

Technical Update • April 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	Name Change Order Code	New Test	Test Discontinued	Special Information	Specimen Requirement	Component Change(s)	Methodology	Days Performed/Reported Reference Range	Stability	CPT	Fee
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2	Aspergillus Ab, CF											
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3	Benzene Quantitation, Whole Blood											
7	Blastomyces Ab, CF											
3	Blastomyces Ab, ID											
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	Coccidioides Ab, CF & ID											
3	Coccidioides Ab, ID											
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Test Update Page #	Summary of Changes by Test Name	Order Code	Name Change	New Test	Special Information	Specimen Requirement	Component Change(s)	Methodology	Days Performed/Reported	Reference Range	Stability	CPT	Fee
4, 7	FISH for XIST												
4, 7	FISH for XY												
4, 7	Fungal Antibodies												
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4	Fungal Antibodies, ID												
5	Hepatitis Be Antibody												
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5	Histoplasma Ab, CF												
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7	Histoplasma Antibodies (CF/ID)												
7	Histoplasma Antibody (CF reflex to ID)												
7	Histoplasmosis/Blastomyces Ab												
5	Rapamune												
6	Respiratory Panel and SARS-CoV-2 by Rapid PCR												
5	Selenium Blood												
5	Sotalol												
6	STRATIFY JCV Antibody and Index with Reflex to Inhibition Assay												
7	Type + Screen Maternal-Fetal Hemorrhage												

Test Changes

Test Name	Order Code	Change	Effective Date
Anti-Nuclear Antibodies by IFA, Synovial Fluid	BFANA	Days Performed: Varies Reported: 6–8 days	Effective immediately
Aspergillus Ab, CF	ASPRCF	Special Information: Contaminated or severely lipemic specimens will be rejected. This test is New York DOH approved. Clinical Information: Cross-reactions with dimorphic fungi are not unusual with the genus Aspergillus. A negative test does not exclude infection, especially in immunocompromised patients. Best use of the test is with paired sera taken three weeks apart to detect a rise in titer against a single antigen. Specimen Requirement: 1 mL serum from a serum separator (gold) tube; Minimum: 0.4 mL; Separate serum from cells ASAP or within 2 hours of collection and transfer to standard aliquot tube; Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt of the acute specimens; Label specimens plainly as 'acute' and 'convalescent;' Refrigerated Stability: Ambient: After separation from cells: 48 hours Refrigerated: After separation from cells: 2 weeks Frozen: After separation from cells: 1 year (Avoid repeated freeze/thaw cycles) Methodology: Semi-Quantitative Complement Fixation Days Performed: Sunday–Saturday Reported: 2–4 days	5/4/21

