



Technical Update • February 2013

Cleveland Clinic Laboratories is dedicated to keeping you updated and informed about recent testing changes. That's why we are happy to provide this technical update on a monthly basis.

Recently changed tests are **bolded**, and could include revisions to methodology, reference range, days performed or CPT code. For your convenience, tests are listed alphabetically and the order and billing codes are provided.

If you wish to compare the new information with previous test demographics, refer to the Test Directory, which can be accessed at clevelandcliniclabs.com.

Deleted tests and new tests are listed separately. 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	Billing Code	Name Change	New Test	Test Discontinued	Specimen Requirement	Special Information	Component Change	Methodology	Reference Range	Days Performed/Reported	CPT
2	BK Virus Quantitation PCR, Plasma												
2	Bordetella pertussis Antibody, IgA by Immunoblot												
2	Bordetella pertussis Antibody, IgG by Immunoblot												
2	Bordetella pertussis Antibody, IgM by Immunoblot												
3	CEBPA Mutation Analysis												
3	Chloramphenicol												
3	Duchenne/Becker Muscular Dystrophy DNA Carrier Test (Females only)												
3	Duchenne/Becker Muscular Dystrophy DNA Del Test (Males only)												
7	Factor V Leiden												
5	Factor V Leiden PCR												
7	FAP Mutation Screen												
3	Gabapentin												
5	Ganglioside Antibodies												
3	Herpes Simplex by PCR												
3	Human Erythrocyte Ag												
3	Hypercoagulation Diagnostic Interpretive Panel												
3	Isopropanol												
6	MAG Antibodies, IgM & SGPG Antibodies, IgM												
3	MEN2 and FMTC Mutation												
3	Mexiletine												
7	Motor Neuropathy Profile Complete												
7	MTHFR by PCR												
6	MTHFR Gene Analysis												

Test Update Page #	Summary of Changes by Test Name	Order Code	Billing Code	Name Change	New Test	Specimen Information	Component Requirement	Reference Range	Methodology	Days Performed/Reported	CPT
3	Neurofibromatosis Type 1, Comprehensive										
6	NS6S Antibody Test										
4	Oncologic CytoScan HD SNP Array										
4	Orotic Acid, Urine										
4	Porphyrins, Urine Fractionated										
7	Prothrombin Gene Mutation										
6	Prothrombin Gene PCR										
4	Rubella IgM Antibody										
4	RHCE Variant Antigen										
4	RHD Variant Antigen										
6	ROS1 gene rearrangement by FISH										
4	Thiopurine Methyltransferase (TPMT)										
4	Torch Antibodies, IgM										
4	Tricyclic Antidepressant ID										
7	Vaginal Pathogens DNA Direct Probes										
4	Voriconazole										

Test Changes

Test Name	Order Code	Billing Code	Change	Effective Date
BK Virus Quantitation PCR, Plasma	BKQUAN	82611	Specimen Requirement: 2 mL plasma from an EDTA lavender top tube; Refrigerated Reference Range: Negative for BK Virus DNA Days Performed: Tuesday, Friday Reported: 5 days	2/26/2013
Bordetella pertussis Antibody, IgA by Immunoblot	BPAA	88015	Includes: <i>B. pertussis</i> , IgA Immunoblot PT <i>B. pertussis</i> , IgA Immunoblot FHA Test build may need to be modified Reference Range: <i>B. pertussis</i> , IgA Immunoblot PT: Negative <i>B. pertussis</i> , IgA Immunoblot FHA: Negative	2/19/2013
Bordetella pertussis Antibody, IgG by Immunoblot	BPAG	88016	Includes: <i>B. pertussis</i> , IgG Immunoblot PT100 <i>B. pertussis</i> , IgG Immunoblot PT <i>B. pertussis</i> , IgG Immunoblot FHA Test build may need to be modified Reference Range: <i>B. pertussis</i> , IgG Immunoblot PT100: Negative <i>B. pertussis</i> , IgG Immunoblot PT: Negative <i>B. pertussis</i> , IgG Immunoblot FHA: Negative	2/19/2013
Bordetella pertussis Antibody, IgM by Immunoblot	BPAM	88017	Includes: <i>B. pertussis</i> , IgM Immunoblot PT <i>B. pertussis</i> , IgM Immunoblot FHA Test build may need to be modified Reference Range: <i>B. pertussis</i> , IgM Immunoblot PT: Negative <i>B. pertussis</i> , IgM Immunoblot FHA: Negative	2/19/2013

