



Cleveland Clinic Laboratories

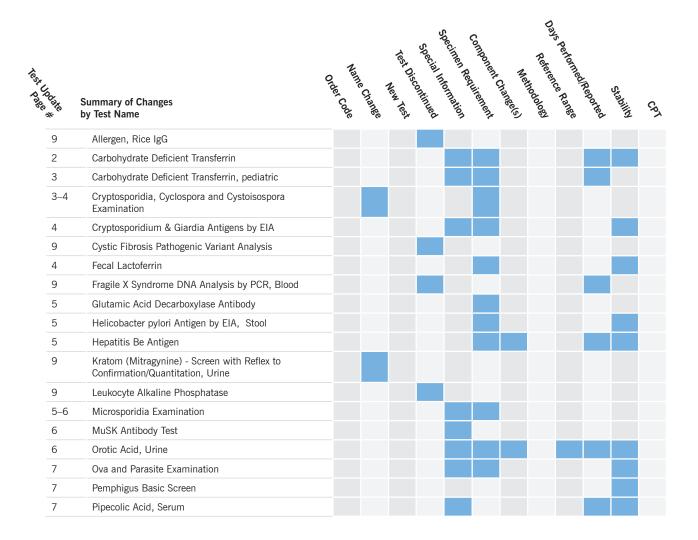
Technical Update • January 2024

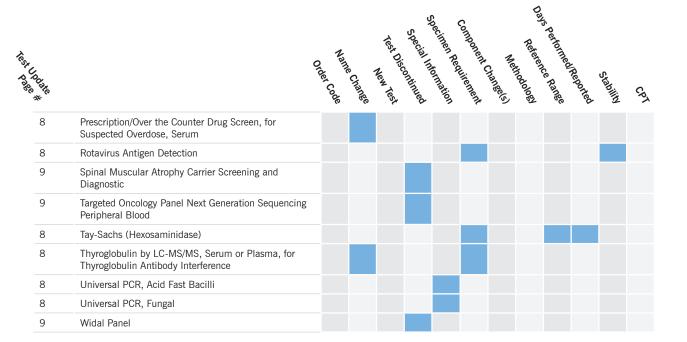
Cleveland Clinic Laboratories is dedicated to keeping you updated and informed about recent testing changes. This Technical Update is provided on a monthly basis to notify you of any changes to the tests in our catalog.

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 Client Services at 216.444.5755 or 800.628.6816, or via email at clientservices@ccf.org.





Test Changes

Carbohydrate Deficient Transferrin	CDTRAN	Includes: Mono-oligo/Di-oligo Ratio Interpretation Special Information: Patient should be greater than or equal to 21 years of age.	effective immediately
		Patient age is required. This test is New York DOH approved.	
		Specimen Requirement: 0.1 mL serum from serum separator (Gold) tube; Minimum 0.05 mL; Frozen *OR* 0.1 mL serum from no additive (Red) tube; Minimum 0.05 mL	
		Stability: Ambient: 7 days Refrigerated: 28 days Frozen: 45 days	
		Days Performed: Wed	
		Reported: 8–11 days	

