



Test Bulletin

February 2023

ACL Implements New Methodology for Cystic Fibrosis Carrier Screening (Test Order Code CFCS / LAB11337)

Effective Tuesday, February 21, 2023, ACL Laboratories will implement a new methodology for Cystic Fibrosis (CF) carrier screening by Next Generation Sequencing (NGS). The TruSight Cystic Fibrosis 139-Variant Assay (Illumina) is a qualitative in vitro diagnostic system used to simultaneously detect 139 clinically relevant cystic fibrosis disease-causing mutations and variants of the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene in genomic DNA isolated from human peripheral whole blood specimens. The variants include those recommended in 2004 by the American College of Medical Genetics (ACMG) and in 2011 by the American College of Obstetricians and Gynecologists (ACOG). The TruSight Cystic Fibrosis 139-Variant Assay is an FDA-approved assay.

Based on an internal evaluation, ACL Laboratories has demonstrated that variants detected on the current CF Luminex 60 variants multiplex assay and the new NGS assay are highly correlated. The new assay is designed to identify a specific subset of known variants in the CFTR gene, but does not include all variants identified in the CFTR gene. The assay offers large CF variant panel to provide comprehensive detection across diverse ethnic demographics.

CFCS is part of Prenatal Carrier Screen Panel (Test Order Code PCSPNL / LAB10171), which includes Next-Generation Sequencing for Cystic Fibrosis Carrier Screening (Test Order Code LAB11337), Fragile X Diagnosis (Test Order Code LAB9926), and Spinal Muscular Atrophy (SMA) Copy Number Analysis (Test Order Code LAB10172).

Effective Tuesday, February 21, 2023, Cystic Fibrosis Mutation Panel (Test Order Code CFMP / LAB8798) will be discontinued.

Required Specimen: 6.0 mL (minimum 1.0 mL) in a pink EDTA or lavender EDTA tube

Transport: Refrigerated

Performed: Weekdays

Reporting time: Final within 10 days

Performing Site: Illinois Central Laboratory – Molecular Pathology

For additional information, please contact:

ACL Laboratories Molecular Pathology Department at 847-349-7182,

Michael Mihalov, MD - Medical Director at 847-349-7401,

Aida Catic, PhD- Clinical Laboratory Director at 847-349-7464, or

Lech Mazur, MS - Technical Director at 847-349-7185

ACL Removes Ordering Restrictions

Estradiol, Pediatric (Test Order Code LAB9518) and LH, Pediatric (Test Order Code LAB9647) orders were restricted and only available to Illinois patients. **Effective Tuesday, February 21, 2023**, restrictions will be removed. Testing will be available to inpatients and outpatients in both Illinois and Wisconsin. Specimen information for each test is found below.

| Specimen Requirements | Estradiol, Pediatric Test Order Code LAB9518 | LH, Pediatric Test Order Code LAB9647 |
|------------------------|---|---|
| Collection Tube | Gold Gel, Lavender (EDTA) or Green (Heparin) tube | Gold Gel or Lavender (EDTA) |
| Specimen Type | Serum or Plasma | Serum or Plasma |
| Volume | 3.0mL | 1.0mL |
| Temperature | Frozen | Frozen |
| Stability | 2 years | 200 days |
| TAT | 12 days | 12 days |
| Performing Lab | Endocrine Sciences | Endocrine Sciences |
| Additional Information | Please submit separate frozen specimens for each test requested | Please submit separate frozen specimens for each test requested |

Please contact ACL Laboratories Referral testing with questions at 847-349-7382.

Molecular Testing/Microbiology Culture Help Chart (Based on testing ordered in addition to a GPPNL)

Organisms detected by **Gastrointestinal Pathogen Panel by PCR (GPPNL)**: Bacteria and Bacterial Toxins (*E. coli* O157, Enteroaggregative *E. coli* (EAEC), Enteropathogenic *E. coli* (EPEC), Enterotoxigenic *E. coli* (ETEC) Shigella/Enteroinvasive *E. coli* (EIEC), *Plesiomonas shigelloides*, *Salmonella* spp, *Campylobacter* spp. Shiga-toxin producing *E. coli* (STEC), *Vibrio cholerae*, *Yersinia enterocolitica*) / Parasites (*Giardia lamblia*, *Entamoeba histolytica*, *Cryptosporidium* spp., *Cyclospora cayetanensis*)/ Viruses (Adenovirus F40/41, Astrovirus, Rotavirus A, Norovirus GI/GII, Sapovirus)

Organisms detected by **Stool, Bacterial Culture (STOCL)**: *Salmonella* spp., *Shigella* spp., Shiga-toxin producing *E. coli*, *Campylobacter*, *Aeromonas*, and *Plesiomonas*. NOTE: *Campylobacter* and Shiga toxin producing *E. coli* are detected by antigen testing rather than culture.

