

Molecular Testing for Infectious Disease Working Bibliography

1. Andrews D, Chetty Y, Cooper BS, et al. Multiplex PCR point of care testing versus routine, laboratory-based testing in the treatment of adults with respiratory tract infections: a quasi-randomised study assessing impact on length of stay and antimicrobial use. *BMC Infect Dis.* 2017;17(1):1-11.
2. Babady NE, England MR, Jurcic Smith KL, et al. Multicenter Evaluation of the ePlex Respiratory Pathogen Panel for the Detection of Viral and Bacterial Respiratory Tract Pathogens in Nasopharyngeal Swabs. *J Clin Microbiol.* 2018;56(2):1-11.
3. Babady NE. The FilmArray® Respiratory panel: an automated, broadly multiplexed molecular test for the rapid and accurate detection of respiratory pathogens. *Expert Rev Mol Diagn.* 2013;13(8):779-788.
4. Barlam TF, Cosgrove SE, Abbo LM, et al. Implementing an Antibiotic Stewardship Program: Guidelines by the Infectious Diseases Society of America and the Society for Healthcare Epidemiology of America. *Clin Infect Dis.* 2016;62(10):51-77.
5. Beal SG, Tremblay EE, Toffel S, Velez L, Rand KH. A gastrointestinal PCR panel improves clinical management and lowers health care costs. *J Clin Microbiol.* 2018;56(1):1-9.
6. Beckmann C, and Hirsch HH. Comparing Luminex NxTAG-Respiratory Pathogen Panel and RespiFinder-22 for Multiplex Detection of Respiratory Pathogens. *J Med Virology.* 2016;88:1319-1324.
7. Belliot G, Lopman BA, Ambert-Balay K, Pothier P. The burden of norovirus gastroenteritis: an important foodborne and healthcare-related infection. *Clin Microbiol Infect.* 2014;20(8):724-730.
8. Benirschke RC, McElvania E, Thomson Jr RB, Kaul KL, Das S. Clinical Impact of Rapid Point-of-Care PCR Influenza Testing in an Urgent Care Setting: a Single-Center Study. *J Clin Microbiol.* 2019;57(3):1-7.
9. Binnicker, MJ. Multiplex molecular panels for diagnosis of gastrointestinal infection: performance, result interpretation, and cost-effectiveness. *J Clin Microbiol.* 2015;53(12):3723-3728.
10. Blaschke AJ, Hersh AL, Beekmann SE, Ince D, Polgreen PM, Hanson KE. Unmet diagnostic needs in infectious disease. *Diagn Microbiol Infect Dis.* 2015;81(1):57-59.
11. Bouzid D, Casalino E, Mullaert J, et al. Added value of rapid respiratory syndromic testing at point of care versus central laboratory testing: a controlled clinical trial. *J Antimicrob Chemother.* 2021;76(Supplement_3):iii20-iii27. doi:10.1093/jac/dkab241
12. Brittain-Long R, Westin J, Olofsson S, Lindh M, Andersson LM. Access to a polymerase chain reaction assay method targeting 13 respiratory viruses can reduce antibiotics: a randomised, controlled trial. *BMC Med.* 2011;9(44):1-10.
13. Buss SN, Leber A, Chapin K, et al. Multicenter evaluation of the BioFire FilmArray gastrointestinal panel for etiologic diagnosis of infectious gastroenteritis. *J Clin Microbiol.* 2015;53(3):915-925.
14. Buss SN, Alter R, Iwen PC, Fey PD. Implications of culture-independent panel-based detection of *Cyclospora cayetanensis*. *J Clin Microbiol.* 2013;51(11):3909.
15. Busson L, Bartiaux M, Brahim S, et al. Prospective evaluation of diagnostic tools for respiratory viruses in children and adults. *J Virology Methods.* 2019;266:1-6.
16. Caliendo AM. Multiplex PCR and emerging technologies for the detection of respiratory pathogens. *Clin Infect Dis.* 2011;52 Suppl 4(Suppl 4):S326-S330. doi:10.1093/cid/cir047

17. Cassidy H, Van Genne M, Lizarazo-Forero E, Gard L, Niesters HGM. A discussion of syndromic molecular testing for clinical care. *J Antimicrob Chemother.* 2021;76(Suppl 3):iii58-iii66. doi:10.1093/jac/dkab243
18. Centers for Disease Control and Prevention. *Burden of Foodborne Illness: Findings.* Atlanta, GA: Centers for Disease Control and Prevention, US Dept of Health and Human Services; 2016.