Test Name	Order Code	Change	Effective Date
Carbohydrate Deficient Transferrin, pediatric	CDTRAP	Includes: Mono-oligo/Di-oligo Ratio A-oligo/Di-oligo Ratio Tri-sialo/Di-oligo Ratio Apo CIII-1/Apo CIII-2 Ratio Apo CIII-0/Apo CIII-2 Ratio Interpretation Special Information: Patient's age and reason for referral are required. Must submit Biochemical Genetics Patient Information form with the specimen. Grossly hemolyzed specimens will be rejected. This test is New York State approved. Clinical Information: This test is for congenital disorders of glycosylation. If looking for evaluation of alcohol abuse, please order Carbohydrate Deficient Transferrin (CDTRAN). Other conditions such as heredity fructose intolerance, galactosemia, and liver disease may result in increased levels of carbohydrate deficient transferrin. Specimen Requirement: 0.1 mL serum from serum separator (Gold) tube; Frozen; Must submit Biochemical Genetics Patient Information form with the specimen. Patient age is required. Centrifuge and transfer serum into standard plastic aliquot tube. *OR* 0.1 mL serum from no additive (Red) tube; Frozen; Must submit Biochemical Genetics Patient Information form with the specimen. Patient age is required. Centrifuge and transfer serum into standard plastic aliquot tube. Reported: 4–7 days	effective immediately
Cryptosporidia, Cyclospora and Cystoisospora Examination	CRYSPO	Name: Previously Cryptosporidia Examination Special Information: Recommend sending a complete STUL kit for submission of all outpatient specimens for any additional add-on testing. Clinical Limitation: Due to intermittent shedding of parasites a single negative test does not rule out a parasitic infection. Recommend testing 3 different stool specimens collected in separate containers on different days (over 5-7 days), preferably at different times of day. This test does not detect other common infectious parasites that cause diarrhea; consider ordering OVAP (other parasites) and MICSPO (for microsporidia). The gastrointestinal pathogen panel (STGIPI) is a molecular test that can also be performed to detect Cryptosporidium and Cyclospora along with other common infectious causes of persistent diarrhea. Clinical Information: Cryptosporidia, Cyclospora and Cystoisospora are protozoan parasites that cause infection in the intestinal tract resulting in diarrhea amongst other symptoms such as abdominal pain, weight loss. Infections can be self limited but can also cause prolonged infection depending on the exposure, age and immune compromise of the host. Transmission is via ingestion of fecally contaminated food or water. Waterborne transmission through swimming pools is a common route for exposure in outbreaks of Cryptosporidiosis. Due to the small size (Cryptosporidium and Cyclospora) and inability to be stained by trichrome stain, a modified acid-fast stain is required to detect these organisms. Specimen Requirement: stool in EcoFix fixative complete to fill line; Minimum 5 mL; Refrigerated; Ecofix available in a STUL kit; submit stool using a STUL kit at refrigerated conditions. STUL kit can be purchased via oracle #1570140. Refer to Stool collection guide (https://clevelandcliniclabs.com/our-laboratories/ laboratory-medicine/microbiology/plmi-collection-guidelines-resources/stool-specimen-collection-guidel) *OR* O.S mL-10 mL body fluid in sterile container; Refrigerated; Body fluids (including but not limit	2/13/24

Test Name	Order Code	Change	Effective Date
Cryptosporidia, Cyclospora and Cystoisospora Examination (continued from page 3)	CRYSPO	Stability: Ambient: Stool—Preserved: 2 months; Unpreserved: Preferred within 6 hours, acceptable within 12 hours. Body fluids—72hours Refrigerated: Stool—Preserved: 2 months; Unpreserved: Preferred within 6 hours, acceptable within 12 hours. Body fluids—72hours Frozen: Stool and body fluids—Unacceptable Days Performed: Mon—Fri 7:00 am—3:30 pm	2/13/24
Cryptosporidium & Giardia Antigens by EIA	OVAPSC	Includes: Confirmation of all Cryptosporidium positive EIA, by microscopy with a modified acid-fast stain (CRYSPO). Additional charges for reflex testing apply. Special Information: Recommend sending a complete STUL kit for submission of all outpatient specimens. Clinical Limitation: Clinical correlation of assay results is suggested. Multiple specimens over several days can increase sensitivity of detection. Rapid immunochromatographic assays can generate false-positive results and confirmation with microscopy is recommended. Interfering substances include barium, bismuth, metamucil, castor oil, mineral oil, or antiamoebic drugs within one week prior to specimen collection can give false negative results. Excessively bloody and mucoid samples can yield false positive results. Clinical Information: Cryptosporidium and Giardia are the most common causes of parasitic intestinal disease. Acute disease is characterized by watery diarrhea, abdominal cramps etc. Cryptosporidium has also been implicated in several waterborne outbreaks. Chronic or asymptomatic infections can also occur. Prevalence of these parasites can vary among geographic areas and populations. A higher prevalence is seen in children and immunosuppressed population. Specimen Requirement: stool in C/S/Cary Blair complete to fill line; Minimum 5 mL; Collect Refrigerated; Transport Refrigerated; CaS/Cairy Blair and Ecofix available in a STUL kit; submit stool using a STUL kit at refrigerated conditions. STUL kit can be purchased via oracle #1570140. Refer to Stool collection guide (https://clevelandcliniclabs.com/our-laboratories/laboratory-medicine/microbiology/plmi-collection-guidelines-resources/stool-specimen-collection-guidelines-resources/stool-specimen-collection-guidelines-resources/stool-specimen-collection-guidelines-resources/stool-specimen-collection-guidelines-resources/stool-specimen-collection-guidelines-resources/stool-specimen-collection-guidelines-resources/stool-specimen-collection-guidelines-resources/stool-specimen-collection-gui	2/13/24
Fecal Lactoferrin	FECWBC	Specimen Requirement: 1 mL stool in sterile container; Refrigerated; Send specimen to Cleveland Clinic Microbiology Laboratory. Stability: Ambient: 2 weeks Refrigerated: 2 weeks Frozen: 2 weeks	2/13/24

