



Cleveland Clinic Laboratories

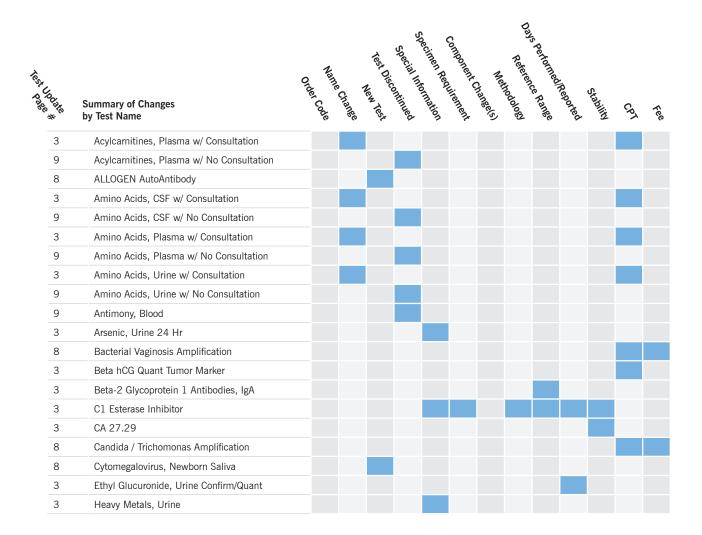
Technical Update • November 2021

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.



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Summary of Changes by Test Name

Standard Reported Name Change Hame Change Hame Change Hame Change Hame Change Hame Change Hame Code Other Code

4	Heavy Metals with Cadmium, Ur							
4	Helicobacter pylori Ab, IgG							
4	Helicobacter pylori Antibodies, IgG and IgA							
5	HIV-1 Integrase Genotype							
5	IDH1/IDH2 Mutation, Blood/Bone marrow							
5	IgVH Mutation Analysis							
5	Iron Stain							
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9	Microscopic Examination for Ehrlichia and Anaplasma							
5	Monoclonal Protein, 24 Hour Urine							
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9	Myeloma Cells, Blood							
5	Neuron Specific Enolase, CSF							
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6	Olanzapine							
6	Organic Acids Ur, Quant w/ Consultation							
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9	Porphyrin Screen, Urine 24 Hour							
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6	Protein Electrophoresis, Ur 24 Hr w/M Protein Quant							
6	Protein Electrophoresis, Urine Random							
6	Protein Electrophoresis, Urine, with IFE							
6	Pyruvic Acid							
9	Rett Syndrome (MECP2), Full Gene Analysis							
6	Serotonin Release Assay (SRA) LMWH							
7	Thiocyanate							
9	Trypanosoma cruzi Antibody, IgM							
7	Vitamin D, 1,25-Dihydroxy							