Test Changes

Test Name	Order Code	Billing Code	Change	Effective Date
CEBPA Mutation Analysis	CEBPA	87639	Specimen Requirement: 5 mL whole blood in an EDTA lavender top tube; Ambient Reference Range: CEBPA mutations are Not Detected Days Performed: 1 day per week Reported: 10 - 14 days	2/28/2013
Chloramphenicol	CLORAM	76115	Reference Range: Therapeutic peak: 10 - 25 µg/mL Toxic: > 25 µg/mL	2/19/2013
Duchenne/Becker Muscular Dystrophy DNA Carrier Test (Females only)	DBMDXS	83006	CPT: 81479	1/1/2013
Duchenne/Becker Muscular Dystrophy DNA Del Test (Males only)	DBMDYS	82119	CPT: 81479	1/1/2013
Gabapentin	GABA	79153	Reference Range: Therapeutic Range: 2 - 20 µg/mL	2/19/2013
Herpes Simplex by PCR	HSPCR	79044	Special Information: Cerebrospinal fluid (CSF) is not an acceptable specimen type for this assay. Orders for this test on CSF will be changed to Herpes Simplex Virus by PCR, CSF (HSPCRC). Please order Herpes Simplex Virus by PCR, CSF (HSPCRC) for CSF samples. This test readily differentiates serotypes I and II.	12/21/2012
Human Erythrocyte Ag	HEA	87880	CPT: 81479	1/1/2013
Hypercoagulation Diagnostic Interpretive Panel	HYPER	173	Includes: Protein C Functional Protein S Clottable Antithrombin III APC Resistance Prothrombin Time (PT) APTT Fibrinogen Cardiolipin Antibodies Homocysteine (plasma) PT Gene Factor VIII C Assay Hexagonal Phase Phospholipid Neutralization C-Reactive Protein Test build may need to be modified	4/2/2013
Isopropanol	ISOPRO	87815	Reference Range: Isopropanol: No therapeutic range Toxic: > 50 mg/dL Acetone: No therapeutic range Toxic: > 100 mg/dL	2/19/2013
MEN2 and FMTC Mutation	MEN2	83405	Days Performed: 2 days per week Reported: 8 - 12 days CPT: 81404, 81405	2/28/2013
Mexiletine	MEXIL	75504	Reference Range: Therapeutic Range: 1.0 - 2.0 µg/mL Toxic: > 2.0 µg/mL	2/19/2013
Neurofibromatosis Type 1, Comprehensive	NFIB1	88611	Includes: Mutations include: truncating mutations (nonsense, frameshift, splicing mutations) missense mutations multi-exon deletions total gene deletions SPRED 1 mutation Test build may need to be modified Specimen Requirement: Collect 3 EDTA lavender top tubes; Collect Monday - Wednesday only; Specimen MUST be sent to Cleveland Clinic Laboratories on the day of collection; A completed 'NF1/SPRED1 Phenotypic Checklist' must be included with the specimen. This form is available through Client Services at 800.628.6816 or 216.444.5755; Ambient	2/28/2013

Test Changes (cont.)

Test Name	Order Code	Billing Code	Change	Effective Date
Oncologic CytoScan HD SNP Array	HDSNP	88609	Days Performed: Monday Reported: 11 - 16 days CPT: 81406	2/28/2013
Orotic Acid, Urine	UOROTC	83406	Specimen Requirement: 2 mL random urine in a clean container; Specimen should be from first morning void; Freeze ASAP or within 2 hours of collection; Critical Frozen Days Performed: Tuesday Reported: 3 - 10 days	2/19/2013
Porphyrins, Urine Fractionated	UPORFR	84120	Includes: Creatinine, Ur mg/dL Creatinine, mg/day Uroporphyrin - ratio to CRT Heptacarboxylate - ratio to CRT Coproporphyrin I - ratio to CRT Coproporphyrin III - ratio to CRT Test build may need to be modified Days Performed: Sunday - Friday Reported: 2 - 6 days	2/19/2013
RHCE Variant Antigen	RHCE	88772	CPT: 81479	1/1/2013
RHD Variant Antigen	RHD	88771	CPT: 81479	1/1/2013
Rubella IgM Antibody	RUBIGM	75618	Specimen Requirement: 1 mL of serum from a serum separator tube; Separate serum from cells ASAP or within 2 hours of collection; Refrigerated Reference Range: ≤ 19.9 AU/mL: Not Detected 20.0 - 24.9 AU/mL: Indeterminate ≥ 25.0 AU/mL: Detected	1/16/2013
Thiopurine Methyltransferase (TPMT)	PPRENZ	81574	CPT: 83789	1/31/2013
Torch Antibodies, IgM	TORCHM	79190	Reference Range: Rubella IgM: ≤ 19.9 AU/mL: Not Detected 20.0 - 24.9 AU/mL: Indeterminate ≥ 25.0 AU/mL: Detected CMV IgM: ≤ 29.9 AU/mL: Not Detected 30.0 - 34.9 AU/mL: Indeterminate ≥ 35.0 AU/mL: Detected Toxoplasma IgM: ≤ 7.9 AU/mL: Not Detected 8.0 - 9.9 AU/mL: Indeterminate ≥ 10.0 AU/mL: Detected HSV Types 1/2 IgM Abs: ≤ 0.89 IV: Not Detected 0.90 - 1.09 IV: Indeterminate ≥ 1.10 IV: Detected	1/16/2013
Tricyclic Antidepressant ID	TADID	79193	Specimen Requirement: 1 mL of serum from a red top tube; Do not use serum separator tube; Separate serum from cells within 2 hours of collection; Refrigerated CPT: 80152, 80182, 80174, 80160, 80166, 80299x4	2/19/2013
Voriconazole	VORCON	84568	Reference Range: Therapeutic Range: 1.0 - 6.0 µg/mL Toxic: > 6.0 µg/mL	2/19/2013