Test Name	Order Code	Change	Effective Date
Glutamic Acid Decarboxylase Antibody	GADCAB	Specimen Requirement: 1 mL serum from serum separator (Gold) tube; Refrigerated *OR* 1 mL serum from no additive (Red) tube; Refrigerated	2/13/24
Helicobacter pylori Antigen by EIA, Stool	HPYLAG	Specimen Requirement: 0.1 mL stool in sterile container; Refrigerated; Non-preserved stool is the only acceptable specimen. Both solid and liquid stools can be tested. Transport promptly to Microbiology. Refrigerated transport is preferred. Alternatively stool can be frozen if delays in transport >72hrs are anticipated. Stability: Ambient: Unacceptable Refrigerated: 72 hours Frozen: Until tested	2/13/24
Hepatitis Be Antigen	HBEAG	For interface clients only–Test build may need to be modified Specimen Requirement: 1 mL serum from serum separator (Gold) tube; Refrigerated *OR* 1 mL serum from no additive (Red) tube; Refrigerated *OR* 1 mL plasma from EDTA (Lavender) tube; Refrigerated; Separate plasma from cells within 2 hours of collection. *OR* 1 mL plasma from lithium heparin plasma separator (Light Green) tube; Refrigerated *OR* 1 mL plasma from sodium heparin (Green) tube; Refrigerated *OR* 1 mL plasma from sodium citrate (Light Blue) tube; Refrigerated Stability: Ambient: 24 hours Refrigerated: 7 days Frozen: 3 months Days Performed: Mon–Fri 7:00 am–3:30 pm	2/13/24
Microsporidia	MICSPO	Special Information: Recommend sending a complete STUL kit for submission of	2/13/24
Examination		all outpatient specimens for any additional add-on testing. Clinical Limitation: Due to intermittent shedding of parasites a single negative test does not rule out a parasitic infection. Recommend testing 3 different stool specimens collected in separate containers on different days (over 5-7 days), preferably at different times of day. Due to the small size of the microsporidium spores and low organism burden diagnosis by microscopy can be challenging. Molecular detection can offer improved sensitivity and speciicity and is available using the gastrointestinal pathogen panel (STGIPI) which also detects other common infectious causes of persistent diarrhea. This test does not detect other common infectious parasites that cause diarrhea; consider ordering OVAP (other parasites) and CRYSPO (for Cryptosporidia, Cyclospora and Cystoisospora). Clinical Information: Microsporidia are considered obligate intracellular parasites that have since been classified within fungi. Transmission routes include ingestion, inhalation or direct inoculation of infective spores. Immunocompromised population specifically patients with AIDS or history of transplant. Infections in immunocompetent individuals have also been reported. Clinical manifestations of microsporidiosis is diverse and can vary with the causal species. Enterocytozoon bieneusi and Encephalitozoon intestinalis are the most common microsporidian species infecting humans and cause gastrointestinal symptoms including diarrhea, fever, malaise and weight loss. Infections in extraintestinal sites is possible and dissemination of infection to other sites have been reported. Microscopy is unable to differentiate and provide a species level identification. Specimen Requirement: stool in EcoFix fixative complete to fill line; Minimum 5 mL; Refrigerated; Ecofix available in a STUL kit; submit stool using a STUL kit at refrigerated conditions. STUL kit can be purchased via oracle #1570140. Refer to Stool collection guide (https://clevelandcliniclabs.com/our-laboratories/labo	

