



**BlueCross BlueShield**  
of Texas

If a conflict arises between a Clinical Payment and Coding Policy and any plan document under which a member is entitled to Covered Services, the plan document will govern. If a conflict arises between a CPCP and any provider contract pursuant to which a provider participates in and/or provides Covered Services to eligible member(s) and/or plans, the provider contract will govern. "Plan documents" include, but are not limited to, Certificates of Health Care Benefits, benefit booklets, Summary Plan Descriptions, and other coverage documents. Blue Cross and Blue Shield of Texas may use reasonable discretion interpreting and applying this policy to services being delivered in a particular case. BCBSTX has full and final discretionary authority for their interpretation and application to the extent provided under any applicable plan documents.

Providers are responsible for submission of accurate documentation of services performed. Providers are expected to submit claims for services rendered using valid code combinations from Health Insurance Portability and Accountability Act approved code sets. Claims should be coded appropriately according to industry standard coding guidelines including, but not limited to: Uniform Billing Editor, American Medical Association, Current Procedural Terminology, CPT® Assistant, Healthcare Common Procedure Coding System, ICD-10 CM and PCS, National Drug Codes, Diagnosis Related Group guidelines, Centers for Medicare and Medicaid Services National Correct Coding Initiative Policy Manual, CCI table edits and other CMS guidelines.

Claims are subject to the code edit protocols for services/procedures billed. Claim submissions are subject to claim review including but not limited to, any terms of benefit coverage, provider contract language, medical policies, clinical payment and coding policies as well as coding software logic. Upon request, the provider is urged to submit any additional documentation.

## Pathogen Panel Testing

**Policy Number:** CPCPLAB045

**Version** 1.0

**Approval Date:** August 1, 2025

**Plan Effective Date:** October 1, 2025

## Description

The Plan has implemented certain lab management reimbursement criteria. Not all requirements apply to each product. Providers are urged to review Plan documents for eligible coverage for services rendered.

## Reimbursement Information:

**NOTE:** This policy is specific to testing in the outpatient setting. Criteria below do not apply to testing in other than the outpatient setting.

1. Multiplex PCR-based panel testing (up to **5** respiratory pathogens) **may be reimbursable** for individuals who are displaying signs and symptoms of a respiratory tract infection, including at least one of the following:
  - a. A temperature  $\geq 102^{\circ}$  F;
  - b. Pronounced dyspnea;
  - c. Tachypnea;
  - d. Tachycardia.
2. Multiplex PCR-based panel testing of **6 or more** respiratory pathogens **is not reimbursable**.
3. Multiplex PCR-based panel testing of pathogens in cerebral spinal fluid (CSF) **is not reimbursable**.
4. Molecular detection-based panel testing of pathogens in the blood **is not reimbursable**.
5. Molecular detection-based panel testing of urine pathogens for the diagnosis of urinary tract infections (e.g., GENETWORx Molecular PCR UTI Test) **is not reimbursable**.
6. Molecular-based panel testing to screen for or diagnose wound infections (e.g., GENETWORx PCR Wound Testing) **is not reimbursable**.
7. Molecular-based panel testing for general screening of microorganisms (e.g., MicroGenDX qPCR+NGS) **is not reimbursable**.

## Procedure Codes

The following is not an all-encompassing code list. The inclusion of a code does not guarantee it is a covered service or eligible for reimbursement.

Codes
87154, 87483, 87631, 87632, 87633, 87636, 87637, 0068U, 0086U, 0109U, 0112U, 0115U, 0140U, 0141U, 0142U, 0152U, 0240U, 0241U, 0321U, 0323U, 0370U, 0371U, 0373U, 0374U, 0441U, 0442U, 0480U, 0504U, 0531U, 0590U, 0593U

