Lavender); Refrigerated; Do not use plasma separator tubes. Separate plasma from cells ASAP or within 2 hours of collection and transfer to standard aliquot tube. Separate specimens must be submitted when multiple tests are ordered. **Reported: 9–12** days	effective immediately
Gonorrhea/Chlamydia NAAT	GCCT	**For interface clients only–Test build may need to be modified** **Name:** Previously Neisseria gonorrhoeae (GC) & Chlamydia trachomatis (CT), NAAT **Clinical Information:** Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (GC) infections are two of the most common sexually transmitted infections (STI) worldwide. CDC STI Treatment Guidelines include testing and screening recommendations for CT and GC and provide guidance on testing methodology and frequency, as well as specimen types for specific patient populations. The CDC recommends the use of nucleic acid amplification tests (NAATs) for the detection of CT and GC in patients with and without symptoms. The Aptima Combo 2 assay is an FDA-cleared second generation NAAT that utilizes target capture, Transcription-Mediated Amplification (TMA), and Dual Kinetic Assay (DKA) technologies. The Aptima Combo 2 assay on the Panther system qualitatively detects CT and/or GC rRNA in clinician-collected endocervical, PreservCyt Solution liquid Pap specimens, vaginal, throat, rectal, and male urethral swab specimens; patient-collected vaginal swab specimens, and female and male urine specimens from symptomatic and asymptomatic individuals. **The assay has been modified and additionally validated to accept rectal swabs self-collected by patients in a healthcare setting.** In 2019, novel C. trachomatis variants were discovered which contain point mutations affecting detection by the original version of the Aptima Combo 2 assay. Variant strains of chlamydia with mutations affecting diagnostic test performance have been reported previously and are a natural product of microbial evolution. The updated version of the Aptima Combo 2 assay provides detection coverage for the variant strains of C. trachomatis that emerged in 2019. **Specimen Requirement:** One endocervical APTIMA Collection Unisex swab; Ambient; Endocervical Unisex (white tube blue swab): Remove excess mucus from cervical os and surrounding mucosa using the white cleaning swab, then DISCARD. Insert blue swab into the endocervical canal and gently rotate clockwise for 10-30 seconds. Place swab into Aptima transport tube. Snap off swab at the score line, and close the tube tightly. *OR* One urethral APTIMA Collection Unisex swab; Ambient; Male Urethral Unisex (white tube blue swab): The patient should not have urinated for at least 1 hr prior to sample collection. Insert the blue swab 2-4 cm into the urethra. Gently rotate the swab clockwise for 2-3 seconds in the urethra. Place swab into Aptima transport tube. Snap off swab at the score line, and close the tube tightly. *OR* One vaginal Aptima Multitest Collection Kit; Ambient; Vaginal Multitest (orange tube pink swab): A vaginal swab is the recommended specimen for female patients who are clinically suspected of having a chlamydial or gonococcal infection. Carefully insert the swab into the vagina about 2 inches past the introitus and gently rotate the swab for 10-30 seconds. Make sure the swab touches the vaginal walls so that moisture is absorbed by the swab. Vaginal swab specimens may be patient-collected in a clinical setting when a pelvic exam is not otherwise indicated (https://www.hologic.com/package-inserts/swab-collection-instructions-vaginal-main-english#4257225834-454981651). *(continued on page 4)*	11/19/24