Test Changes

Test Name	Order Code	Change	Effective Date
Acylcarnitines, Plasma w/ Consultation	ACYLBI	Test Name: Previously Acylcarnitines, Plasma w/ Basic Consultation Note: Professional billing for consultation will be removed	12/14/21
Amino Acids, CSF w/ Consultation	CAABI	Test Name: Previously Amino Acids, CSF w/ Basic Consultation Note: Professional billing for consultation will be removed	12/14/21
Amino Acids, Plasma w/ Consultation	PAABI	Test Name: Previously Amino Acids, Plasma w/ Basic Consultation Note: Professional billing for consultation will be removed	12/14/21
Amino Acids, Urine w/ Consultation	UAABI	Test Name: Previously Amino Acids, Urine w/ Basic Consultation Note: Professional billing for consultation will be removed	12/14/21
Arsenic, Urine 24 Hr	UARSND	Clinical Information: Preferred test for the assessment of acute or chronic arsenic exposure. If total arsenic concentration is between 35–2000 ug/L, then Arsenic, Fractionated, will be added to determine the proportion of organic, inorganic, and methylated forms. Additional charges apply. The ACGIH Biological Exposure Index is 35 ug/L, for the sum of the inorganic and methylated forms of arsenic. If low-level chronic poisoning is suspected, the ug/gCRT ratio may be more sensitive than the total arsenic concentration. For specimens with elevated total arsenic results, fractionation is automatically performed at additional cost to determine the proportions of inorganic, methylated and organic species.	11/15/21
Beta hCG Quant Tumor Marker	BHCG	CPT: 84702	effective immediately
Beta-2 Glycoprotein 1 Antibodies, IgA	BETAA	Reference Range: Less than or equal to 20 SAU	11/15/21
C1 Esterase Inhibitor	C1EST	Special Information: Grossly hemolyzed or lipemic specimens will be rejected. Specimen Requirement: 1 mL serum from a Serum Separator (Gold) tube; Refrigerated; Separate serum from cells within 2 hours of collection; Minimum: 0.5 mL Stability: Ambient: Unacceptable Refrigerated: 2 weeks Frozen: 1 month Methodology: Turbidimetry (TURB) Reference Range: 21–38 mg/dL Days Performed: Sun–Sat	11/15/21
CA 27.29	CA2729	Stability: Ambient: 24 hours Refrigerated: 30 days Frozen: 30 days	11/2/21
Ethyl Glucuronide, Urine Confirm/Quant	UEGQNT	Days Performed: Sun, Tue-Sat Reported: 2-8 days	11/15/21
Heavy Metals, Urine	UTXM3	Clinical Information: Useful in the assessment of acute and chronic exposure to arsenic, mercury and lead. Quantification of urine excretion rates before or after chelation therapy has been used as an indicator of lead exposure. Urinary excretion of $>125~{\rm mg}$ of lead per 24 hours is usually associated with related evidence of lead toxicity. Urinary mercury levels predominantly reflect acute or chronic elemental or inorganic mercury exposure. Urine concentrations in unexposed individuals are typically less than $10~\mu g/L$. 24 hour urine concentrations of 30 to $100~\mu g/L$ may be associated with subclinical neuropsychiatric symptoms and tremor while concentrations greater than $100~\mu g/L$ can be associated with overt neuropsychiatric disturbances and tremors. Urine mercury levels may be useful in monitoring chelation therapy. The ACGIH Biological Exposure Index (BEI) for arsenic in urine is $35~\mu g/L$. The ACGIH BEI is based on the sum of inorganic and methylated species. For specimens with elevated total arsenic results, fractionation is automatically performed at additional cost to determine the proportions of inorganic, methylated and organic species.	11/15/21