## References:

- Almonacid, D. E., Kraal, L., Ossandon, F. J., Budovskaya, Y. V., Cardenas, J. P., Bik, E. M., Goddard, A. D., Richman, J., & Apte, Z. S. (2017). 16S rRNA gene sequencing and healthy reference ranges for 28 clinically relevant microbial taxa from the human gut microbiome. *PLOS ONE*, *12*(5), e0176555.  
<https://doi.org/10.1371/journal.pone.0176555>
- American Society for Microbiology. (2017). *MolDX: Multiplex Nucleic Acid Amplified Tests for Respiratory Viral Panels (DL37301)*.  
<https://www.amp.org/AMP/assets/File/position-statements/2017/JointCommentLettertoNoridioanJeforMultiplexViralPanelTests-Respiratory-DL37301.pdf>
- Armstrong, D., & Meyr, A. (2024, January 12). *Basic principles of wound management*.  
<https://www.uptodate.com/contents/basic-principles-of-wound-management>
- ASCP. (2019). *Do not routinely order broad respiratory pathogen panels unless the result will affect patient management*. <https://www.choosingwisely.org/clinician-lists/ascp-broad-respiratory-pathogen-panels/>
- Axelrad, J. E., Freedberg, D. E., Whittier, S., Greendyke, W., Lebwohl, B., & Green, D. A. (2019). Impact of Gastrointestinal Panel Implementation on Health Care Utilization and Outcomes. *J Clin Microbiol*, *57*(3).  
<https://doi.org/10.1128/jcm.01775-18>
- Babady, N. E., England, M. R., Jurcic Smith, K. L., He, T., Wijetunge, D. S., Tang, Y. W., Chamberland, R. R., Menegus, M., Swierkosz, E. M., Jerris, R. C., & Greene, W. (2018). Multicenter Evaluation of the ePlex Respiratory Pathogen Panel for the Detection of Viral and Bacterial Respiratory Tract Pathogens in Nasopharyngeal Swabs. *J Clin Microbiol*, *56*(2). <https://doi.org/10.1128/jcm.01658-17>
- Banerjee, R., Teng, C. B., Cunningham, S. A., Ihde, S. M., Steckelberg, J. M., Moriarty, J. P., Shah, N. D., Mandrekar, J. N., & Patel, R. (2015). Randomized Trial of Rapid Multiplex Polymerase Chain Reaction-Based Blood Culture Identification and Susceptibility Testing. *Clin Infect Dis*, *61*(7), 1071-1080.  
<https://doi.org/10.1093/cid/civ447>
- Beal, S. G., Tremblay, E. E., Toffel, S., Velez, L., & Rand, K. H. (2018). A Gastrointestinal PCR Panel Improves Clinical Management and Lowers Health Care Costs. *J Clin Microbiol*, *56*(1). <https://doi.org/10.1128/jcm.01457-17>
- BioCode. (2024a). *FDA-Cleared Gastrointestinal Pathogen Panel (GPP)*.  
[https://www.apbiocode.com/gi\\_panel.htm](https://www.apbiocode.com/gi_panel.htm)
- BioCode. (2024b). *FDA-Cleared Respiratory Pathogen Panel (RPP)*.  
[https://apbiocode.com/rpp\\_panel.htm](https://apbiocode.com/rpp_panel.htm)
- BioFire. (2023a). *The BioFire® FilmArray® Blood Culture Identification (BCID) Panel*.  
<https://www.biofiredx.com/products/the-filmarray-panels/filmarraybcid/>
- BioFire. (2023b). *The BioFire® FilmArray® Gastrointestinal (GI) Panel*.  
<https://www.biofiredx.com/products/the-filmarray-panels/filmarraygi/>
- BioFire. (2023c). *The BioFire® FilmArray® Meningitis/Encephalitis (ME) Panel*.  
<https://www.biofiredx.com/products/the-filmarray-panels/filmarrayme/>
- BioFire. (2023d). *The BioFire® FilmArray® Respiratory 2.1 (RP2.1) Panel*.  
<https://www.biofiredx.com/products/the-filmarray-panels/filmarrayrp/>
- Bonkat, G., Bartoletti, R., Bruyere, F., Cai, T., Geerlings, S. E., Koves, B., Schubert, F., Wagenlehner, F., Devlies, W., Horvath, J., Mantica, G., Mezei, T., Pilatz, A.,

- Pradere, B., & Veeratterapillay, R. (2023, March ). *European Association of Urology (EAU) Guidelines on Urological Infections*. <http://uroweb.org/guideline/urological-infections/#3>
- Bonnin, P., Miszczak, F., Kin, N., Resa, C., Dina, J., Gouarin, S., Viron, F., Morello, R., & Vabret, A. J. B. I. D. (2016). Study and interest of cellular load in respiratory samples for the optimization of molecular virological diagnosis in clinical practice [journal article]. *16*(1), 384. <https://doi.org/10.1186/s12879-016-1730-9>
- Buss, S. N., Leber, A., Chapin, K., Fey, P. D., Bankowski, M. J., Jones, M. K., Rogatcheva, M., Kanack, K. J., & Bourzac, K. M. (2015). Multicenter evaluation of the BioFire FilmArray gastrointestinal panel for etiologic diagnosis of infectious gastroenteritis. *J Clin Microbiol*, *53*(3), 915-925. <https://doi.org/10.1128/jcm.02674-14>
- Caliendo, A. M. (2011). Multiplex PCR and Emerging Technologies for the Detection of Respiratory Pathogens. *Clinical Infectious Diseases*, *52*(suppl\_4), S326-S330. <https://doi.org/10.1093/cid/cir047>
- Caliendo, A. M., Gilbert, D. N., Ginocchio, C. C., Hanson, K. E., May, L., Quinn, T. C., Tenover, F. C., Alland, D., Blaschke, A. J., Bonomo, R. A., Carroll, K. C., Ferraro, M. J., Hirschhorn, L. R., Joseph, W. P., Karchmer, T., MacIntyre, A. T., Reller, L. B., Jackson, A. F., & for the Infectious Diseases Society of, A. (2013). Better Tests, Better Care: Improved Diagnostics for Infectious Diseases. *Clinical Infectious Diseases*, *57*(suppl\_3), S139-S170. <https://doi.org/10.1093/cid/cit578>
- Cardwell, S. M., Crandon, J. L., Nicolau, D. P., McClure, M. H., & Nailor, M. D. (2016). Epidemiology and economics of adult patients hospitalized with urinary tract infections. *Hosp Pract (1995)*, *44*(1), 33-40. <https://doi.org/10.1080/21548331.2016.1133214>
- CDC. (2024a). *About Meningococcal Disease*. <https://www.cdc.gov/meningococcal/about/index.html>
- CDC. (2024b). *About Sepsis*. <https://www.cdc.gov/sepsis/about/>
- CDC. (2024c). *Bacterial Meningitis*. <https://www.cdc.gov/meningitis/about/bacterial-meningitis.html>
- CDC. (2024d, 03/06/2024). *Clinical Testing and Diagnosis for CDI*. <https://www.cdc.gov/c-diff/hcp/diagnosis-testing/index.html>
- CDC. (2024e). *Fungal Meningitis*. <https://www.cdc.gov/meningitis/about/fungal-meningitis.html>
- Chang, S.-S., Hsieh, W.-H., Liu, T.-S., Lee, S.-H., Wang, C.-H., Chou, H.-C., Yeo, Y. H., Tseng, C.-P., & Lee, C.-C. (2013). Multiplex PCR System for Rapid Detection of Pathogens in Patients with Presumed Sepsis – A Systemic Review and Meta-Analysis. *PLOS ONE*, *8*(5), e62323. <https://doi.org/10.1371/journal.pone.0062323>
- Claas, E. C., Burnham, C. A., Mazzulli, T., Templeton, K., & Topin, F. (2013). Performance of the xTAG(R) gastrointestinal pathogen panel, a multiplex molecular assay for simultaneous detection of bacterial, viral, and parasitic causes of infectious gastroenteritis. *J Microbiol Biotechnol*, *23*(7), 1041-1045.
- CMS. (2022). *Local Coverage Determination (LCD): Foodborne Gastrointestinal Panels Identified by Multiplex Nucleic Acid Amplification Tests (NAATs) (L37766)*. <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=37766>