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Aspergillus Ab, ID	ASPRID	Clinical Information: Aspergillus antibody test by immunodiffusion may be used as an aid in diagnosis of chronic pulmonary aspergillosis, including chronic cavitary pulmonary aspergillosis and chronic fibrosing pulmonary aspergillosis. Immunodiffusion test is more specific but less sensitive than complement fixation test. Clinical correlation is required.	5/4/21
Benzene Quantitation, Whole Blood	BENZE	Days Performed: Varies Reported: 6–9 days	Effective immediately
Blastomyces Ab, ID	BLSTID	Clinical Information: Blastomyces antibody test by Immunodiffusion may be used as an aid in diagnosis of infection with the dimorphic fungus Blastomyces dermatitidis. Blastomyces serology has low overall diagnostic sensitivity, especially in localized disease. Immunodiffusion test is more specific but less sensitive than complement fixation test. Clinical and epidemiological correlation is required.	5/4/21
Coccidioides Ab, CF	COCICF	Special Information: Hemolyzed, icteric, or lipemic specimens will be rejected. This test is New York DOH approved. Clinical Information: Complement Fixation (CF) measures both IgM and IgG. As single antibody titers are generally not diagnostic, paired specimens are preferred. Acute and convalescent specimens (drawn at least 21 days apart), showing at least a fourfold rise in titer, are diagnostic. Negative fungal serology does not rule out the possibility of current infection. Any titer suggests past or current infection and may aid in monitoring coccidioidomycosis (Valley fever) and treatment response. However, greater than 30% of cases with chronic residual pulmonary disease have negative Complement Fixation (CF) tests. Titers of less than 1:32 (even as low as 1:2) may indicate past infection or self-limited disease; anticoccidioidal CF antibody titers in excess of 1:16 may indicate disseminated infection. CF serology may be used to follow therapy. Specimen Requirement: 1 mL serum from a serum separator (gold) tube; Minimum: 0.4 mL; Separate serum from cells ASAP or within 2 hours of collection and transfer to standard aliquot tube; Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt of the acute specimens; Label specimens plainly as 'acute' and 'convalescent;' Refrigerated Stability: Ambient: After separation from cells: 48 hours Refrigerated: After separation from cells: 2 weeks Frozen: After separation from cells: 1 year (Avoid repeated freeze/thaw cycles) Methodology: Semi-Quantitative Complement Fixation Days Performed: Sunday–Saturday Reported: 3–5 days	5/4/21
Coccidioides Ab, ID	COCIID	Clinical Information: Coccidioides antibody test by Immunodiffusion may be used as an aid in diagnosis of infection with the dimorphic fungus Coccidioides spp. Cannot exclude acute infection if the specimen is collected within 4–6 weeks after onset of signs and symptoms. Immunodiffusion test is more specific but less sensitive than complement fixation test. Clinical and epidemiological correlation is required.	5/4/21
Cytomegalovirus DNA Detection and Quantitation by PCR	CMVQNT	Special Information: Store and transport whole blood at 2–25 °C for no longer than 36 hours. Plasma must be separated from whole blood within 36 hours of collection by centrifugation for samples stored at 2–25 °C. Transfer plasma to a sterile, screw-capped polypropylene tube. Bone Marrow is not accepted. Please order CMV by PCR, non-blood specimens (CMVCSF) for CMV PCR on cerebrospinal fluid/fluid/tissue/bone marrow. Specimen Requirement: 2 mL plasma from an EDTA (lavender) tube; Minimum: 1 mL; Plasma must be separated from whole blood within 36 hours of collection by centrifugation for samples stored at 2–25 °C; Transfer plasma to a sterile, screw-capped polypropylene tube; Centrifuge, aliquot and refrigerate ASAP *OR* 2 mL plasma from an EDTA (pink) tube; Minimum: 1 mL; Plasma must be separated from whole blood within 36 hours of collection by centrifugation for samples stored at 2–25 °C; Transfer plasma to a sterile, screw-capped polypropylene tube; Centrifuge, aliquot and refrigerate ASAP	4/1/21

(continued on page 4)