Organisms detected by **Gastrointestinal Parasites Panel by PCR (GPAX)**: Parasites (*Giardia lamblia*, *Entamoeba histolytica*, *Cryptosporidium* spp.)

| Test Ordered (in Addition to GPPNL) | | Test Performed by | Action | Explanation | Specimen Container Type |
|-------------------------------------|--------------------------|---|---|--|---|
| STOCL | Stool, Bacterial Culture | <p>STOCL</p> <p>For WI Sites: ACL Microbiology – Wisconsin</p> <p>For IL Sites: ACL Microbiology – Illinois</p> <p>GPPNL</p> <p>For WI Sites: ACL Microbiology – Wisconsin</p> <p>For IL Sites: ACL Microbiology – Illinois</p> | <p>If STOCL and GPPNL are ordered together on the same specimen: STOCL will be canceled and re-ordered as Aeromonas, Bacterial Culture (AESTCL). This will occur automatically in most cases when ordered in EPIC for inpatients and ADMG orders (notification not required).</p> <p>For outpatients, call clients to verify preferred orders. If client requests, cancel the STOCL and order AESTCL.</p> | <p>Advantages of GPPNL over STOCL:</p> <ul style="list-style-type: none"> The GPPNL tests for the majority of the pathogens screened for by the STOCL, but with a greater sensitivity of detection (can generally detect a smaller amount of organism in a sample) because it uses PCR, which detects organism DNA/RNA. GPPNL tests for more organisms than culture, such as some parasites and viruses <p>Disadvantages of GPPNL over STOCL:</p> <ul style="list-style-type: none"> GPPNL cannot currently detect <i>Aeromonas</i>, which is currently screened for by the STOCL. Need <i>Aeromonas</i>, Bacterial culture (AESTCL) to cover screening for this organism. GPPNL is much more expensive than culture. GPPNL should not be used as test of cure since it can detect both living and dead organisms. Sensitivities cannot be performed on a positive GPPNL unless a subsequent STOCL is ordered. Sensitivities can readily be performed on a positive STOCL for appropriate organisms. | Cary Blair (Enteric Pathogen Preservative Vial) |
| ROTV | Rotavirus Antigen Screen | <p>For WI Sites: ACL Microbiology – Wisconsin</p> <p>For IL Sites: ACL Microbiology – Illinois</p> | Take No Action | The Rapid Rotavirus Antigen Screen can be performed in addition to the GPPNL since it offers immediate results to the physician for treatment purposes before the GPPNL can be performed. | Sterile container. (Unpreserved stool) |
| VIBCL | Vibrio Culture | <p>For WI Sites: ACL Microbiology – Wisconsin</p> <p>For IL Sites: ACL Microbiology – Illinois</p> | Credit as a Duplicate (if physician is only looking for <i>Vibrio cholerae</i>) | <p>The GPPNL only tests for <i>Vibrio cholerae</i> with a greater sensitivity of detection over culture.</p> <p>However, it does not test for other <i>Vibrio</i> species such as <i>V. parahaemolyticus</i>.</p> | Cary Blair (Enteric Pathogen Preservative Vial) |

| Test Ordered (in Addition to GPPNL) | | Test Performed by | Action | Explanation | Specimen Container Type |
|-------------------------------------|------------------------------|---|--|---|---|
| YERCL | Yersinia Culture | For WI Sites: ACL Microbiology – Wisconsin For IL Sites: ACL Microbiology – Illinois | Credit as a Duplicate (if physician is only looking for <i>Yersinia enterocolitica</i>) | The GPPNL tests for <i>Yersinia enterocolitica</i> with a greater sensitivity of detection over culture. However, it does not test for other <i>Yersinia</i> species such as <i>Y. pseudotuberculosis</i> or <i>Y. pestis</i> . | Cary Blair (Enteric Pathogen Preservative Vial) |
| O&P Fecal | Ova and Parasite Exam, Fecal | For WI Sites: ARUP (Sendout) For IL Sites: ARUP (Sendout) | Take No Action | While the GPPNL test for a few parasites (<i>Cryptosporidium</i> , <i>Cyclospora</i> , <i>Giardia</i> and <i>Entamoeba histolytica</i>), it is not a comprehensive parasite exam like the OVAP. | SAF (Formalin Preservative vial) |

The charts below have been updated. Please review and if you have questions or need further clarification, please contact ACL Client Services at 1.800.877.7016.



Validated Specimen Matrix



| Collection Kit | Sample Type | LAB9913 (CT/NG) | LAB9912 (CT) | LAB9928 (NG) | LAB9964 (TV) | LAB9957 (BV) | LAB9958 (CV/TV) | LAB9960 (MG) | LAB9961 (BV/CV/TV/MG) | LAB9934 (HSV 1&2) | Aptima HPV | Aptima HPV Genotype |
|---|-----------------------------|-----------------|--------------|--------------|--------------|--------------|-----------------|--------------|-----------------------|-------------------|------------|---------------------|
| ThinPrep Pap Vial  | Cervicovaginal | X | X | X | X | | | | | | X | X |
| | Anal/rectal | | | | | | | | | | X | X |
| Aptima Multitest Swab  | Vaginal (Clinician Collect) | X | X | X | X | X | X | X | X | X | | |
| | Vaginal (Patient Collect) | X | X | X | | X | X | X | X | | | |
| | Throat | X | X | X | | | | | | | | |
| | Anal/rectal | X | X | X | | | | | | | | |
| | Anogenital Lesion | | | | | | | | | X | | |
| Aptima Unisex Swab  | Endocervical | X | X | X | X | | | X | | | | |
| | Male Urethral | X | X | X | X | | | X | | X | | |
| | Anogenital Lesion | | | | | | | | | X | | |
| Aptima Urine Specimen  | Female Urine | X | X | X | X | | | X | | X | | |
| | Male Urine | X | X | X | X | | | X | | X | | |