- Couturier, M. R., Lee, B., Zelyas, N., & Chui, L. (2011). Shiga-toxigenic *Escherichia coli* detection in stool samples screened for viral gastroenteritis in Alberta, Canada. *J Clin Microbiol*, *49*(2), 574-578. <https://doi.org/10.1128/jcm.01693-10>
- Cybulski, R. J., Jr., Bateman, A. C., Bourassa, L., Bryan, A., Beail, B., Matsumoto, J., Cookson, B. T., & Fang, F. C. (2018). Clinical Impact of a Multiplex Gastrointestinal Polymerase Chain Reaction Panel in Patients With Acute Gastroenteritis. *Clin Infect Dis*, *67*(11), 1688-1696. <https://doi.org/10.1093/cid/ciy357>
- Dando, S. J., Mackay-Sim, A., Norton, R., Currie, B. J., St John, J. A., Ekberg, J. A., Batzloff, M., Ulett, G. C., & Beacham, I. R. (2014). Pathogens penetrating the central nervous system: infection pathways and the cellular and molecular mechanisms of invasion. *Clin Microbiol Rev*, *27*(4), 691-726. <https://doi.org/10.1128/cmr.00118-13>
- Fernandez-Soto, P., Sanchez-Hernandez, A., Gandasegui, J., Bajo Santos, C., Lopez-Aban, J., Saugar, J. M., Rodriguez, E., Vicente, B., & Muro, A. (2016). Strong-LAMP: A LAMP Assay for *Strongyloides* spp. Detection in Stool and Urine Samples. Towards the Diagnosis of Human Strongyloidiasis Starting from a Rodent Model. *PLoS Negl Trop Dis*, *10*(7), e0004836. <https://doi.org/10.1371/journal.pntd.0004836>
- GenetWorx. (2024). *Wounds Pathogen Panel*. <https://www.genetworx.com/services/wound-pathogen-panel>
- GenMark. (2020). *Blood Culture Identification (BCID) Panels*. <https://pubmed.ncbi.nlm.nih.gov/31996444/>
- GenMark. (2023). *Respiratory Pathogen (RP) Panel and NEW Respiratory Pathogen Panel 2 (RP2)*. <https://www.genmarkdx.com/solutions/panels/eplex-panels/respiratory-pathogen-panel/>
- Ginocchio, C. C. (2007). Detection of respiratory viruses using non-molecular based methods. *J Clin Virol*, *40 Suppl 1*, S11-14. [https://doi.org/10.1016/s1386-6532\(07\)70004-5](https://doi.org/10.1016/s1386-6532(07)70004-5)
- Ginocchio, C. C., Zhang, F., Manji, R., Arora, S., Bornfreund, M., Falk, L., Lotlikar, M., Kowerska, M., Becker, G., Korologos, D., de Geronimo, M., & Crawford, J. M. (2009). Evaluation of multiple test methods for the detection of the novel 2009 influenza A (H1N1) during the New York City outbreak. *J Clin Virol*, *45*(3), 191-195. <https://doi.org/10.1016/j.jcv.2009.06.005>
- Gyawali, B., Ramakrishna, K., & Dharmoon, A. S. (2019). Sepsis: The evolution in definition, pathophysiology, and management. *SAGE Open Med*, *7*, 2050312119835043. <https://doi.org/10.1177/2050312119835043>
- Hansen, L. S., Lykkegaard, J., Thomsen, J. L., & Hansen, M. P. (2020). Acute lower respiratory tract infections: Symptoms, findings and management in Danish general practice. *Eur J Gen Pract*, *26*(1), 14-20. <https://doi.org/10.1080/13814788.2019.1674279>
- Hanson, K. E., Azar, M. M., Banerjee, R., Chou, A., Colgrove, R. C., Ginocchio, C. C., Hayden, M. K., Holodiny, M., Jain, S., Koo, S., Levy, J., Timbrook, T. T., & Caliendo, A. M. (2020). Molecular Testing for Acute Respiratory Tract Infections: Clinical and Diagnostic Recommendations From the IDSA's Diagnostics Committee. *Clin Infect Dis*, *71*(10), 2744-2751. <https://doi.org/10.1093/cid/ciaa508>
- Hill, A. T., Gold, P. M., El Solh, A. A., Metlay, J. P., Ireland, B., & Irwin, R. S. (2019). Adult Outpatients With Acute Cough Due to Suspected Pneumonia or Influenza: CHEST

