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PATHOLOGY LABORATORIES
A Sonic Healthcare Clinical Laboratory

Client Communication

TORCH Testing Updates

Effective December 12, 2022

Pathology Laboratories, Inc. (PathLabs) is in the process of making updates to TORCH tests based on changes being made by our reference laboratory partner, Clinical Pathology Laboratories (CPL), our Sonic Healthcare USA, Inc. affiliate of Austin, Texas.

Specifically, CPL's changes reflect the consolidation of components of TORCH testing onto a single test system, using Roche cobas e801 instrumentation. This consolidation increases efficiency, optimizes handling of low-volume specimens, and offers improved throughput.

As a result of this new platform, providers will see changes in methodology, reference ranges, and reporting units used to describe Non-reactive (Negative), Borderline (Equivocal), and Reactive (Positive) results. It is important to keep in mind that values determined on patient samples by different methodologies cannot be directly compared to one another.

CPL's new instrumentation utilizes the electrochemiluminescence immunoassay (ECLIA) methodology.

Further details are provided below and within the context of this publication.

Client Communication

The test updates include changes and data for certain tests in the following areas:

- CPT Codes *(no changes)*
- Methodology
- Preferred Specimen
- Reference Ranges
- Reporting Units
- Supplemental Test Information

The enclosed listing, as disclosed in the chart provided herein, contains specific information as to the modifications to the Order Codes that are affected. All changes are marked as **bright blue**.

CPT Codes

The CPT codes for this testing remain unchanged.

Methodology Updates

CURRENT METHODOLOGY: CHEMILUMINESCENT IMMUNOASSAY (CLIA)
NEW METHODOLOGY: ROCHE COBAS ELECTROCHEMILUMINESCENT IMMUNOASSAY (ECLIA)

Preferred Specimen

Serum from Serum Separator Tube (SST). **Refrigerate.**
Preferred Volume **2 mL.**

Reference Ranges and Reporting Units

Order Codes Affected:

Order Code	Reporting Title	Current Reporting	New Reporting
75018	CYTOMEGALOVIRUS IGG	NEGATIVE: <0.60 U/ML EQUIVOCAL: 0.60-0.69 U/ML POSITIVE: >=0.70 U/ML	**NON-REACTIVE: <0.500 INDEX** **BORDERLINE: 0.500-0.999 INDEX** **REACTIVE: >=1.000 INDEX**
75017	CYTOMEGALOVIRUS IGM	NEGATIVE: <30.0 AU/ML EQUIVOCAL: 30.0-34.9 AU/ML POSITIVE: =>35.0 AU/ML	**NON-REACTIVE: <0.700 INDEX** **BORDERLINE: 0.700-0.999 INDEX** **REACTIVE: >=1.000 INDEX**
37380	HERPES SIMPLEX 1, IGG	NEGATIVE: <=0.90 INDEX EQUIVOCAL: 0.91-1.09 INDEX POSITIVE: =>1.10 INDEX	**NON-REACTIVE: <1.000 INDEX** **REACTIVE: >=1.000 INDEX**
37406	HERPES SIMPLEX 2, IGG	NEGATIVE: <=0.90 INDEX EQUIVOCAL: 0.91-1.09 INDEX POSITIVE: =>1.10 INDEX	**NON-REACTIVE: <1.000 INDEX** **REACTIVE: >=1.000 INDEX**
37444	RUBELLA AB, IGM	NEGATIVE: <20.0 AU/ML EQUIVOCAL: 20.0-24.9 AU/ML POSITIVE: =>25.0 AU/ML	**NON-REACTIVE: <0.800 INDEX** **BORDERLINE: 0.800-0.999 INDEX** **REACTIVE: >=1.000 INDEX**

For Panels listed below, see individual Order Codes above for reporting changes. Specimen volumes required are per analyte and increase when more than one analyte is tested in a panel.

36871 CYTOMEGALOVIRUS IGG/IGM PANEL
37413 HERPES SIMPLEX IGG 1 AND 2 ANTIBODIES
39402 HERPES SIMPLEX IGG 1/2 AND IGM ANTIBODIES
258 TORCH PANEL IGG
378 TORCH PANEL IGM

NOTE: TOXOPLASMA ANTIBODY, IGG (37326), TOXOPLASMA ANTIBODY, IGM (38014), and RUBELLA IGG (16510) are already performed using Roche cobas e801 instrumentation using ROCHE COBAS ELECTROCHEMILUMINESCENT IMMUNOASSAY (ECLIA) methodology.

Supplemental Test Information

The tests in a TORCH panel are used to help diagnose infections that could cause harm to a baby during pregnancy. PathLabs' TORCH Panels include testing for:

- **Toxoplasmosis:** This infection is caused by a parasite commonly picked up from cat stools. Fetuses may be affected in utero via transplacental infection to produce congenital toxoplasmosis. If untreated, it can cause blindness, deafness, seizures, and intellectual disability.
- **Rubella:** Also called German measles, this is a viral infection that can easily be passed from person to person through sneezing or coughing. Rubella is less common today because standard MMR vaccination offers protection against it; however, the virus may be passed to the fetus, which can cause miscarriage, premature birth, or congenital rubella syndrome.
- **Cytomegalovirus (CMV):** CMV is a type of herpes virus and is the most common congenital infection in babies. Mothers can get CMV by sexual contact or contact with bodily fluids, such as saliva from a person who has CMV. CMV can have long-term consequences in babies, including problems with vision, hearing, and mental development.
- **Herpes Simplex Virus (HSV):** Those that are pregnant can acquire genital herpes simplex virus through sexual contact with an infected individual or through reactivation of latent virus. Virus can be passed to the developing fetus transplacentally or during delivery. Congenital HSV can cause low birth weight, miscarriage, and preterm birth. Perinatal infection may cause lesions that affect skin, eyes, and mouth, or in rare cases, can cause serious brain and organ damage.

Our online test directory will be updated to reflect this information on December 12, 2022.

This Client Communication will be posted to our website for reference.

Please review the information and make changes as applicable to your practice/facility. If you have any questions, please contact our Client Service Department at 419-255-4601/800-281-8804 or your account executive. Thank you.

NOTE: CPT codes are provided for information only and are based on Pathology Laboratories' current understanding of Medicare rules and carrier instructions and in accordance with the current issue of physician's Current Procedural Terminology (CPT), published by the American Medical Association. Medicare coding may differ from coding used by other third party payers. Questions regarding coding should be confirmed with the payer being billed. Pathology Laboratories cannot accept responsibility for the reimbursement clients may or may not receive based on the procedure codes provided.