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Gonorrhea/Chlamydia NAAT *(continued from page 3)*	GCCT	**Specimen Requirement (continued):** Place swab into Aptima transport tube. Snap off swab at the score line, and close the tube tightly. *OR* One rectal Aptima Multitest Collection Kit; Ambient; Rectal Multitest (orange tube pink swab): Carefully insert the swab into the rectum about 1-2 inches past the anal margin and gently rotate the swab for about 5-10 seconds. Place swab into Aptima transport tube. Snap off swab at the score line, and close the tube tightly. *OR* One throat specimen in Aptima Multitest Collection Kit; Ambient; Throat Multitest (orange tube pink swab): Carefully insert swab into the throat ensuring contact with bilateral tonsils (if present) and the posterior pharyngeal wall, then withdraw the swab without touching the inside of the cheeks or tongue. Place swab into Aptima transport tube. Snap off swab at the score line, and close the tube tightly. *OR* 2 mL first-catch urine in APTIMA Urine specimen collection kit; Ambient; First-catch urine is the optimal specimen for screening asymptomatic male patients. Urine may also be used for testing any symptomatic patient, but vaginal specimens are preferred when available due to greater test sensitivity. The patient should not have urinated for at least 1 hour prior to specimen collection. The patient should collect first portion of random voided urine (first part of stream) into a sterile, plastic, preservative-free container. Transfer 2 mL of urine into the Aptima urine specimen transport tube using the disposable pipette provided within 24 hours of collection. Close the tube tightly. Work with one specimen at a time. The correct volume of urine has been added when the fluid level is between the black fill lines (window) on the urine transport tube. Do not overfill or underfill the APTIMA Urine transport tube. *OR* 2 mL first-catch urine in sterile container; Ambient; First-catch urine is the optimal specimen for screening asymptomatic male patients. Urine may also be used for testing any symptomatic patient, but vaginal specimens are preferred when available due to greater test sensitivity. The patient should not have urinated for at least 1 hour prior to specimen collection. The patient should collect first portion of random voided urine (first part of stream) into a sterile, plastic, preservative-free container. *OR* unspecified cervical specimen in Cytyc PreservCyt solution (Thin Prep); Ambient; PreservCyt Solution (ThinPrep) is an acceptable specimen when added onto a ThinPrep Pap Test and no dedicated vaginal or endocervical swab specimens are available. It is not a recommended due to lower test sensitivity compared to other specimen types. For this reason, it is not available as a selectable specimen source/type during order entry, only as a laboratory add-on. In order to place an order on this specimen type, you must place a call to lab client services. If consulted prior to specimen collection, lab client services should advise the provider to collect a separate dedicated Vaginal Multitest Swab for optimal test performance characteristics. If consulted after specimen collection, lab client services should assist the provider in placing an add on order with "Fluid, Cervix" as the specimen source, and have cytology perform the aliquot as below prior to cytology testing. Prior to cytology testing and within 30 days of collection, cytology will transfer a 1 mL aliquot into an APTIMA Specimen Transfer Tube. The specimen must have been stored at 2-30C. **Reference Range:** Neisseria gonorrhoeae **RNA**: Not detected Chlamydia trachomatis **RNA**: Not detected	11/19/24
Melanocyte Stimulation Hormone, Alpha (a-MSH)	MSHA	**Specimen Requirement:** 3 mL plasma from EDTA (Lavender) tube; Critical Frozen; Separate plasma from cells ASAP or within 2 hours of collection. **Transfer plasma to standard aliquot tube and** freeze immediately. Separate specimens must be submitted when multiple tests are ordered. **Reported: 2–3 weeks**	effective immediately
Mycoplasma genitalium NAAT	MYGAMP	**For interface clients only–Test build may need to be modified** **Name:** Previously Mycoplasma genitalium, NAAT **Reference Range:** Mycoplasma genitalium **RNA**: Not detected	11/19/24