- Guideline and Expert Panel Report. *Chest*, 155(1), 155-167.  
<https://doi.org/10.1016/j.chest.2018.09.016>
- Hooton, T. M., & Gupta, K. (2024, March 19). *Acute complicated urinary tract infection (including pyelonephritis) in adults*. Wolters Kluwer.  
<https://www.uptodate.com/contents/acute-complicated-urinary-tract-infection-including-pyelonephritis-in-adults>
- Humphrey, J. M., Ranbhise, S., Ibrahim, E., Al-Romaihi, H. E., Farag, E., Abu-Raddad, L. J., & Glesby, M. J. (2016). Multiplex Polymerase Chain Reaction for Detection of Gastrointestinal Pathogens in Migrant Workers in Qatar. *95*(6), 1330-1337.  
<https://doi.org/10.4269/ajtmh.16-0464>
- Humphries, R. M., & Linscott, A. J. (2015). Laboratory diagnosis of bacterial gastroenteritis. *Clin Microbiol Rev*, 28(1), 3-31. <https://doi.org/10.1128/cmr.00073-14>
- Jo, S. J., Kang, H. M., Kim, J. O., Cho, H., Heo, W., Yoo, I. Y., & Park, Y. J. (2021). Evaluation of the BioFire Gastrointestinal Panel to Detect Diarrheal Pathogens in Pediatric Patients. *Diagnostics (Basel)*, 12(1).  
<https://doi.org/10.3390/diagnostics12010034>
- La Hoz, R. M., & Morris, M. I. (2019). Intestinal parasites including *Cryptosporidium*, *Cyclospora*, *Giardia*, and *Microsporidia*, *Entamoeba histolytica*, *Strongyloides*, *Schistosomiasis*, and *Echinococcus*: Guidelines from the American Society of Transplantation Infectious Diseases Community of Practice. *Clin Transplant*, 33(9), e13618. <https://doi.org/10.1111/ctr.13618>
- Lamy, B., Sundqvist, M., & Idelevich, E. A. (2020). Bloodstream infections - Standard and progress in pathogen diagnostics. *Clin Microbiol Infect*, 26(2), 142-150.  
<https://doi.org/10.1016/j.cmi.2019.11.017>
- Leber, A. L., Everhart, K., Balada-Llasat, J. M., Cullison, J., Daly, J., Holt, S., Lephart, P., Salimnia, H., Schreckenberger, P. C., Desjarlais, S., Reed, S. L., Chapin, K. C., LeBlanc, L., Johnson, J. K., Soliven, N. L., Carroll, K. C., Miller, J. A., Dien Bard, J., Mestas, J., . . . Bourzac, K. M. (2016). Multicenter Evaluation of BioFire FilmArray Meningitis/Encephalitis Panel for Detection of Bacteria, Viruses, and Yeast in Cerebrospinal Fluid Specimens. *J Clin Microbiol*, 54(9), 2251-2261.  
<https://doi.org/10.1128/jcm.00730-16>
- Liesenfeld, O., Lehman, L., Hunfeld, K. P., & Kost, G. (2014). Molecular diagnosis of sepsis: New aspects and recent developments. *European journal of microbiology & immunology*, 4(1), 1-25. <https://doi.org/10.1556/EuJMI.4.2014.1.1>
- Liesman, R. M., Strasburg, A. P., Heitman, A. K., Theel, E. S., Patel, R., & Binnicker, M. J. (2018). Evaluation of a Commercial Multiplex Molecular Panel for Diagnosis of Infectious Meningitis and Encephalitis. *J Clin Microbiol*, 56(4).  
<https://doi.org/10.1128/jcm.01927-17>
- Liu, J., Kabir, F., Manneh, J., Lertsethtakarn, P., Begum, S., Gratz, J., Becker, S. M., Operario, D. J., Taniuchi, M., Janaki, L., Platts-Mills, J. A., Haverstick, D. M., Kabir, M., Sobuz, S. U., Nakjarung, K., Sakpaisal, P., Silapong, S., Bodhidatta, L., Qureshi, S., . . . Houpt, E. R. (2014). Development and assessment of molecular diagnostic tests for 15 enteropathogens causing childhood diarrhoea: a multicentre study. *Lancet Infect Dis*, 14(8), 716-724. [https://doi.org/10.1016/s1473-3099\(14\)70808-4](https://doi.org/10.1016/s1473-3099(14)70808-4)
- Luminex. (2023a). *NxTAG® Respiratory Pathogen Panel*.  
<https://www.luminexcorp.com/nxtag-respiratory-pathogen-panel/>