New Tests

Test Name	Order Code	Billing Code	Test Information	Effective Date
Factor V Leiden PCR	FVLEI	79827	Includes: Factor V Leiden Interpretation Factor V Leiden Review Specimen Requirement: 4 mL whole blood in an EDTA lavender top tube; Refrigerated Methodology: Fluorescence Monitoring Polymerase Chain Reaction (PCR) Reference Range: Normal Days Performed: Tuesday, Thursday Reported: 7 - 10 days CPT: 81241 Price: \$284.00	3/26/2013
Ganglioside Antibodies	GANGAB	89208	Includes: Asialo-GM1 IgG/IgM GM1 IgG/IgM GM2 IgG/IgM GD1a IgG/IgM GD1b IgG/IgM GQ1b IgG/IgM Specimen Requirement: 0.3 mL serum from a serum separator tube; Separate serum from cells ASAP; Refrigerated Methodology: Enzyme-Linked Immunosorbent Assay (ELISA) Reference Range: Asialo-GM1 Antibodies, IgG/IgM ≤ 29 IV: Negative 30 - 50 IV: Equivocal 51 - 100 IV: Positive ≥ 101 IV: Strong Positive GM1 Antibodies, IgG/IgM ≤ 29 IV: Negative 30 - 50 IV: Equivocal 51 - 100 IV: Positive ≥ 101 IV: Strong Positive GM2 Antibodies, IgG/IgM ≤ 29 IV: Negative 30 - 50 IV: Equivocal 51 - 100 IV: Positive ≥ 101 IV: Strong Positive GD1a Antibodies, IgG/IgM ≤ 29 IV: Negative 30 - 50 IV: Equivocal 51 - 100 IV: Positive ≥ 101 IV: Strong Positive GD1b Antibodies, IgG/IgM ≤ 29 IV: Negative 30 - 50 IV: Equivocal 51 - 100 IV: Positive ≥ 101 IV: Strong Positive GQ1b Antibodies, IgG/IgM ≤ 29 IV: Negative 30 - 50 IV: Equivocal 51 - 100 IV: Positive ≥ 101 IV: Strong Positive Days Performed: Monday, Wednesday, Friday Reported: 2 - 5 days CPT: 83516x6 Price: \$155.00 (non-discountable)	2/14/2013

New Tests (cont.)

