ACL Laboratories
Every Sample is a Life™

Test Bulletin

January 2019

ACL Laboratories Implements New Genetic Test Panel for Prenatal Carrier Screening

Effective Wednesday, January 16, 2019, ACL Laboratories will offer a new test for Prenatal Carrier Screening – Prenatal Carrier Screen Panel (Test Order Code PCSPNL).

Prenatal Carrier Screen Panel (Test Order Code PCSPNL) is composed of three tests Cystic Fibrosis Mutation Panel (Test Order Code CFMP), Fragile X Diagnosis (Test Order Code FMR1), and Spinal Muscular Atrophy [SMA] Copy Number Analysis (Test Order Code SMACN) and designed to provide one comprehensive ordering and testing option to patients and physicians.

PCSPNL panel is validated on whole blood and requires only one pink 6.0 mL EDTA tube to be drawn for all three tests.

For additional information regarding this panel, as well as specimen collection requirements, please contact ACL Client Services at 1.800.877.7016 or visit our website at www.acllaboratories.com/test-catalog/.

Reference Laboratory Discontinues Test Order Codes JAK2R and REF801

Effective immediately, send out Test Order Codes JAK2R and REF801 are no longer performed due to the reference laboratory discontinuing these tests. ACL Laboratories recommends REF803 (ARUP Test Order Code 2012085) in place of JAK2R, and REF804 (ARUP Test Order Code 2012084) in place of REF801 as suitable equivalent tests in the management of myeloproliferative neoplasms.

REF803 (ARUP Test Order Code 2012085) is most often used when a diagnosis of polycythemia vera (PV) is suspected.

The reflex test (REF804 – ARUP Test Order Code 2012084) is most often used when a diagnosis of essential thrombocythemia (ET) or primary myelofibrosis (PMF) is suspected. This reflex testing cascade sequentially evaluates for the common major gene mutations associated with non-*BCR/ABL1*-positive myeloproliferative neoplasms until a mutation is identified. The testing sequence is based on the reported frequency of gene mutations in this disease group. Initial testing evaluates for the presence of the *JAK2* V617F mutation. If this result is negative, testing proceeds with assessment for *CALR* mutations. If the *CALR* result is also negative, then testing proceeds to evaluate for mutations in exon 9 of the *MPL* gene. If either *JAK2* V617F or *CALR* mutations are detected in the process, the testing algorithm ends; therefore, the complete reflex is followed only in the event of sequential negative mutation. An integrated report is issued with the summary of test results.

The specimen requirements are the same for both REF803 and REF804:

- Collection: 1 Lavender EDTA (minimum 1.0 mL whole blood or bone marrow)
- Transport: Refrigerate

  Do Not Freeze

For additional information regarding these tests, as well as specimen collection requirements, please contact ACL Client Services at 1.800.877.7016 or visit our website at www.acllaboratories.com/test-catalog/.

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Notification of Change: Cigna Coverage Policy for Molecular Microbe Testing

Diagnostic molecular microbe testing (see CPT® code list below) is considered medically necessary for signs or symptoms associated with the following sexually transmitted diseases listed below when ANY of the associated diagnoses as listed in the coding/billing information section of this Coverage Policy is present:

Sexually Transmitted Disease	CPT Codes
Chlamydia (*Chlamydia trachomatis*)	87490, 87491, 87492
Gardnerella vaginalis	87510, 87511, 87512
Genital Herpes (Herpes Simplex Virus Types 1 and 2	87528, 87529, 87530
Gonorrhea (*Neisseria gonorrhea*)	87590, 87591, 87592
Human Papillomavirus (HPV), high-risk types (e.g., types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68)	87624
Invasive Candidiasis, Candidemia	87480, 87481, 87482
Trichomoniasis (*Trichomonas vaginalis*)	87660, 87661

Effective 2/15/2019

Diagnostic molecular microbe testing is considered not medically necessary if the criteria described above are not met.

Diagnostic microbe testing for syphilis as listed below is considered medically necessary when ANY of the following criteria are met for ANY of the clinical circumstances (as described by ICD-10 Diagnosis Code) listed in the coding/billing information section for syphilis testing:

- Qualitative syphilis test (CPT 86592)
- Quantitative syphilis test (CPT 86593)
- Treponema pallidum test (CPT 86780) for ANY of the following:
  - Positive qualitative syphilis test (CPT 86592)
  - Symptoms suggestive of tertiary syphilis (e.g., meningoencephalitis, tabes dorsalis, or general paresis), despite negative qualitative test

Not Medically Necessary

Diagnostic molecular microbe testing is considered not medically necessary for ANY of the following indications:

- Noninvasive or mucosal candidiasis (e.g., vaginal candidiasis).
- Human papilloma virus (HPV), low-risk types (e.g., types 6, 11, 42, 43, 44)
- Syphilis

Not Reimbursable

Use of Not Otherwise Specified (NOS) CPT codes 87797, 87798, 87799 for molecular microbe testing is not reimbursable when a more specific CPT/HCPCS code is available for use.

ACL Laboratories Discontinues Treponema Pallidum Antibody, IgG by IFA (FTA-ABS), Serum (Test Order Code FTABR)

Effective Wednesday, January 16, 2019, ACL Laboratories will discontinue Treponema Pallidum Antibody, IgG by IFA (FTA-ABS), Serum (Test Order Code FTABR). Laboratory testing for Syphilis requires both non-treponemal (ie RPR) as well as treponemal testing, usually syphilis IgG antibodies (SYPIGG), to make an accurate diagnosis. When there is discordance between the results of these two assay types, a second treponemal test is required for a more accurate diagnosis. With the advent of newer, high throughput, sensitive treponemal-specific tests, FTA-ABS is no longer recommended as a secondary confirmation test for syphilis because of its complexity and being highly subject to interpretation.

Recent CDC Guidelines recommend that Treponema pallidum Antibody by TP-PA (Test Order Code MHATP) is ordered in place of TPA-ABS for secondary syphilis confirmation in both the reverse and traditional testing algorithms. As a result, ACL Laboratories will discontinue offering Treponema Pallidum Antibody, IgG by IFA (FTA-ABS), Serum (Test Order Code FTABR). TP-PA is a useful diagnostic aid in patients positive with RPR but negative for Syphilis IgG antibodies and patients who present with atypical signs of primary, secondary, or late syphilis. In late syphilis, TP-PA results agree with FTA 99%.

Reference:
CDC 2015 Sexually Transmitted Diseases Treatment Guidelines https://www.cdc.gov/std/tg2015/syphilis.htm