- Luminex. (2023b). *xTAG® Gastrointestinal Pathogen Panel (GPP)*.  
<https://www.luminexcorp.com/gastrointestinal-pathogen-panel/>
- Mahony, J. B., Blackhouse, G., Babwah, J., Smieja, M., Buracond, S., Chong, S., Ciccotelli, W., Shea, T., Alnakhli, D., Griffiths-Turner, M., & Goeree, R. (2009). Cost Analysis of Multiplex PCR Testing for Diagnosing Respiratory Virus Infections [10.1128/JCM.00556-09]. *Journal of Clinical Microbiology*, 47(9), 2812.  
<http://jcm.asm.org/content/47/9/2812.abstract>
- McCarty, T. P., Cumagun, P., Meeder, J., Moates, D., Edwards, W. S., Hutchinson, J., Lee, R. A., & Leal, S. M., Jr. (2023). Test Performance and Potential Clinical Utility of the GenMark Dx ePlex Blood Culture Identification Gram-Negative Panel. *Microbiol Spectr*, 11(1), e0409222. <https://doi.org/10.1128/spectrum.04092-22>
- McDonald, Gagliardo, C., Chiu, S., & Di Pentima, M. C. (2020). Impact of a Rapid Diagnostic Meningitis/Encephalitis Panel on Antimicrobial Use and Clinical Outcomes in Children. *Antibiotics (Basel)*, 9(11).  
<https://doi.org/10.3390/antibiotics9110822>
- McDonald, Gerding, D. N., Johnson, S., Bakken, J. S., Carroll, K. C., Coffin, S. E., Dubberke, E. R., Garey, K. W., Gould, C. V., Kelly, C., Loo, V., Shaklee Sammons, J., Sandora, T. J., & Wilcox, M. H. (2018). Clinical Practice Guidelines for Clostridium difficile Infection in Adults and Children: 2017 Update by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA). *Clin Infect Dis*, 66(7), 987-994. <https://doi.org/10.1093/cid/ciy149>
- Medical Diagnostics. (2024a). *OneSwab*. <https://www.mdlab.com/>
- Medical Diagnostics. (2024b). *UroSwab*. <https://www.mdlab.com/>
- Medina, M., & Castillo-Pino, E. (2019). An introduction to the epidemiology and burden of urinary tract infections. *Ther Adv Urol*, 11, 1756287219832172.  
<https://doi.org/10.1177/1756287219832172>
- Meyrier, A. (2024, July 1). *Sampling and evaluation of voided urine in the diagnosis of urinary tract infection in adults*. Wolters Kluwer.  
<https://www.uptodate.com/contents/sampling-and-evaluation-of-voided-urine-in-the-diagnosis-of-urinary-tract-infection-in-adults>
- MicroGenDX. (2019a). *Urology*. <https://microgendx.com/urology/>
- MicroGenDX. (2019b). *Wound Care* <https://microgendx.com/wound-care/>
- Miller, J. M., Pritt, B. S., Theel, E. S., Yao, J. D., Binnicker, M. J., Patel, R., Campbell, S., Carroll, K. C., Chapin, K. C., Gilligan, P. H., Gonzalez, M. D., Jerris, R. C., Kehl, S. C., Richter, S. S., Robinson-Dunn, B., Schwartzman, J. D., Snyder, J. W., Telford, S., III, Thomson, R. B., Jr., & Weinstein, M. P. (2018). A Guide to Utilization of the Microbiology Laboratory for Diagnosis of Infectious Diseases: 2018 Update by the Infectious Diseases Society of America and the American Society for Microbiology. *Clinical Infectious Diseases*, 67(6), e1-e94.  
<https://doi.org/10.1093/cid/ciy381>
- Mormeneo Bayo, S., López González, E., Bellés Bellés, A., Bernet Sánchez, A., Aramburu Arnuelos, J., Jiménez Pérez de Tudela, I., Prats Sánchez, I., & García González, M. (2022). Detection and pathological role of intestinal protozoa in children. *Parasitol Int*, 88, 102558. <https://doi.org/10.1016/j.parint.2022.102558>
- NICE. (2017). *Integrated multiplex PCR tests for identifying gastrointestinal pathogens in people with suspected gastroenteritis (xTAG Gastrointestinal Pathogen Panel, FilmArray GI Panel and Faecal Pathogens B assay)*.  
<https://www.nice.org.uk/guidance/dg26/chapter/1-Recommendations>