19. Centers for Disease Control and Prevention. CDC's diagnostic multiplex assay for Flu and COVID-19 at public health laboratories and supplies. Retrieved from <https://www.cdc.gov/coronavirus/2019-ncov/lab/multiplex.html> on September 30, 2020 at 1506.
20. Centers for Disease Control and Prevention (CDC). Incidence and trends of infection with pathogens transmitted commonly through food – Foodborne Diseases Active Surveillance Network, 10 US sites, 1996-2012. *MMWR Morb Mortal Wkly Rep.* 2013;62(15):283-287.
21. CLSI. *Molecular Diagnostic Methods for Infectious Diseases.* 3rd ed. CLSI report MM03. Wayne, PA: Clinical and Laboratory Standards Institute; 2015.
22. Cohen SH, Gerding DN, Johnson S, et al. Clinical Practice Guidelines for Clostridium difficile infection in adults: 2010 update by the Society for Healthcare Epidemiology of America (SHEA) and the Infectious Diseases Society of America (IDSA). *Infect Control Hosp Epidemiol.* 2010;31(5):431-455.
23. Connor BA, Rogova M, Whyte O. Use of a multiplex DNA extraction PCR in the identification of pathogens in travelers' diarrhea. *J Travel Med.* 2018;25(1):1-23.
24. Coste JF, Vuiblet V, Moustapha B, et al. Microbiological diagnosis of severe diarrhea in kidney transplant recipients by use of multiplex PCR assays *J Clin Microbiol.* 2013;51(6):1841-1849.
25. Couturier MR, Bard JD. Direct-from-Specimen Pathogen Identification: Evolution of Syndromic Panels. *Clin Lab Med.* 2019;39(3):433-451. doi:10.1016/j.cll.2019.05.005
26. Cybulski RJ, Bateman AC, Bourassa L, et al. Clinical impact of a multiplex gastrointestinal polymerase chain reaction panel in patients with acute gastroenteritis. *Clin Infect Dis.* 2018;67(11):1688-1696.
27. Diaz-Decaro JD, Green NM, Godwin HA. Critical evaluation of FDA-approved respiratory multiplex assays for public health surveillance. *Expert Rev Mol Diagn.* 2018;18(7):631-643. doi:10.1080/14737159.2018.1487294
28. Dien Bard J, McElvania E. Panels and Syndromic Testing in Clinical Microbiology. *Clin Lab Med.* 2020;40(4):393-420. doi:10.1016/j.cll.2020.08.001
29. Dien Bard J, Babady NE. The Successes and Challenges of SARS-CoV-2 Molecular Testing in the United States. *Clin Lab Med.* 2022;42(2):147-160. doi:10.1016/j.cll.2022.02.007
30. Dumkow LE, Worden LJ, Rao SN. Syndromic diagnostic testing: a new way to approach patient care in the treatment of infectious diseases. *J Antimicrob Chemother.* 2021;76(Suppl 3):iii4-iii11. doi:10.1093/jac/dkab245
31. Dunbar S, Das S. Amplification chemistries in clinical virology. *J Clin Virology.* 2019;115:18-31.
32. Dupont HL. Persistent diarrhea: a clinical review. *JAMA.* 2016;315(24):2712-2723.
33. Echavarría M, Marcone DN, Querci M, et al. Clinical impact of rapid molecular detection of respiratory pathogens in patients with acute respiratory infection. *J Clin Virology.* 2018;108:90-95.
34. Ecker, D.J., Sampath, R., Willett, P. et al. The Microbial Rosetta Stone Database: A compilation of global and emerging infectious microorganisms and bioterrorist threat agents. *BMC Microbiol* 5, 19 (2005). <https://doi.org/10.1186/1471-2180-5-19>
35. Edin A, Eilers H, Allard A. Evaluation of the Biofire Filmarray Pneumonia panel plus for lower respiratory tract infections. *Infect Dis.* 2020;52(7):479-488.

36. Fox AS, Rao SN. Syndromic testing for the diagnosis of infectious diseases: the right test if used for the right patient. *J Antimicrob Chemother.* 2021 Sep 23;76(Suppl 3):iii2-iii3. doi: 10.1093/jac/dkab248. PMID: 34555153; PMCID: PMC8460101.
37. Freeman K, Mistry H, Tsertsvadza A, et al. Multiplex tests to identify gastrointestinal bacteria, viruses and parasites in people with suspected infectious gastroenteritis: a systematic review and economic analysis. *Health Technol Assess.* 2017;21(23):1-188.