Test Name	Order Code	Billing Code	Test Information	Effective Date
MAG Antibodies, IgM & SGPG Antibodies, IgM	MASGPG	89215	Specimen Requirement: 0.5 mL serum from a serum separator tube; Separate serum from cells ASAP or within 2 hours of collection; Refrigerated Methodology: Enzyme-Linked Immunosorbent Assay (ELISA) Reference Range: MAG Antibody, IgM: < 1000 Titer Units SGPG Antibody, IgM: < 1.00 IV Days Performed: Tuesday Reported: 2 - 9 days CPT: 83516x2 Price: \$102.00 (non-discountable)	2/14/2013
MTHFR Gene Analysis	MTHF	81692	Includes: MTHFR Interpretation MTHFR Review Specimen Requirement: 4 mL whole blood in an EDTA lavender top tube; Refrigerated Methodology: Fluorescence Monitoring Polymerase Chain Reaction (PCR) Reference Range: Normal Days Performed: Thursday Reported: 10 - 14 days CPT: 81291 Price: \$286.00 (non-discountable)	3/19/2013
NS6S Antibody Test	NS6S	89214	Specimen Requirement: 2 mL serum from a serum separator tube; Deliver to Cleveland Clinic Laboratories on the day of collection; Refrigerated Methodology: Enzyme-Linked Immunosorbent Assay (ELISA) Reference Range: Positive, presence of NS6S Antibodies Days Performed: Monday - Friday Reported: 15 - 16 days CPT: 83516 Price: \$700.00 (non-discountable)	2/14/2013
Prothrombin Gene PCR	PTGEN	80095	Includes: Prothrombin Gene Interpretation Prothrombin Gene Review Specimen Requirement: 4 mL whole blood in an EDTA lavender top tube; Refrigerated Methodology: Fluorescence Monitoring Polymerase Chain Reaction (PCR) Reference Range: Normal Days Performed: Monday, Wednesday, Friday Reported: 7 - 10 days CPT: 81240 Price: \$180.00	4/2/2013
ROS1 gene rearrangement by FISH	ROS1	89243	Specimen Requirement: Formalin-fixed, paraffin-embedded tissue specimen block; Refrigerated Methodology: Fluorescent In-Situ Hybridization (FISH) Days Performed: Sunday - Saturday Reported: 4 - 6 days CPT: 88368x2 Price: \$453.00 (non-discountable)	3/21/2013

New Tests (cont.)

Test Name	Order Code	Billing Code	Test Information	Effective Date
Vaginal Pathogens DNA Direct Probes	VAGDNA	88354	<p>Special information:</p> <p>1. The vaginal specimen must be collected and transported using the BD Affirm VPIII Ambient Temperature Transport System only. 2. BD Affirm VPIII Ambient Temperature Sample Collection Tubes > 72 hours old will be rejected. 3. Vaginal specimens are the only acceptable specimen type. All others will be rejected. 4. Swabs submitted in any other media or collection system will be rejected. 5. Frozen samples will be rejected. 6. Vaginal specimens collected and received in the BD Affirm Ambient Temperature Sample Collection tube will be tested for all three organisms: Candida species, Gardnerella vaginalis and Trichomonas vaginalis. 7. This test is not recommended for premenarchal or postmenopausal women. ***Note: If only bacterial vaginosis is suspected, the clinician should order a miscellaneous Gram stain and obtain the appropriate collection device (swab). If only Candida species is suspected, the clinician should order a fungal smear and obtain the appropriate collection device (swab). If an order for bacterial vaginosis or Candida detection is placed, but the specimen is submitted in the BD Affirm Ambient Temperature Sample Collection tube, the order will be changed to include all three components of the assay (Vaginal Pathogens DNA Direct Probe/VAGDNA). If only Trichomonas is suspected the clinician must order the Vaginal Pathogens DNA Direct Probe and obtain the appropriate collection device (BD Affirm Ambient Temperature Sample Collection tube).</p> <p>Includes:</p> <ul style="list-style-type: none"> Candida species DNA Probe Gardnerella DNA Probe Trichomonas vaginalis DNA Probe <p>Specimen Requirement: Vaginal swab placed into BD Affirm VPIII Ambient Temperature Sample Collection Tube; Ambient</p> <p>Methodology: Qualitative DNA Probe</p> <p>Reference Range: Negative</p> <p>Days Performed: Monday - Friday</p> <p>Reported: 2 - 3 days</p> <p>CPT: 87480, 87510, 87660</p> <p>Price: \$189.00</p>	3/5/2013

Discontinued Tests

Test Name	Order Code	Billing Code	Test Information	Effective Date
Factor V Leiden	FVLEID	79827	This test will no longer be available. Suggest ordering Factor V Leiden PCR (FVLEI)	3/26/2013
FAP Mutation Screen	FAPSCR	82499	This test will no longer be available.	1/31/2013
MTHFR by PCR	MTHFR	81692	This test will no longer be available. Suggest ordering MTHFR Gene Analysis (MTHF)	3/19/2013
Motor Neuropathy Profile Complete	MOTNEU	82183	This test will no longer be available.	2/14/2013
Prothrombin Gene Mutation	PTGENE	80095	This test will no longer be available. Suggest ordering Prothrombin Gene PCR (PTGEN)	4/2/2013