ACL Test Order Codes



| Test Order Code | Directory Link | Test Name | Acceptable Collection | | | | Sample Type |
|------------------------------|---|--|-----------------------|------------------|---------------|--------------|-------------------------------------|
| | | | ThinPrep | Aptima MultiTest | Aptima Unisex | Aptima Urine | |
| LAB10332* or Pap Order | https://apps.aurora.org/dos/public/lab/lab10332 | ThinPrep Image-Guided Liquid Based Pap Test (GYN) | X | | | | Cervicovaginal |
| | | ThinPrep Image-Guided Liquid Based Pap Test with reflex to Aptima HPV | | | | | |
| | | ThinPrep Image-Guided Liquid Based Pap Test and Aptima HPV | | | | | |
| | | ThinPrep Image-Guided Liquid Based Pap Test and Aptima HPV with reflex to HPV Genotype 16, 18/45 | | | | | |
| LAB9939 or HPVHR | https://apps.aurora.org/dos/public/lab/lab9939 | Aptima HPV | X | | | | Cervicovaginal, anal/rectal, vulvar |
| LAB9938 or HPVGT | https://apps.aurora.org/dos/public/lab/lab9938 | Aptima HPV Genotype 16, 18/45 | X | | | | Cervicovaginal, anal/rectal, vulvar |
| LAB9053 or CYTOLOGY | https://apps.aurora.org/dos/public/lab/cytology | Cytology Non-Gynecological | X | | | | Anal/rectal, vulvar |

*Note Chlamydia, Gonorrhea and Trichomonas can be added

| Test Order Code | Directory Link | Test Name | Acceptable Collection | | | | Sample Type |
|-------------------------|---|---|-----------------------|------------------|---------------|--------------|--|
| | | | ThinPrep | Aptima MultiTest | Aptima Unisex | Aptima Urine | |
| LAB9913 or CGRNA | https://apps.aurora.org/dos/public/lab/lab9913 | Chlamydia trachomatis / Neisseria gonorrhoeae by NAA | X | X | X | X | Vaginal (clinician or patient collect), Endocervical, Male Urethral, Throat, Rectal, Urine |
| LAB9912 or CTRNA | https://apps.aurora.org/dos/public/lab/lab9912 | Chlamydia trachomatis by NAA | X | X | X | X | Vaginal (clinician or patient collect), Endocervical, Male Urethral, Throat, Rectal, Urine |
| LAB9928 or NGRNA | https://apps.aurora.org/dos/public/lab/lab9928 | Neisseria gonorrhoeae by NAA | X | X | X | X | Vaginal (clinician or patient collect), Endocervical, Male Urethral, Throat, Rectal, Urine |
| LAB9964 or TVRNA | https://apps.aurora.org/dos/public/lab/lab9964 | Trichomonas Vaginalis by NAA | X | X | X | X | Vaginal (clinician collect only), Endocervical, Male Urethral, Urine |
| LAB9960 or SWOMG | https://apps.aurora.org/dos/public/lab/swomg | SwabOne Mycoplasma genitalium by NAA | | X | X | X | Vaginal (clinician or patient collect), Endocervical, Male Urethral, Urine |
| LAB9957 or SWOBV | https://apps.aurora.org/dos/public/lab/swobv | SwabOne Vaginosis by NAA <small>(Lactobacillus species, Gardnerella vaginalis and Atopobium vaginae - 1 test result)</small> | | X | | | Vaginal (clinician or patient collect) |
| LAB9958 or SWOCN | https://apps.aurora.org/dos/public/lab/swocn | SwabOne Candida/Trichomonas Panel by NAA <small>(Candida species, C. glabrata, Trichomoniasis - 3 test results)</small> | | X | | | Vaginal (clinician or patient collect) |
| LAB9961 or SWOPNL | https://apps.aurora.org/dos/public/lab/swopnl | SwabOne Vaginitis Panel by NAA <small>(Bacterial vaginosis, Candida vaginitis, Trichomoniasis, Mycoplasma genitalium - 5 test results)</small> | | X | | | Vaginal (clinician or patient collect) |
| LAB9934 or HSVPCR | https://apps.aurora.org/dos/public/lab/lab9934 | Herpes Simplex Virus 1 & 2 by NAA | | X | X | X | Anogenital lesion, Vaginal (clinician collect only), Male Urethral, Urine |

1/31/2023