- Nijhuis, R. H. T., Guerendiain, D., Claas, E. C. J., & Templeton, K. E. (2017). Comparison of ePlex Respiratory Pathogen Panel with Laboratory-Developed Real-Time PCR Assays for Detection of Respiratory Pathogens. *J Clin Microbiol*, 55(6), 1938-1945. <https://doi.org/10.1128/jcm.00221-17>
- NovaDX. (2023). *NOVADX ABX DIAGNOSIS*. <https://www.novadx.com/abx-uti-testing-menu>
- Onori, M., Coltella, L., Mancinelli, L., Argentieri, M., Menichella, D., Villani, A., Grandin, A., Valentini, D., Raponi, M., & Russo, C. (2014). Evaluation of a multiplex PCR assay for simultaneous detection of bacterial and viral enteropathogens in stool samples of paediatric patients. *Diagn Microbiol Infect Dis*, 79(2), 149-154. <https://doi.org/10.1016/j.diagmicrobio.2014.02.004>
- Operario, D. J., & Houpt, E. (2011). Defining the causes of diarrhea: novel approaches. *Curr Opin Infect Dis*, 24(5), 464-471. <https://doi.org/10.1097/QCO.0b013e32834aa13a>
- Palavecino, E. (2019). *One Sample, Multiple Results The Use of Multiplex PCR for Diagnosis of Infectious Syndromes*. Retrieved 11/1 from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7127374/>
- Pammi, M. (2024, April 4). *Clinical features and diagnosis of bacterial sepsis in the preterm infant (<34 weeks gestation)*. Wolters Kluwer. <https://www.uptodate.com/contents/clinical-features-and-diagnosis-of-bacterial-sepsis-in-the-preterm-infant-less-than34-weeks-gestation>
- Petti, C. A., & Polage, C. R. (2024, June 21). *Molecular diagnosis of central nervous system infections*. Wolters Kluwer. Retrieved 4/5 from <https://www.uptodate.com/contents/molecular-diagnosis-of-central-nervous-system-infections>
- QIAGEN. (2024). *QIAstat-Dx Respiratory SARS-CoV-2 Panel*. <https://www.qiagen.com/us/products/diagnostics-and-clinical-research/infectious-disease/qiastat-dx-syndromic-testing/qiastat-dx-eua-us/>
- Ramers, C., Billman, G., Hartin, M., Ho, S., & Sawyer, M. H. (2000). Impact of a diagnostic cerebrospinal fluid enterovirus polymerase chain reaction test on patient management. *Jama*, 283(20), 2680-2685.
- Ray, G. T., Suaya, J. A., & Baxter, R. (2013). Incidence, microbiology, and patient characteristics of skin and soft-tissue infections in a U.S. population: a retrospective population-based study. *BMC Infect Dis*, 13, 252. <https://doi.org/10.1186/1471-2334-13-252>
- Rhodes, A., Evans, L. E., Alhazzani, W., Levy, M. M., Antonelli, M., Ferrer, R., Kumar, A., Sevransky, J. E., Sprung, C. L., Nunnally, M. E., Rochweg, B., Rubenfeld, G. D., Angus, D. C., Annane, D., Beale, R. J., Bellingham, G. J., Bernard, G. R., Chiche, J. D., Coopersmith, C., . . . Dellinger, R. P. (2017). Surviving Sepsis Campaign: International Guidelines for Management of Sepsis and Septic Shock: 2016. *Crit Care Med*, 45(3), 486-552. <https://doi.org/10.1097/ccm.0000000000002255>
- Riddle, M. S., DuPont, H. L., & Connor, B. A. (2016). ACG Clinical Guideline: Diagnosis, Treatment, and Prevention of Acute Diarrheal Infections in Adults. *Am J Gastroenterol*, 111(5), 602-622. <https://doi.org/10.1038/ajg.2016.126>
- Robinson, C. C., Willis, M., Meagher, A., Giesecker, K. E., Rotbart, H., & Glode, M. P. (2002). Impact of rapid polymerase chain reaction results on management of pediatric patients with enteroviral meningitis. *Pediatr Infect Dis J*, 21(4), 283-286.