38. Gadsby NJ, Russell CD, McHugh MP, et al. Comprehensive Molecular Testing for Respiratory Pathogens in Community-Acquired Pneumonia. *Clin Infect Dis.* 2016;62(7):817-823.
39. Garvey MI, Wilkinson MAC, Bradley CW, et al. Impact of a PCR point of care test for influenza A/B on an acute medical unit in a large UK teaching hospital: results of an observational, pre and post intervention study. *Antimicrob Resist Infect Control.* 2019;8:1-8.
40. Gelfer G, Leggett J, Myers J, Wang L, Gilbert DN. The clinical impact of the detection of potential etiologic pathogens of community-acquired pneumonia. *Diagn Microbiol Infect Dis.* 2015;83:400-406.
41. Goldenberg SD, Bacelar M, Brazier P, Bisnauthsing K, Edgeworth JD. A cost benefit analysis of the Luminex xTAG Gastrointestinal Pathogen Panel for detection of infectious gastroenteritis in hospitalised patients. *J Infect.* 2015;70(5):504-511.
42. Graf EH, Pancholi P. Appropriate Use and Future Directions of Molecular Diagnostic Testing. *Curr Infect Dis Rep.* 2020;22(5):1-9.
43. Hammond SP, Gagne LS, Stock SR, et al. Respiratory Virus Detection in Immunocompromised Patients with FilmArray Respiratory Panel Compared to Conventional Methods. *J Clin Microbiol.* 2012;50(10):3216-3221.
44. Hanson KE, Caliendo AM, Arias CA, et al. The Infectious Diseases Society of America Guidelines on the Diagnosis of COVID-19: Molecular Diagnostic Testing [published online ahead of print, 2021 Jan 22]. *Clin Infect Dis.* 2021;ciab048. doi:10.1093/cid/ciab048
45. Hanson KE, Couturier MR. Multiplexed Molecular Diagnostics for Respiratory, Gastrointestinal, and Central Nervous System Infections. *Clin Infect Dis.* 2016;63(10):1361-1367. doi:10.1093/cid/ciw494
46. Hill AT, Gold PM, El Solh AA, et al. Adult Outpatients With Acute Cough Due to Suspected Pneumonia or Influenza. *CHEST.* 2019;155(1):155-167.
47. Huang HS, Tsai CL, Chang J, Hsu TC, Lin S, Lee CC. Multiplex PCR system for the rapid diagnosis of respiratory virus infection: systematic review and meta-analysis. *Clin Microbiol Infect.* 2018;24(10):1055-1063. doi:10.1016/j.cmi.2017.11.018
48. Huang JY, Henao OL, Griffin PM, et al. Infection with pathogens transmitted commonly through food and the effect of increasing use of culture-independent diagnostic tests on surveillance – Foodborne Diseases Active Surveillance Network, 10 US Sites, 2012-2015. *MMWR Morb Mortal Wkly.* 2016;65(14):368-371.
49. Jain S, Self WH, Wunderink RG, et al. Community-Acquired Pneumonia Requiring Hospitalization among U.S. Adults. *N Engl J Med.* 2015;373:415-427.
50. Jiang ZD, DuPont HL. Etiology of travellers' diarrhea. *J Travel Med.* 2017;24(1):S13-S16.
51. Keske S, Ergönül Ö, Tutucu F, Karasian D, Palaoglu E, Can F. The rapid diagnosis of viral respiratory tract infections and its impact on antimicrobial stewardship programs. *Eur J Clin Microbiol Infect Dis.* 2018;37:779-783.
52. Khare R, Espy MJ, Celedinski E, et al. Comparative evaluation of two commercial multiplex panels for detection of gastrointestinal pathogens by use of clinical stool specimens. *J Clin Microbiol.* 2014;52(10):3667-3673.

53. Krishna NK, Cunnion KM. Role of molecular diagnostics in the management of infectious disease emergencies. *Med Clin North Am.* 2012 Nov;96(6):1067-78. doi: 10.1016/j.mcna.2012.08.005. Epub 2012 Sep 27. PMID: 23102477; PMCID: PMC7172584.
54. Lee SH, Ruan SY, Pan SC, Lee TF, Chien JY, Hsueh PR. Performance of a multiplex PCR pneumonia panel for the identification of respiratory pathogens and the main determinants of resistance from the lower respiratory tract specimens of adult patients in intensive care units. *J Microbiol Immunol Infect.* 2019;52(6):920-928. doi:10.1016/j.jmii.2019.10.009
55. Lindsay L, Wolter J, De Coster I, Van Damme P, Verstraeten T. A decade of norovirus disease risk among older adults in upper-middle and high income countries: a systematic review. *BMC Infect Dis.* 2015;15:1-16.