Test Name	Order Code	Change	Effective Date
Heavy Metals with Cadmium, Ur	UTXM4	Clinical Information: Useful in the assessment of acute and chronic exposure to arsenic, cadmium, mercury, and lead. Urine cadmium levels can be used to assess cadmium body burden. In chronic exposures, the kidneys are the primary target organ. Symptoms associated with cadmium toxicity vary based upon route of exposure and may include tubular proteinuria, fever, headache, dyspnea, chest pain, conjunctivitis, rhinitis, sore throat and cough. Ingestion of cadmium in high concentration may cause vomiting, diarrhea, salivation, cramps, and abdominal pain. Quantification of urine excretion rates before or after chelation therapy has been used as an indicator of lead exposure. Urinary excretion of >125 mg of lead per 24 hours is usually associated with related evidence of lead toxicity. Urinary mercury levels predominantly reflect acute or chronic elemental or inorganic mercury exposure. Urine concentrations in unexposed individuals are typically less than $10~\mu g/L$. 24 hour urine concentrations of 30 to $100~\mu g/L$ may be associated with subclinical neuropsychiatric symptoms and tremor while concentrations greater than $100~\mu g/L$ can be associated with overt neuropsychiatric disturbances and tremors. Urine mercury levels may be useful in monitoring chelation therapy. The ACGIH Biological Exposure Index (BEI) for arsenic in urine is $35~\mu g/L$. The ACGIH BEI is based on the sum of inorganic and methylated species. For specimens with elevated total arsenic results , fractionation is automatically performed at additional cost to determine the proportions of inorganic, methylated and organic species.	11/15/21
Helicobacter pylori Ab, IgG	HPYLRI	For Interfaced Clients Only: Test build may need to be modified Includes: H. pylori IgG, Qual Note: Helicobacter pylori Ab, IgG will be removed Special Information: Samples may be frozen-thawed 5 times. Clinical Limitation: Grossly hemolyzed samples, lipemic samples, and samples containing particulate matter or exhibiting obvious microbial contamination will be rejected. Bacterial contamination of samples may affect the test results. Do not heat inactivate serum. Heterophilic antibodies in human serum can react with reagent immunoglobulins, interfering with in vitro immunoassays. Patients routinely exposed to animals or to animal serum products can be prone to this interference and anomalous values may be observed. The assay has not been evaluated in a pediatric population. Stability: Ambient: 24 hours Refrigerated: 8 days Frozen: 14 days Methodology: Chemiluminescence Immunoassay (CLIA) Reported: 1–4 days	12/7/21
Helicobacter pylori Antibodies, IgG and IgA	HPYGA	For Interfaced Clients Only: Test build may need to be modified Includes: Note: Helicobacter pylori Ab, IgG will be removed Special Information: FOR H.PYLORI IgA: Grossly hemolyzed or lipemic serum should be avoided. Microbially contaminated, heat treated, or specimens containing visible particulate should not be used. FOR H.PYLORI IgG: Patients with equivocal results should have a second sample collected within a reasonable time (eg: one week) Clinical Limitation: FOR H.PYLORI IgA: This assay has not been established for patients under the age of 18. Negative results may be obtained if specimens are drawn too early in the infection. If H.pylori is suspected, new samples should be obtained 4-6 weeks later. FOR H.PYLORI IgG: Grossly hemolyzed samples, lipemic samples, and samples containing particulate matter or exhibiting obvious microbial contamination will be rejected. Bacterial contamination of samples may affect the test results. Do not heat inactivate serum. Heterophilic antibodies in human serum can react with reagent immunoglobulins, interfering with in vitro immunoassays. Patients routinely exposed to animals or to animal serum products can be prone to this interference and anomalous values may be observed. The assay has not been evaluated in a pediatric population. Methodology: Chemiluminescence Immunoassay (CLIA)	12/7/21