Test Name	Order Code	Change	Effective Date
Microsporidia Examination (continued from page 5)	MICSPO	Use of non-standard (eg. food containers) is discouraged. Refer to Stool collection guide (https://clevelandcliniclabs.com/our-laboratories/laboratory-medicine/microbiology/plmi-collection-guidelines-resources/stool-specimen-collection-guide/) *OR* stool in 10% formalin complete to fill line; Minimum 5 mL; Refrigerated *OR* stool in SAF complete to fill line; Minimum 5 mL; Refrigerated Stability: Ambient: Stool-Preserved: 2 months; Unpreserved: Preferred within 6 hours, acceptable within 12 hours. Body fluids-72hours Refrigerated: Stool-Preserved: 2 months; Unpreserved: Preferred within 6 hours, acceptable within 12 hours. Body fluids-72hours Frozen: Stool and body fluids-Unacceptable Methodology: Microscopy Days Performed: Mon-Fri 7:00 am-3:30 pm Reported: 1-7 days	2/13/24
MuSK Antibody Test	MUSK	Special Information: This test is New York State approved.	effective immediately
Orotic Acid, Urine	UOROTC	For interface clients only—Test build may need to be modified Clinical Information: The intended use of the urinary orotic acid test is to identify elevations of orotic acid in patients with folate malabsorption or hereditary orotic aciduria (uridine-5'- monophosphate synthase deficiency), and to aid in the differential diagnosis of hyperammonemia and urea cycle defects. Elevated excretion of orotic acid also has been observed in patients with Reye syndrome and patients receiving treatment with allopurinol or 6-azauridine. Orotic acid is an intermediate in the pyrimidine de novo synthetic pathway. Conditions such as urea cycle defects produce orotic aciduria by increasing the availability of its precursor, carbamylphosphate, resulting in increased production of orotic acid. Assessment of urinary orotic acid can aid in differentiating between ornithine transcarbamylase deficiency (elevated orotic acid) and carbamylphosphate synthetase deficiency (no elevation). Elevated orotic acid may be observed in other conditions with hyperammonemia-homocitrullinuria syndrome. Deficient activity of uridine-5'-monophosphate synthase produces orotic aciduria by preventing the conversion of orotic acid to orotidine-5'-monophosphate. Patients with this condition have megaloblastic anemia and orotic acid crystalluria. Folate malabsorption may be primary or can be secondary to celiac disease, treatment with some medications, or heavy alcohol use. Specimen Requirement: 3 mL first catch urine in clean container; Minimum 0.5 mL; CRITICAL FROZEN. Specimen must be stored refrigerated until frozen. Transfer 2 mL urine to a standard aliquot tube and freeze immediately. Separate specimens must be submitted when multiple tests are ordered. *OR* 3 mL random urine in clean container; Minimum 0.5 mL; CRITICAL FROZEN. Specimen must be stored refrigerated until frozen. Transfer 2 mL urine to a standard aliquot tube and freeze immediately. Separate specimens must be submitted when multiple tests are ordered. Stability: Ambient: Unacceptable	2/22/24

Test Name	Order Code	Change	Effective Date
Ova and Parasite Examination	OVAP	Special Information: Recommend sending a complete STUL kit for submission of all outpatient specimens for any additional add-on testing. Clinical Limitation: Due to intermittent shedding of parasites a single negative test does not rule out a parasitic infection. Recommend testing 3 different stool specimens collected in separate containers on different days (over 5-7 days), preferably at different times of day. Staining procedures used in this test can not identify Cryptosporidium, Cyclospora and Cystoisospora (order CRYSPO), and microsporidia (order MICSPO). Presence of specific parasites are not indicative of active infection or causative agent of symptoms; clinical correlation needed. Clinical Information: This test can identify a variety of different parasites—protozoa and helminths. Infections by some parasites can be asymptomatic but can also cause gastrointestinal symptoms such as diarrhea, abdominal pain etc. Parasitic infections are not currently common within the United States and exposure, travel history to locations with poor sanitation are indicators for an ova and parasite examination. Within the United States Cryptosporidium and Giardia are the most common parasitic agents and OVAPSC is the test of choice in individuals with no international travel history or risk of exposure to unsanitary conditions. Disseminated parasitic infections to extraintestinal sites is possible and can present asymptomatically or with symptoms including but not limited to cough, fever, bloody sputum, skin lesions. Specimen Requirement: 0.5 mL-10 mL body fluid in sterile container; Collect Refrigerated; Transport Refrigerated; Body fluids (including but not limited to Gl aspirates, respiratory secretions, CSF) should be submitted to the lab in a securely tightened sterile screw-top container. A minimum volume of 0.5ml needed, however larger volumes are concentrated to increase sensitivity of detection. For urine specimens, a CA+hour urine specimen collection is preferred for identification of Schistosoma. For CSF spe	2/13/24
Pemphigus Basic Screen	PEMGUS	Stability: Ambient: 5 days Refrigerated: 5 days Frozen: 1 year (Avoid repeated freeze/thaw cycles)	effective immediately
Pipecolic Acid, Serum	PIPE	Special Information: This test is New York DOH approved. Stability: Ambient: Unacceptable Refrigerated: 14 days Frozen: 94 days Days Performed: Thu Reported: 3–10 days	effective immediately