56. May L, Tatro G, Poltavskiy E, et al. Rapid Multiplex Testing for Upper Respiratory Pathogens in the Emergency Department: A Randomized Controlled Trial. *Open Forum Infect Dis.* 2019;6(12):1-8.
57. McDonald LC, Gerding DN, Johnson S, et al. 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.* 2018;66(7):e1-e48.
58. Messacar K, Parker SK, Todd JK, Dominguez SR. Implementation of Rapid Molecular Infectious Disease Diagnostics: the Role of Diagnostic and Antimicrobial Stewardship. *J Clin Microbiol.* 2017;55(3):715-723. doi:10.1128/JCM.02264-16
59. Metlay JP, Waterer GW, Long AC, et al. Diagnosis and Treatment of Adults with Community-acquired Pneumonia. An Official Clinical Practice Guideline of the American Thoracic Society and Infectious Diseases Society of America. *Am J Respir Crit Care Med.* 2019;200(7):45-67.
60. Miller JM, Binnicker MJ, Campbell S, et al. 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. *Clin Infect Dis.* 2018;67(6):e1-e94. doi:10.1093/cid/ciy381
61. Murali S, Langston AA, Nolte FS, Banks, G, Caliendo RN, Caliendo AM. Detection of Respiratory viruses with a multiplex polymerase chain reaction assay (MultiCode-PLx Respiratory Virus Panel) in patients with hematologic malignancies. *Leukemia & Lymphoma.* April 2009;50(4):619-624.
62. Murphy CN, Fowler RC, Iwen PC, Fey PD. Evaluation of the BioFire FilmArray® gastrointestinal panel in a midwestern academic hospital. *Eur J Clin Microbiol Infect Dis.* 2017;36(4):747-754.
63. Muthuri SG, Venkatesan S, Myles PR, et al. Effectiveness of neuraminidase inhibitors in reducing mortality in patients admitted to hospital with influenza A H1N1pdm09 virus infection: a meta-analysis of individual participant data. *Lancet Respir Med.* 2014; 2(5):395-404.
64. Palavecino EL, Williamson JC, Ohl CA. Collaborative Antimicrobial Stewardship: Working with Microbiology. *Infect Dis Clin North Am.* 2020;34(1):51-65. doi:10.1016/j.idc.2019.10.006
65. Patel R. New Developments in Clinical Bacteriology Laboratories. *Mayo Clin Proc.* 2016;91(10):1448-1459. doi:10.1016/j.mayocp.2016.06.020
66. Pawlowski SW, Warren CA, Guerrant R. Diagnosis and Treatment of Acute or Persistent Diarrhea. *Gastroenterology.* 2009 May;136(6):1874-1886.
67. Piralla A, Lunghi G, Ardissino G, et al. FilmArray™ GI panel performance for the diagnosis of acute gastroenteritis or hemorrhagic diarrhea. *BMC Microbiol.* 2017;17(1):1-10.
68. Platts-Mills JA, Operario DJ, Houpt ER. Molecular Diagnosis of Diarrhea: Current Status and Future Potential. *Curr Infect Dis Rep.* 2012 February;14(1):41-46.

69. Poelman R, der Meer JV, der Spek CV, et al. Improved diagnostic policy for respiratory tract infections essential for patient management in the emergency department. *Future Microbiol.* 2020;15(8):623-632. doi:10.2217/fmb-2019-0119
70. Polage CR, Stoddard GJ, Rolfs RT, Petti CA. Physician use of parasite tests in the United States from 1997 to 2006 and in a Utah *Cryptosporidium* outbreak in 2007. *J Clin Microbiol.* 2011;49(2):591-596.
71. Prakash VP, LeBlanc L, Alexander-Scott NE, et al. Use of a culture-independent gastrointestinal multiplex PCR panel during a Shigellosis outbreak: considerations for clinical laboratories and public health. *J Clin Microbiol.* 2015;53(3):1048-1049.
72. Procop GW. Molecular diagnostics for the detection and characterization of microbial pathogens. *Clin Infect Dis.* 2007;45 Suppl 2:S99-S111. doi:10.1086/519259
73. Rader TS 4th, Stevens MP, Bearman G. Syndromic Multiplex Polymerase Chain Reaction (mPCR) Testing and Antimicrobial Stewardship: Current Practice and Future Directions. *Curr Infect Dis Rep.* 2021;23(4):5. doi:10.1007/s11908-021-00748-z
74. Rajagopalan S, Yoshikawa TT. Norovirus infections in long-term care facilities. *J Am Geriatr Soc.* 2016;64(5):1097-1103.