Test Name	Order Code	Change	Effective Date
HIV-1 Integrase Genotype	HIVIGT	For Interfaced Clients Only: Test build may need to be modified Includes: Value of Last Viral Load (VILOAD) Date Viral Load Collected (VILODA) Raltegravir Resistance (RALRES) Elvitegravir Resistance (EVGRES) Dolutegravir Resistance (DTGRES) Bictegravir Resistance (BICRES) Cabotegravir Resistance (CABRES)	12/20/21
IDH1/IDH2 Mutation, Blood/Bone marrow	IDH12	Special Information: Plasma, serum, FFPE tissue blocks/slides, or frozen tissue, or extracted DNA will be rejected. Specimens collected in anticoagulants other than EDTA or sodium heparin are unacceptable. Clotted or grossly hemolyzed specimens will be rejected. This test is New York DOH approved. Specimen Requirement: Note: Extracted DNA is no longer acceptable. Stability: Ambient: Blood, bone marrow: 24 hours Refrigerated: Blood, bone marrow: 5 days Frozen: Blood, bone marrow: Unacceptable	11/15/21
IgVH Mutation Analysis	IGVH	Special Information: This assay is designed for individuals with a confirmed diagnosis of CLL, and for these individuals testing will include sequencing at an additional cost. All other diagnoses will terminate after amplification and will not have the sequencing component. Refrigerated specimens should be received at the performing lab within 48 hours of collection for optimal viability. This test is New York DOH approved. Reported: 9–13 days	11/15/21
Iron Stain	FESTMS	Specimen Requirement: 1–2 mL Bronch (BAL) in sterile container; Minimum 0.5 mL; Ambient; Send enough specimen to make 3 smears on glass slides. Label specimen with patient's name, patient number, time and date of collection. Note: Blood is no longer acceptable.	11/9/21
Kleihauer Betke Stain	HBFSTN	Stability: Ambient: Sample must be received within 30 Hours of collection Refrigerated: Sample must be received within 30 Hours of collection Frozen: Frozen samples are not acceptable for this test and will be rejected. Days Performed: Sun–Sat 24 hours	12/22/21
Lactate/Pyruvate	LACPYR	Reference Range: Pyruvate (PYRU) 0.03–0.10 mmol/L	effective immediately
Monoclonal Protein, 24 Hour Urine	U24MPA	Specimen Requirement: 15 mL 24-hour (well-mixed) Urine in clean container; Refrigerate during collection; Refrigerated; Minimum: 7 mL	12/7/21
Monoclonal Protein, Urine	URMPA	Specimen Requirement: 15 mL Random Urine in clean container; Refrigerated; Minimum: 7 mL	12/7/21
Neuron Specific Enolase, CSF	CNSE	Special Information: Hemolyzed specimens will be rejected. Clinical Information: This test is performed using the BRAHMS NSE Kryptor Immunoassay. Results obtained with different methods or kits cannot be used interchangeably. Results cannot be interpreted as absolute evidence of the presence or absence of malignant disease. Specimen Requirement: 0.5 mL Cerebrospinal fluid (CSF) in a clean container; Refrigerated; Minimum 0.5 mL; Separate from cells within 1 hour of collection and transfer to standard aliquot tube. Stability: Ambient: Unacceptable Refrigerated: 1 week Frozen: 1 year (Avoid repeated freeze/thaw cycles) Methodology: Immunoassay (IA) Reference Range: Less than or equal to 27.3 ng/mL Days Performed: Mon, Wed, Fri CPT: 86316	11/15/21

Test Name	Order Code	Change	Effective Date
Neuron-Specific Enolase, Serum	NSE	Special Information: Plasma specimens are unacceptable. Hemolyzed specimens will be rejected. Clinical Information: Use as a tumor marker for evaluation of neuroendocrine tumors. This assay is performed using the BRAHMS NSE Kryptor Immunoassay. Results obtained with different assay methods or kits cannot be used interchangeably. Results cannot be interpreted as absolute evidence of the presence or absence of malignant disease. Specimen Requirement: 1 mL serum from a Serum Separator (Gold) tube; Refrigerated; Minimum: 0.5 mL; Allow specimen to clot completely at room temperature. Centrifuge within 2 hours of collection and transfer to standard aliquot tube. *OR* 1 mL serum from a No additive (Red) tube; Refrigerated; Allow specimen to clot completely at room temperature. Centrifuge within 2 hours of collection and transfer to standard aliquot tube. Stability: Ambient: Unacceptable Refrigerated: 1 week Frozen: 1 year (Avoid repeated freeze/thaw cycles) Methodology: Immunoassay (IA) Reference Range: Less than or equal to 12.7 ng/mL	11/15/21
Olanzapine	OLANZ	Special Information: Specimen should be collected prior to next dose—at steady state concentration. Hemolyzed specimens will be rejected. Clinical Information: Olanzapine is an antipsychotic drug indicated for the treatment of depression and bipolar disorder. The therapeutic range is based on serum, predose (trough) draw collection at steady-state concentration. Adverse effects may include dizziness, akathisia, postural hypotension, delirium, somnolence, neuroleptic malignant syndrome, hyperglycemia, and agitation. Noroxycodone causes an analytical interference and impacts the quantitation of Olanzapine. Stability: Ambient: Unacceptable Refrigerated: Unacceptable Frozen: 1 month Reference Range: Therapeutic Range: 20-80 ng/mL Toxic: Greater than or equal to 100 ng/mL Days Performed: Tue, Fri Reported: 2–8 days	11/15/21
Organic Acids Ur, Quant w/ Consultation	UORABI	Test Name: Previously Organic Acids Ur, Quant w/ Basic Consultation Note: Professional billing for consultation will be removed	12/14/21
Protein Electro- phoresis, Ur 24 Hr w/M Protein Quant	UEPG24	Specimen Requirement: 15 mL 24-hour (well-mixed) Urine in clean container; Refrigerate during collection; Refrigerated; Minimum: 7 mL	12/7/21
Protein Electrophoresis, Urine Random	UEPG	Specimen Requirement: 15 mL Random Urine in clean container; First morning void preferred; Ambient; Minimum: 7 mL *OR* 15 mL 24-hour (well-mixed) Urine in clean container; Refrigerate during collection; Minimum: 7 mL	12/7/21
Protein Electrophoresis, Urine, with IFE	UEPGRX	Specimen Requirement: 15 mL Random Urine in clean container; First morning void preferred; Ambient; Minimum: 10 mL *OR* 15 mL 24-hour (well-mixed) Urine in clean container; Refrigerate during collection; Refrigerated; Minimum: 10 mL	12/7/21
Pyruvic Acid	PYRUV	Reference Range: 0.03–0.10 mmol/L	effective immediately
Serotonin Release Assay (SRA) LMWH	SRALMW	Specimen Requirement: 1 mL serum from No additive (Red) tube; Frozen, Critical *OR* 1 mL serum from Serum Separator (Gold) tube; Frozen, Critical Stability: Ambient: Unacceptable Refrigerated: Unacceptable Frozen: 6 months	12/20/21