Selenium Blood	SELEN	**Special Information: Specimen must be received in a certified metal free tube.** **Clinical Information: Selenium measurement in whole blood by ICP-MS is useful to assess selenium stores and mid- to long-term nutritional status.** **Specimen Requirement:** 2 mL whole blood in EDTA (Royal blue) tube; Refrigerated; **Send whole blood specimen in original tube. Do not aliquot.**	effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Sulfonylurea Hypoglycemics	SULFON	**Specimen Requirement:** 1 mL serum from no additive (Red) tube; Frozen; Do not use serum separator tubes. Separate serum from cells ASAP or within 2 hours of collection **and transfer to standard aliquot tube.** Separate specimens must be submitted when multiple tests are ordered. *OR* 1 mL plasma from potassium oxalate/sodium fluoride (Gray) tube; Frozen; Do not use plasma separator tubes. Separate plasma from cells ASAP or within 2 hours of collection **and transfer to standard aliquot tube.** Separate specimens must be submitted when multiple tests are ordered. **Reported: 9–12** days **CPT:** 80377/**G0480**	effective immediately
Synthetic Glucocorticoid Screen, Urine	UGLUCO	**For interface clients only–Test build may need to be modified** **Includes:** Betamethasone Budesonide Dexamethasone Fludrocortisone Megestrol acetate Methylprednisolone Prednisolone Prednisone Triamcinolone acetonide **Special Information: This test is New York State approved.** **Clinical Information: This test is useful for confirming the presence of the listed synthetic glucocorticoids and the cause of secondary adrenal insufficiency.** Cutoff Concentrations: Betamethasone: 0.10 mcg/dL; Budesonide: 0.10 mcg/dL; Dexamethasone: 0.10 mcg/dL; Fludrocortisone: 0.10 mcg/dL; Megestrol acetate: 0.10 mcg/dL; Methylprednisolone: 0.10 mcg/dL; Prednisolone: 0.10 mcg/dL; Prednisone: 0.10 mcg/dL; Triamcinolone acetonide: 0.10 mcg/dL. Lack of detection does not preclude use of synthetic glucocorticoid because adrenal suppression may persist for some time after the exogenous steroid is discontinued. This assay cannot detect all of the available synthetic steroids either available as pharmaceutical compounds or chemicals present in food. This assay confirms only the listed synthetic glucocorticoids. **Stability:** Ambient: **Unacceptable** Refrigerated: **Unacceptable** Frozen: 14 days **Reported: 6–12** days **CPT: 80299**	effective immediately
Syphilis Treponemal with reflex	SYPHTX	**Name:** Previously Syphilis Total with reflex	10/8/24
Trichomonas vaginalis NAAT	TRVAMP	**For interface clients only–Test build may need to be modified** **Name:** Previously Trichomonas vaginalis, NAAT **Special Information:** Microbiology Preanalytic Guidance: http://portals.ccf.org/plmi/Laboratory-Medicine/Microbiology-Specimen-Collection-Transport-Information. Up to two tests can be run on a single Aptima Multitest Swab specimen (ie. GCCT+TRVAMP)–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. Common reasons for specimen rejection: 1. Inappropriate collection device for source selected. 2. Transport tubes containing a cleaning swab or more than 1 swab. 3. Overfilled or underfilled urine transport tubes. 4. Collection device expired prior to specimen collection. **Reference Range:** Trichomonas vaginalis **RNA**: Not detected	11/19/24

New Tests

Test Name	Order Code	Change	Effective Date
Chitotriosidase Assay	CHITO	**Includes:** Ethnicity Patient History Family History Clinical Indication Chitotriosidase Interpretation Comments **Special Information:** Grossly hemolyzed or lipemic specimens will be rejected. Specimens must be received in performing laboratory within four days of collection. **Specimen Requirement:** 2 mL serum from serum separator (Gold) tube; Minimum 1 mL; Frozen; Separate serum from cells and transfer to standard aliquot tube. Must be received in performing laboratory within four days of collection. **Stability:** Ambient: Unacceptable Refrigerated: 4 days Frozen: 4 days **Methodology:** Fluorometric enzyme assay **Reference Range:** Chitotriosidase: 4–120 nmoles/hr/mL **Days Performed:** Varies **Reported:** 8–15 days	10/29/24
FLT3 ITD MRD Assay	F3IMRD	**Clinical Information:** This test is intended exclusively for follow-up testing of known FLT3 positive patients. **Specimen Requirement:** 3 mL whole blood in EDTA (Lavender) tube; Minimum: 1 mL; Refrigerated *OR* 1 mL bone marrow in EDTA (Lavender) tube; Minimum: 0.25 mL; Refrigerated *OR* 1 ug extracted DNA in sterile container; Refrigerated **Stability:** Ambient: Whole blood/Bone marrow: 72 hours; Extracted DNA: Acceptable Refrigerated: Whole blood/Bone marrow: 7 days; Extracted DNA: Acceptable Frozen: Whole blood/Bone marrow/Extracted DNA: Unacceptable **Methodology:** Next Gen Sequencing **Reported:** 8–11 days **CPT:** 0046U	10/24/24