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Cytomegalovirus DNA Detection and Quantitation by PCR <i>(continued from page 3)</i>		<p>Stability: Ambient: Transport and store whole blood up to 25 °C for no longer than 24 hours; Separate plasma from whole blood within 24 hours of collection if stored at temperatures up to 25 °C Refrigerated: Store and transport whole blood at 2–25 °C for no longer than 36 hours; Separate plasma from whole blood within 36 hours; Plasma specimens stored refrigerated (2–8 °C) are stable for up to 7 days Frozen: Plasma specimens may be transported and stored at minus 20 °C; Plasma specimens stored frozen (minus 20 °C) are stable for 12 weeks</p>	
Everolimus	EVEROL	<p>Reference Range: 0–99 Years: 3.0–8.0 ng/mL</p> <p>Urgent Range: 0–99 Years: > 30.0 ng/mL</p>	5/4/21
FISH for Chronic Lymphocytic Leukemia	CLLFISH	CPT: 88237 x 1, 88271 x 7, 88275 x 3, 88291 x 1	5/11/21
FISH for SRY	SRYFSH	CPT: 88271 x 2, 88273 x 1	5/25/21
FISH for XIST	XSTFSH	CPT: 88271 x 2, 88273 x 1	5/25/21
FISH for XY	XYFSH	CPT: 88271 x 2, 88273 x 1	5/25/21
Fungal Antibodies	FUNCF	<p>For Interfaced Clients Only: Test build may need to be modified</p> <p>Includes: Coccidioides Antibody by CF Histoplasma Mycelia, CF Histoplasma Yeast, CF Aspergillus Antibody by CF Blastomyces Antibody by EIA, Serum</p> <p>Test Name: Previously Fungal Antibodies, CF</p> <p>Special Information: Hemolyzed, icteric, or lipemic specimens will be rejected. This test is New York DOH approved.</p> <p>Clinical Information: Negative fungal serology does not rule out the possibility of current infection. If Blastomyces antibodies are equivocal or positive by Enzyme-Linked Immunosorbent Assay (EIA), then Blastomyces Immunodiffusion will be added at additional cost.</p> <p>Specimen Requirement: 1 mL serum from a serum separator (gold) tube; Minimum: 0.6 mL; Separate serum from cells ASAP or within 2 hours of collection and transfer to standard aliquot tube; Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt of the acute specimens; Label specimens plainly as 'acute' and 'convalescent;' Refrigerated</p> <p>Stability: Ambient: After separation from cells: 48 hours Refrigerated: After separation from cells: 2 weeks Frozen: After separation from cells: 1 year (Avoid repeated freeze/thaw cycles)</p> <p>Methodology: Semi-Quantitative Complement Fixation Semi Quantitative Enzyme-Linked Immunosorbent Assay</p> <p>Reference Range: Coccidioides Antibody by CF: < 1:2 Histoplasma Mycelia, CF: Refer to report Histoplasma Yeast, CF: Refer to report Aspergillus Antibody by CF: < 1:8 Blastomyces Antibody by EIA, Serum: 0.9 IV or less: Negative 1.0–1.4 IV: Equivocal 1.5 IV or greater: Positive</p> <p>Days Performed: Sunday–Saturday Reported: 3–7 days</p>	5/4/21
Fungal Antibodies, ID	FUNID	<p>Clinical Information: Fungal antibody test by immunodiffusion may be used as an aid in diagnosis of infection with endemic dimorphic fungi. Aspergillus serology may be used as an aid in diagnosis of chronic pulmonary aspergillosis. This test combination may rarely be indicated. Please consider individual testing where clinically and epidemiologically indicated.</p>	5/4/21