- Scallan, E., Griffin, P. M., Angulo, F. J., Tauxe, R. V., & Hoekstra, R. M. (2011). Foodborne illness acquired in the United States--unspecified agents. *Emerg Infect Dis*, 17(1), 16-22. <https://doi.org/10.3201/eid1701.091101p2>
- Schultz, G., Bjarnsholt, T., James, G. A., Leaper, D. J., McBain, A. J., Malone, M., Stoodley, P., Swanson, T., Tachi, M., & Wolcott, R. D. (2017). Consensus guidelines for the identification and treatment of biofilms in chronic nonhealing wounds. *Wound Repair Regen*, 25(5), 744-757. <https://doi.org/10.1111/wrr.12590>
- Seegene. (2020). *Sepsis*. <http://www.arrowdiagnostics.it/download/microbiologia/sepsi/Magicplex-Sepsis-Real-time-Test.pdf>
- Seegene. (2023). *Magicplex™ Sepsis Real-time Test*. [https://www.seegene.com/assays/magicplex\\_sepsis\\_realtime\\_test](https://www.seegene.com/assays/magicplex_sepsis_realtime_test)
- Shane, A. L., Mody, R. K., Crump, J. A., Tarr, P. I., Steiner, T. S., Kotloff, K., Langley, J. M., Wanke, C., Warren, C. A., Cheng, A. C., Cantey, J., & Pickering, L. K. (2017). 2017 Infectious Diseases Society of America Clinical Practice Guidelines for the Diagnosis and Management of Infectious Diarrhea. *Clin Infect Dis*, 65(12), 1963-1973. <https://doi.org/10.1093/cid/cix959>
- Stellrecht, K. A., Harding, I., Woron, A. M., Lepow, M. L., & Venezia, R. A. (2002). The impact of an enteroviral RT-PCR assay on the diagnosis of aseptic meningitis and patient management. *J Clin Virol*, 25 Suppl 1, S19-26.
- Stockmann, C., Rogatcheva, M., Harrel, B., Vaughn, M., Crisp, R., Poritz, M., Thatcher, S., Korgenski, E. K., Barney, T., Daly, J., & Pavia, A. T. (2015). How well does physician selection of microbiologic tests identify *Clostridium difficile* and other pathogens in paediatric diarrhoea? Insights using multiplex PCR-based detection. *Clin Microbiol Infect*, 21(2), 179.e179-115. <https://doi.org/10.1016/j.cmi.2014.07.011>
- Subramony, A., Zachariah, P., Krones, A., Whittier, S., & Saiman, L. (2016). Impact of Multiplex Polymerase Chain Reaction Testing for Respiratory Pathogens on Healthcare Resource Utilization for Pediatric Inpatients. *J Pediatr*, 173, 196-201.e192. <https://doi.org/10.1016/j.jpeds.2016.02.050>
- Surawicz, C. M., Brandt, L. J., Binion, D. G., Ananthakrishnan, A. N., Curry, S. R., Gilligan, P. H., McFarland, L. V., Mellow, M., & Zuckerbraun, B. S. (2013). Guidelines for diagnosis, treatment, and prevention of *Clostridium difficile* infections. *Am J Gastroenterol*, 108(4), 478-498; quiz 499. <https://doi.org/10.1038/ajg.2013.4>
- T2Biosystems. (2024). *T2Bacteria Panel*. <https://www.t2biosystems.com/products-technology/t2bacteria-panel/>
- Thomas, M., & Bomar, P. A. (2023). Upper Respiratory Tract Infection. In *StatPearls*. StatPearls Publishing LLC. <https://pubmed.ncbi.nlm.nih.gov/30422556/>
- Trujillo-Gómez, J., Tsokani, S., Arango-Ferreira, C., Atehortúa-Muñoz, S., Jimenez-Villegas, M. J., Serrano-Tabares, C., Veroniki, A. A., & Florez, I. D. (2022). Biofire FilmArray Meningitis/Encephalitis panel for the aetiological diagnosis of central nervous system infections: A systematic review and diagnostic test accuracy meta-analysis. *EClinicalMedicine*, 44, 101275. <https://doi.org/10.1016/j.eclinm.2022.101275>
- Truong, J., Cointe, A., Le Roux, E., Bidet, P., Michel, M., Boize, J., Mariani-Kurkdjian, P., Caseris, M., Hobson, C. A., Desmarest, M., Titomanlio, L., Faye, A., & Bonacorsi, S.

- (2021). Clinical impact of a gastrointestinal PCR panel in children with infectious diarrhoea. *Arch Dis Child*. <https://doi.org/10.1136/archdischild-2021-322465>
- Tunkel, A. R., Glaser, C. A., Bloch, K. C., Sejvar, J. J., Marra, C. M., Roos, K. L., Hartman, B. J., Kaplan, S. L., Scheld, W. M., & Whitley, R. J. (2008). The Management of Encephalitis: Clinical Practice Guidelines by the Infectious Diseases Society of America. *Clinical Infectious Diseases*, 47(3), 303-327. <https://doi.org/10.1086/589747>
- Tzanakaki, G., Tsopanomichalou, M., Kesanopoulos, K., Matzourani, R., Sioumala, M., Tabaki, A., & Kremastinou, J. (2005). Simultaneous single-tube PCR assay for the detection of *Neisseria meningitidis*, *Haemophilus influenzae* type b and *Streptococcus pneumoniae*. *Clin Microbiol Infect*, 11(5), 386-390. <https://doi.org/10.1111/j.1469-0691.2005.01109.x>
- Uyeki, T. M., Bernstein, H. H., Bradley, J. S., Englund, J. A., File, T. M., Jr., Fry, A. M., Gravenstein, S., Hayden, F. G., Harper, S. A., Hirshon, J. M., Ison, M. G., Johnston, B. L., Knight, S. L., McGeer, A., Riley, L. E., Wolfe, C. R., Alexander, P. E., & Pavia, A. T. (2018). Clinical Practice Guidelines by the Infectious Diseases Society of America: 2018 Update on Diagnosis, Treatment, Chemoprophylaxis, and Institutional Outbreak Management of Seasonal Influenzaa. <https://doi.org/10.1093/cid/ciy866>
- V. Wintzingerode, F., Göbel, U. B., & Stackebrandt, E. (1997). Determination of microbial diversity in environmental samples: pitfalls of PCR-based rRNA analysis. 21(3), 213-229. <https://doi.org/doi:10.1111/j.1574-6976.1997.tb00351.x>
- van Asten, S. A. V., Boers, S. A., de Groot, J. D. F., Schuurman, R., & Claas, E. C. J. (2021). Evaluation of the Genmark ePlex® and QIAstat-Dx® respiratory pathogen panels in detecting bacterial targets in lower respiratory tract specimens. *BMC Microbiol*, 21(1), 236. <https://doi.org/10.1186/s12866-021-02289-w>
- van Rijn, A. L., Nijhuis, R. H. T., Bekker, V., Groeneveld, G. H., Wessels, E., Feltkamp, M. C. W., & Claas, E. C. J. (2018). Clinical implications of rapid ePlex(R) Respiratory Pathogen Panel testing compared to laboratory-developed real-time PCR. *Eur J Clin Microbiol Infect Dis*, 37(3), 571-577. <https://doi.org/10.1007/s10096-017-3151-0>
- Viracor. (2024). *Skin and Soft Tissue Infection Panel TEM-PCR™*. <https://www.eurofins-viracor.com/test-menu/220798p-skin-and-soft-tissue-infection-panel-tem-pcr/>
- Visseaux, B., Le Hingrat, Q., Collin, G., Bouzid, D., Lebourgeois, S., Le Pluart, D., Deconinck, L., Lescure, F.-X., Lucet, J.-C., Bouadma, L., Timsit, J.-F., Descamps, D., Yazdanpanah, Y., Casalino, E., & Houhou-Fidouh, N. (2020). Evaluation of the QIAstat-Dx Respiratory SARS-CoV-2 Panel, the First Rapid Multiplex PCR Commercial Assay for SARS-CoV-2 Detection. *Journal of Clinical Microbiology*, 58(8), e00630-00620. <https://doi.org/10.1128/JCM.00630-20>
- Ward, C., Stocker, K., Begum, J., Wade, P., Ebrahimsa, U., & Goldenberg, S. D. (2015). Performance evaluation of the Verigene(R) (Nanosphere) and FilmArray(R) (BioFire(R)) molecular assays for identification of causative organisms in bacterial bloodstream infections. *Eur J Clin Microbiol Infect Dis*, 34(3), 487-496. <https://doi.org/10.1007/s10096-014-2252-2>
- Watts, G. S., Youens-Clark, K., Slepian, M. J., Wolk, D. M., Oshiro, M. M., Metzger, G. S., Dhingra, D., Cranmer, L. D., & Hurwitz, B. L. (2017). 16S rRNA gene sequencing on a benchtop sequencer: accuracy for identification of clinically important