HEX4, urine	UHEX4	**Special Information:** Fasting sample preferred. Send completed UHEX4 Patient Information Form with specimen. **Clinical Limitation:** Hex4 may be elevated in a number of pathological and physiological conditions and is not specific to Pompe disease. **Clinical Information:** This test is useful to monitor patients with Pompe disease (GSD II) on enzyme replacement therapy. It is also useful for the diagnosis of Pompe disease when performed in conjunction with the blood acid alpha glucosidase enzyme assay. The reported Hex4 value in this assay is a measure of Glc4. **Specimen Requirement:** 1 mL random urine in clean container; Minimum: 0.25 mL; Frozen; Fasting sample preferred. Send completed UHEX4 Patient Information Form with specimen. **Stability:** Ambient: 4 hours Refrigerated: 24 hours Frozen: Acceptable **Methodology:** Ultraperformance Liquid Chromatography-Tandem Mass Spectrometry (UPLC-MS/MS) **Days Performed:** Mon–Fri **Reported:** 15–16 days **CPT:** 82542; 82570	10/29/24

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Oxysterols, Plasma	OXSTRL	**Includes:** Cholestane-3beta,5alpha,6beta-triol 7-Ketocholesterol Lyso-sphingomyelin Interpretation **Special Information:** Chill specimen on ice and use refrigerated centrifuge (if possible) to separate plasma from cells. Without disturbing the buffy coat layer, transfer plasma to standard aliquot tube and freeze immediately. Separate specimens must be submitted when multiple tests are ordered. This test is New York State approved. **Clinical Limitation:** This test is not useful for the identification of carriers. Nonspecific neonatal cholestasis may result in elevations of cholestane-3-beta, 5-alpha, 6-beta-triol and lyso-sphingomyelin 509. **Clinical Information:** This test is useful for investigating a possible diagnosis of Niemann-Pick disease types A, B, or C using plasma specimens. It is also useful for monitoring individuals with Niemann-Pick type C disease. An elevation of cholestane-3-beta, 5-alpha, 6-beta-triol is highly suggestive of Niemann-Pick disease type C (NPC). An elevation of lyso-sphingomyelin (LSM) is highly suggestive of Niemann-Pick type A or B (NPA or NPB) disease. An elevation of LSM 509 is suggestive of NPA, NPB, or NPC disease. **Specimen Requirement:** 0.3 mL plasma from EDTA (Lavender) tube; Place specimen on ice after draw. Critical Frozen; Chill specimen on ice and use refrigerated centrifuge (if possible) to separate plasma from cells. Without disturbing the buffy coat layer, transfer plasma to standard aliquot tube and freeze immediately. Separate specimens must be submitted when multiple tests are ordered. *OR* 0.3 mL plasma from sodium or lithium heparin (Green) tube; Place specimen on ice after draw. Critical Frozen; Chill specimen on ice and use refrigerated centrifuge (if possible) to separate plasma from cells. Without disturbing the buffy coat layer, transfer plasma to standard aliquot tube and freeze immediately. Separate specimens must be submitted when multiple tests are ordered. *OR* 0.3 mL plasma from acid citrate dextrose (ACD) B (Yellow) tube; Place specimen on ice after draw. Critical Frozen; Chill specimen on ice and use refrigerated centrifuge (if possible) to separate plasma from cells. Without disturbing the buffy coat layer, transfer plasma to standard aliquot tube and freeze immediately. Separate specimens must be submitted when multiple tests are ordered. **Stability:** Ambient: Unacceptable Refrigerated: Unacceptable Frozen: After separation from cells: 65 days **Methodology:** Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) Precipitation **Reference Range:** Cholestane-3beta-5alpha,6beta-triol: Cutoff: </= 0.070 nmol/mL 7-Ketocholesterol: Cutoff: </= 0.100 nmol/mL Lyso-sphingomyelin: Cutoff: </= 0.100 nmol/mL **Days Performed:** Tue, Thu **Reported:** 4–8 days **CPT:** 82542	10/29/24

Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
Celiac Gluten Free Panel	CELGLU	Test will no longer be orderable. Recommended replacement test is Celiac Associated HLA-DQ genotyping (CELIA).	10/15/24