Test Name	Order Code	Change	Effective Date
Thiocyanate	THIOCY	Specimen Requirement: 2 mL plasma from Lavender (EDTA) tube; Refrigerated; Collect immediately prior to next dose. Centrifuge and immediately separate plasma specimens from the cells into transport tube	effective immediately
		OR 2 mL serum from No additive (Red) tube; Refrigerated; Collect immediately prior to next dose. Centrifuge and immediately separate serum specimens from the cells into transport tube	
Vitamin D, 1,25-Dihydroxy	125VTD	For Interfaced Clients Only: Test build may need to be modified Includes: Vitamin D, 1,25 Dihydroxy	12/7/21
		Special Information: Samples may be frozen-thawed up to 4 times.	
		Clinical Limitation: Grossly hemolyzed samples, lipemic samples, and samples containing particulate matter or exhibiting obvious microbial contamination will be rejected. Do not heat inactivate serum or plasma. Heterophilic antibodies in human serum can react with reagent immunoglobulins, interfering with the assay. Patients routinely exposed to animals or to animal serum products can be prone to this interference and anomalous values may be observed. The assay has been shown to cross-react with Zemplar (paricalcitol) an active form of Vitamin D.	
		Specimen Requirement: 0.75 mL serum from a Serum Separator (Gold) tube; Refrigerated; Minimum: 0.4 mL	
		OR 0.75 mL plasma from a Lithium Heparin Plasma Separator (Light Green) tube; Minimum: 0.4 mL	
		OR 0.75 mL plasma from an EDTA (Lavender) tube; Minimum: 0.4 mL; Plasma samples should be centrifuged and the plasma removed from the cells immediately after centrifugation.	
		Stability: Ambient: 7 days Refrigerated: 14 days Frozen: 30 days	
		Methodology: Chemiluminescence Immunoassay (CLIA)	
		Reference Range: 19.9-79.3 pg/mL	
		Days Performed: Mon-Fri	
		Reported: 1–4 days	