Test Name	Order Code	Change	Effective Date
Prescription/Over the Counter Drug Screen, for Suspected Overdose, Serum	BDRUG	Name: Previously Drug Screen, Blood	2/15/24
Rotavirus Antigen Detection	EROTA	Specimen Requirement: 50 uL stool in sterile container; Refrigerated; Specimens collected using preservatives or transport media will be rejected. Refrigerated transport is preferred. Alternatively stool can be frozen if delays in transport > 72hrs are anticipated. Stability: Ambient: Unacceptable Refrigerated: 72 hours Frozen: Until tested	2/13/24
Tay-Sachs (Hexosaminidase)	нех	Specimen Requirement: 1 mL serum from serum separator (Gold) tube; Frozen; Patient must fast for 4 hours prior to collection. *OR* 1 mL serum from no additive (Red) tube; Frozen; Patient must fast for 4 hours prior to collection. Reference Range: Normal: 1.23–2.59 U/L Indeterminate: 1.16-1.22 U/L Carrier: 0.58-1.15 U/L Days Performed: Monthly Reported: 30–45 days	effective immediately
Thyroglobulin by LC-MS/MS, Serum or Plasma, for Thyroglobulin Antibody Interference	TGMSMS	Name: Previously LC-MS/MS Thyroglobulin measurement for Thyroglobulin Antibody Interference Specimen Requirement: 1.5 mL serum from serum separator (Gold) tube; Refrigerated; Separate from cells and transfer into standard aliquot tube. *OR* 1.5 mL plasma from sodium or lithium heparin (Green) tube; Refrigerated; Separate from cells and transfer into standard aliquot tube.*OR* 1.5 mL plasma from EDTA (Lavender) tube; Refrigerated; Separate from cells and transfer into standard aliquot tube. *OR* 1.5 mL blood from no additive (Red) tube; No special collection requirements;Transport Refrigerated; Separate from cells and transfer into standard aliquot tube.	effective immediately
Universal PCR, Acid Fast Bacilli	AFBPCR	Special Information: ICD9/Diagnosis codes preferred, but not required. If tissue specimen is held at any condition other than frozen as described in the stability section, add a note to the test order so that the appropriate disclaimer can be added. Swabs, direct blood, serum, plasma, and stool specimens will be rejected. Tissues floating in excess formalin will be rejected.	effective immediately
Universal PCR, Fungal	FUNPCR	Special Information: ICD9/Diagnosis codes preferred, but not required. If tissue specimen is held at any condition other than frozen as described in the stability section, add a note to the test order so that the appropriate disclaimer can be added. Swabs, direct blood, serum, plasma, stool, upper respiratory, and genitourinary specimens will be rejected. Tissues floating in excess formalin will be rejected.	effective immediately

New Tests

Test Name	Order Code	Change	Effective Date
Kratom (Mitragynine) – Screen with Reflex to Confirmation/ Quantitation, Urine	UKRTOM	Name: New test was previously announced in the December 2023 update as Mitragynine (Kratom), urine	effective immediately

Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
Allergen, Rice IgG	RICIGG	Test will no longer be orderable. Recommended replacement test is Allergen, Rice IgE (RICE).	1/22/24
Cystic Fibrosis Pathogenic Variant Analysis	CFMDX	Test will no longer be orderable. There is no recommended replacement.	effective immediately
Fragile X Syndrome DNA Analysis by PCR, Blood	FRAX	Test will no longer be orderable. There is no recommended replacement.	effective immediately
Leukocyte Alkaline Phosphatase	LAPSN	Test will no longer be orderable. Recommended replacement test is BCR/ABL1 p210 and p190 Diagnostic PCR Blood (BCRPB1).	2/13/24
Spinal Muscular Atrophy Carrier Screening and Diagnostic	SMAGEN	Test will no longer be orderable. There is no recommended replacement.	effective immediately
Targeted Oncology Panel Next Generation Sequencing Peripheral Blood	TOPPB	Test will no longer be orderable.	effective immediately
Widal Panel	SALM	Test will no longer be orderable.	2/13/24