bacteria. *Journal of applied microbiology*, 123(6), 1584-1596.  
<https://doi.org/10.1111/jam.13590>

Weiss, S. L., Peters, M. J., Alhazzani, W., Agus, M. S. D., Flori, H. R., Inwald, D. P., Nadel, S., Schlapbach, L. J., Tasker, R. C., Argent, A. C., Brierley, J., Carcillo, J., Carrol, E. D., Carroll, C. L., Cheifetz, I. M., Choong, K., Cies, J. J., Cruz, A. T., De Luca, D., . . . Tissieres, P. (2020). Surviving Sepsis Campaign International Guidelines for the Management of Septic Shock and Sepsis-Associated Organ Dysfunction in Children. *Pediatr Crit Care Med*, 21(2), e52-e106.  
<https://doi.org/10.1097/pcc.0000000000002198>

WHO. (2024). *Diarrhoeal disease*. <https://www.who.int/news-room/fact-sheets/detail/diarrhoeal-disease>

Yan, Y., Zhang, S., & Tang, Y. W. (2011). Molecular assays for the detection and characterization of respiratory viruses. *Semin Respir Crit Care Med*, 32(4), 512-526.  
<https://doi.org/10.1055/s-0031-1283288>

Yoo, I. H., Kang, H. M., Suh, W., Cho, H., Yoo, I. Y., Jo, S. J., Park, Y. J., & Jeong, D. C. (2021). Quality Improvements in Management of Children with Acute Diarrhea Using a Multiplex-PCR-Based Gastrointestinal Pathogen Panel. *Diagnostics (Basel)*, 11(7). <https://doi.org/10.3390/diagnostics11071175>

Yoo, J., Park, J., Lee, H. K., Yu, J. K., Lee, G. D., Park, K. G., Oak, H. C., & Park, Y. J. (2019). Comparative Evaluation of Seegene Allplex Gastrointestinal, Luminex xTAG Gastrointestinal Pathogen Panel, and BD MAX Enteric Assays for Detection of Gastrointestinal Pathogens in Clinical Stool Specimens. *Arch Pathol Lab Med*, 143(8), 999-1005. <https://doi.org/10.5858/arpa.2018-0002-OA>

Zhan, Z., Guo, J., Xiao, Y., He, Z., Xia, X., Huang, Z., Guan, H., Ling, X., Li, J., Diao, B., Zhao, H., Kan, B., & Zhang, J. (2020). Comparison of BioFire FilmArray gastrointestinal panel versus Luminex xTAG Gastrointestinal Pathogen Panel (xTAG GPP) for diarrheal pathogen detection in China. *Int J Infect Dis*, 99, 414-420.  
<https://doi.org/10.1016/j.ijid.2020.08.020>

Zhang, H., Morrison, S., & Tang, Y. W. (2015). Multiplex polymerase chain reaction tests for detection of pathogens associated with gastroenteritis. *Clin Lab Med*, 35(2), 461-486. <https://doi.org/10.1016/j.cll.2015.02.006>

## Policy Update History:

Approval Date	Effective Date; Summary of Changes
08/01/2025	10/01/2025; Added codes 0590U, 0593U effective 10/01/2025.
02/05/2025	05/15/2025; Document updated with literature review. The following changes were made to Reimbursement Information: Added note indicating the policy is specific to testing in the outpatient setting. Statements revised to remove leading "In the outpatient setting." Added codes 0441U, 0442U, 0480U, 0531U; removed codes 0151U, 0408U, 0416U. References revised.
09/13/2024	01/01/2025: New policy.