New Tests

Test Name	Order Code	Change	Effective Date
ALLOGEN AutoAntibody	TTAUTO	NOTE* This new test was announced in the July 2021 External Technical Update for a go live of July 15th, under the code LAB1507. The order code has been changed to TTAUTO and is effective immediately. Please refer to the July 2021 External Technical Update under LAB1507 for details for order code TTAUTO.	effective immediately
Bacterial Vaginosis Amplification	BVAMP	NOTE* New test was announced in the September update, but financial information was not available at that time CPT: 87801 Price: \$245.00	effective immediately
Candida / Trichomonas Amplification	CVTV	NOTE* New test was announced in the September update, but financial information was not available at that time CPT: 87481 (x1); 87661 (x1) Price: \$196.00	effective immediately
Cytomegalovirus, Newborn Saliva	CMVSAL	Special Information: Testing will be performed daily, 7 days per week. Results should generally be available within 1-2 days of receipt in Microbiology. Clinical Limitation: 1. Saliva sample should be obtained at least one-hour after breast feeding to avoid contamination from cytomegalovirus which may result in a false positive result. Current treatment guidelines suggest waiting at least an hour after breastfeeding to obtain the sample. 2. Viral transport media fill volumes greater than 1 mL are not acceptable for use with the Alethia CMV assay. 3. Samples containing mucin at concentrations >25 mg/mL may produce invalid results with the Alethia CMV assay. 4. The results of the Alethia CMV assay are not intended to be used as the sole basis for diagnosis, treatment, or other patient management decisions. 5. The Alethia CMV assay is a qualitative assay and does not provide quantitative values or information about viral load. 6. Viral nucleic acid may persist in vivo, independent of viability. The Alethia CMV assay does not distinguish between viable and nonviable virus. Clinical Information: The Alethia CMV DNA Amplification Assay, performed on the Alethia instrument, is a qualitative, in vitro diagnostic test system for the direct detection of Cytomegalovirus (CMV) DNA in saliva samples from neonates younger than 21 days of age. The test is used as an aid in the diagnosis of congenital CMV infection. The results of this test should be used in conjunction with the results of other clinical findings. Specimen Requirement: 1 mL Saliva Swab in Universal Transport Media (UTM) Note: viral transport media tube (no more than 1 mL); Ambient; Collect saliva swab samples and place into a transport tube (with or without viral transport media) according to established laboratory methods. No special preparation of the neonate is required in order to collect the sample. *OR* Saliva Swab; Ambient; Collect saliva swab samples and place into a transport tube (with or without viral transport media) according to established la	12/28/21

Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
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Acylcarnitines, Plasma w/ No Consultation	ACYLNI	This test will no longer be available. All Plasma Acylcarnitines will be ordered as Acylcarnitines, Plasma w/ Consultation (ACYLBI).	12/14/21
Amino Acids, CSF w/ No Consultation	CAANI	This test will no longer be available. All CSF Amino Acids will be ordered as Amino Acids, CSF w/ Consultation (CAABI).	12/14/21
Amino Acids, Plasma w/ No Consultation	PAANI	This test will no longer be available. All Plasma Amino Acids will be ordered as Amino Acids, Plasma w/ Consultation (PAABI).	12/14/21
Amino Acids, Urine w/ No Consultation	UAANI	This test will no longer be available. All Urine Amino Acids will be ordered as Amino Acids, Urine w/ Consultation (UAABI).	12/14/21
Antimony, Blood	ANTMBL	This test will no longer be available.	effective immediately
Microscopic Examination for Ehrlichia and Anaplasma	EHRLSM	This test will no longer be available. Recommended replacement test: Ehrlichia and Anaplasma Species by PCR (EHRANA).	1/3/22
Myeloma Cells, Blood	MYCELL	This test will no longer be available.	effective immediately
Organic Acids Ur, Quant w/ No Consultation	UORANI	This test will no longer be available. All Organic Acids will be ordered as Organic Acids Ur, Quant w/ Consultation (UORABI)	12/14/21
Porphyrin Screen, Urine 24 Hour	UPORD	This test will no longer be available. Recommended replacement test: Porphyrins, Urine Fractionated (UPORF).	effective immediately
Porphyrin Screen, Urine Random	UPORR	This test will no longer be available. Recommended replacement test: Porphyrins, Urine Fractionated (UPORF).	effective immediately
Rett Syndrome (MECP2), Full Gene Analysis	RETTFG	This test will no longer be available.	11/15/21
Trypanosoma cruzi Antibody, IgM	TCAIGM	This test will no longer be available.	effective immediately