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Hepatitis Be Antibody	AHBE	<p>Special Information: Bacterial contamination or heat inactivation of the specimen may affect the test result. Do not heat inactivate sera.</p> <p>Clinical Limitation: This assay is not approved for use in screening blood, plasma or tissue donors. This assay is not designed to test body fluids other than human serum.</p> <p>Specimen Requirement: 0.5 mL serum from a serum separator (gold) tube; Minimum: 0.3 mL (Minimum volume will not allow for repeat or additional testing. Sending of 0.5 mL is preferred when possible); Separate serum from cells as soon as possible; Transfer serum to standard aliquot tube and refrigerate; Refrigerated</p> <p>Stability: Ambient: After separation from cells: 4 days Refrigerated: After separation from cells: 7 days Frozen: After separation from cells: 14 days; Up to six freeze/thaw cycles are acceptable</p> <p>Methodology: Chemiluminescence Immunoassay (CLIA)</p>	5/25/21
Hepatitis C Genotyping	HEPGEN	<p>Days Performed: 2 days per week</p> <p>Reported: 3–6 days</p>	Effective immediately
Histoplasma Ab, CF	HISTCF	<p>Special Information: Contaminated or severely lipemic specimens will be rejected. This test is New York DOH approved.</p> <p>Clinical Information: An antibody titer greater than or equal to 1:8 is generally considered presumptive evidence of histoplasmosis. Greater than 1:32 or rising titers indicate strong presumptive evidence of histoplasmosis. Yeast phase is regarded as more sensitive. Approximately 90-95% of cases have positive titers to one or both antigens. Titers to mycelial antigen are higher in chronic infection. Cross-reactions, usually at lower titers, may occur with other fungal disease. Rising titers suggest progression of infection. Skin tests in individuals previously exposed may cause titer elevation in 17–20% of cases. Negative fungal serology does not rule out the possibility of current infection.</p> <p>Specimen Requirement: 1 mL serum from a serum separator (gold) tube; Minimum: 0.4 mL; Separate serum from cells ASAP or within 2 hours of collection and transfer to standard aliquot tube; Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt of the acute specimens; Label specimens plainly as 'acute' and 'convalescent;' Refrigerated</p> <p>Stability: Ambient: After separation from cells: 48 hours Refrigerated: After separation from cells: 2 weeks Frozen: After separation from cells: 1 year (Avoid repeated freeze/thaw cycles)</p> <p>Methodology: Semi-Quantitative Complement Fixation</p> <p>Days Performed: Sunday–Saturday</p> <p>Reported: 2–4 days</p>	5/4/21
Histoplasma Ab, ID	HISTID	<p>Clinical Information: Histoplasma antibody test by Immunodiffusion may be used as an aid in diagnosis of infection with the dimorphic fungus Histoplasma capsulatum. Histoplasma antibody test has low overall diagnostic sensitivity especially with localized disease. Immunodiffusion test is more specific but less sensitive than complement fixation test. Clinical and epidemiological correlation is required.</p>	5/4/21
Rapamune	RAPAM	<p>Reference Range: 3.0–18.0 ng/mL</p> <p>Urgent Range: > 30.0 ng/mL</p>	5/4/21
Selenium Blood	SELEN	<p>Stability: Ambient: 30 days Refrigerated: 30 days Frozen: 30 days</p>	5/4/21
Sotalol	SOTAL	<p>Specimen Requirement: 1 mL serum from a plain no additive (red) tube; Minimum: 0.2 mL; Do not draw serum separator tubes; Separate serum from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube; Refrigerated</p> <p>*OR* 1 mL plasma from an EDTA (lavender) tube; Minimum: 0.2 mL; Do not draw plasma separator tubes; Separate plasma from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube; Refrigerated</p> <p>Days Performed: Varies</p> <p>Reported: 9–12 days</p>	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
STRATIFY JCV Antibody and Index with Reflex to Inhibition Assay	JCVIDX	<p>Specimen Requirement: 0.5 mL serum from a serum separator (gold) tube; Minimum: 0.25 mL; Frozen</p> <p>*OR* 0.5 mL serum from a plain no additive (red) tube; Minimum: 0.25 mL; Frozen</p> <p>*OR* 0.5 mL plasma from an EDTA (lavender) tube; Minimum: 0.25 mL; Frozen</p>	Effective immediately

New Tests

Test Name	Order Code	Change	Effective Date
Blastomyces dermatitidis Antibodies by EIA with Reflex to Immunodiffusion, Serum	BLASAB	<p>Special Information: Contaminated, hemolyzed, or severely lipemic specimens will be rejected. This test is New York DOH approved.</p> <p>Clinical Information: Negative fungal serology does not rule out the possibility of current infection. If Blastomyces antibodies are equivocal or positive by Enzyme-Linked Immunosorbent Assay (EIA), then Blastomyces Immunodiffusion will be added at additional cost.</p> <p>Specimen Requirement: 1 mL serum from a serum separator (gold) tube; Minimum: 0.3 mL; Separate serum from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube; Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt of the acute specimens; Label specimens plainly as 'acute' or 'convalescent;' Refrigerated</p> <p>Stability: Ambient: After separation from cells: 48 hours Refrigerated: After separation from cells: 2 weeks Frozen: After separation from cells: 1 year (Avoid repeated freeze/thaw cycles)</p> <p>Methodology: Semi-Quantitative Enzyme-Linked Immunosorbent Assay</p> <p>Days Performed: Sunday–Saturday</p> <p>Reported: 3–7 days</p> <p>CPT: 86612 x 1</p> <p>Price: \$46.00 (non-discountable)</p>	5/4/21
Respiratory Panel and SARS-CoV-2 by Rapid PCR	RPRACV	<p>Note: <i>This test was previously announced in the March Technical Update.</i></p> <p>Price: \$675.00 (non-discountable)</p> <p>CPT: 0202U x 1</p>	Effective immediately

Fee Increases

Test Name	Order Code	List Fee	CPT Code	Effective Date
Bordetella pertussis and Bordetella parapertussis by Molecular Detection	BORAMP	\$236.00	87798 x 2	Effective immediately
Hepatitis C Genotyping	HEPGEN	\$498.00	87902	Effective immediately

Fee Reductions

Test Name	Order Code	List Fee	CPT Code	Effective Date
FISH for SRY	SRYFSH	\$688.00 (non-discountable)	88271 x 2, 88273	5/25/21
FISH for XIST	XSTFSH	\$688.00 (non-discountable)	88271 x 2, 88273	5/25/21
FISH for XY	XYFSH	\$688.00 (non-discountable)	88271 x 2, 88273	5/25/21
Fungal Antibodies	FUNCF	\$214.00	86606, 86612, 86635, 86698 x 2	5/4/21

Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
Aspergillus Antibodies (CF/ID)	ASPRAB	This test will no longer be available. Suggest ordering Aspergillus Ab, CF (ASPRCF) and Aspergillus Ab, ID (ASPRID)	5/4/21
Aspergillus Antibody (CF reflex to ID)	ASPCF	This test will no longer be available. Suggest ordering Aspergillus Ab, CF (ASPRCF) and Aspergillus Ab, ID (ASPRID)	5/4/21
Blastomyces Ab, CF	BLSTCF	This test will no longer be available. Suggest ordering Blastomyces dermatitidis Antibodies by EIA with Reflex to Immunodiffusion, Serum (BLASAB)	5/4/21
Blastomyces Antibodies (CF/ID)	BLSTAB	This test will no longer be available. Suggest ordering Blastomyces Ab, ID (BLSTID) and Blastomyces dermatitidis Antibodies by EIA with Reflex to Immunodiffusion, Serum (BLASAB)	5/4/21
Blastomyces Antibody (CF reflex to ID)	BLSCF	This test will no longer be available. Suggest ordering Blastomyces Ab, ID (BLSTID) and Blastomyces dermatitidis Antibodies by EIA with Reflex to Immunodiffusion, Serum (BLASAB)	5/4/21
Coccidioides Ab, CF & ID	COCIAB	This test will no longer be available. Suggest ordering Coccidioides Ab, CF (COCICF) and Coccidioides Ab, ID (COCIID)	5/4/21
Coccidioides Antibody (CF reflex to ID)	COCCF	This test will no longer be available. Suggest ordering Coccidioides Ab, CF (COCICF) and Coccidioides Ab, ID (COCIID)	5/4/21
Fungal Antibodies (CF/ID)	FUNBAT	This test will no longer be available. Suggest ordering Fungal Antibodies (FUNCF) and Fungal Antibodies, ID (FUNID)	5/4/21
Histoplasma Antibodies (CF/ID)	HISTAB	This test will no longer be available. Suggest ordering Histoplasma Ab, CF (HISTCF) and Histoplasma Ab, ID (HISTID)	5/4/21
Histoplasma Antibody (CF reflex to ID)	HISCF	This test will no longer be available. Suggest ordering Histoplasma Ab, CF (HISTCF) and Histoplasma Ab, ID (HISTID)	5/4/21
Histoplasmosis/ Blastomyces Ab	HISBLA	This test will no longer be available. Suggest ordering Blastomyces Ab, ID (BLSTID), Blastomyces dermatitidis Antibodies by EIA with Reflex to Immunodiffusion, Serum (BLASAB), Histoplasma Ab, CF (HISTCF), and Histoplasma Ab, ID (HISTID)	5/4/21
Type + Screen Maternal-Fetal Hemorrhage	TSKB	This test will no longer be available.	Effective immediately