75. Ramanan P, Bryson AL, Binnicker MJ, Pritt BS, Patel R. Syndromic Panel-Based Testing in Clinical Microbiology. *Clin Microbiol Rev.* 2017;31(1):e00024-17. Published 2017 Nov 15. doi:10.1128/CMR.00024-17
76. Ramirez JA, Musher DM, Evans SE, et al. Treatment of Community-Acquired Pneumonia in Immunocompromised Adults: A Consensus Statement Regarding Initial Strategies. *CHEST.* 2020. Online publication June 16, 2020.
77. Rand KH, Tremblay EE, Hoidal M, Fisher LB, Grau KR, Karst SM. Multiplex gastrointestinal pathogen panels: implications for infection control. *Diagn Microbiol Infect Dis.* 2015;82(2):154-157.
78. Rappo U, Schuetz AN, Jenkins SG, et al. Impact of Early Detection of Respiratory Viruses by Multiplex PCR Assay on Clinical Outcomes in Adult Patients. *J Clin Microbiol.* 2016;54(8):2096-2103. doi:10.1128/JCM.00549-16
79. Riddle MS, DuPont HL, Connor BA. ACG Clinical Guideline: diagnosis, treatment and prevention of acute diarrheal infections in adults. *Am J Gastroenterology.* 2016;111:602-622.
80. Riddle MS, Connor BA, Beeching NJ, et al. Guidelines for the prevention and treatment of travelers' diarrhea: a graded expert panel report. *J Travel Med.* 2017;24(1):S63-S80.
81. Rossignol JF, Ayoub A, Ayers MS. Treatment of diarrhea caused by *Giardia intestinalis* and *Entamoeba histolytica* or *E. dispar*: a randomized, double-blind, placebo-controlled study of nitazoxanide. *J Infect Dis.* 2001;184(3):381-384.
82. Samuel LP, Hansen GT, Kraft CS, Pritt BS; ASM Clinical and Public Health Microbiology Committee. The Need for Dedicated Microbiology Leadership in the Clinical Microbiology Laboratory. *J Clin Microbiol.* 2021;59(8):e0154919. doi:10.1128/JCM.01549-19
83. Sanghavi SK, Bullotta A, Husain S, Rinaldo CR. Clinical Evaluation of Multiplex Real-Time PCR Panels for Rapid Detection of Respiratory Viral Infections. *J. Med. Virol.* 2012;84:162-162.
84. Scallan E, Hoekstra RM, Angulo FJ, et al. Foodborne illness acquired in the United States—major pathogens. *Emerg Infect Dis.* 2011;17(1):7-15.
85. Schutze GE, Willoughby RE. *Clostridium difficile* infection in infants and children. *Pediatrics.* 2013;131:196-200.

86. Shane AL, Mody RK, Crump JA, et al. 2017 Infectious Disease Society of America Clinical Practice Guidelines for the diagnosis and management of infectious diarrhea. *Clin Infect Dis*. 2017;65(12):e45-e80.
87. She RC, Polage CR, Caram LB, et al. Performance of diagnostic tests to detect respiratory viruses in older adults. *Diagn Microbiol Infect Dis*. 2010;67(3):246-250.
88. Shea S, Kubota KA, Maguire H, et al. Clinical microbiology laboratories' adoption of culture-independent diagnostic tests is a threat to foodborne-disease surveillance in the United States. *J Clin Microbiol*. 2017;55(1):10-19.
89. Simner PJ, Miller S, Carroll KC. Understanding the Promises and Hurdles of Metagenomic Next-Generation Sequencing as a Diagnostic Tool for Infectious Diseases. *Clin Infect Dis*. 2018;66(5):778-788. doi:10.1093/cid/cix881
90. Spina A, Kerr KG, Cormican M, et al. Spectrum of enteropathogens detected by the FilmArray GI Panel in a multicentre study of community-acquired gastroenteritis. *Clin Microbiol Infect*. 2015;21(8):719-728.
91. Templeton KE, Scheltinga SA, van den Eeden WCJFM, Graffelman AW, van den Broek PJ, Class ECJ. Improved Diagnosis of the Etiology of Community-Acquired Pneumonia with Real-Time Polymerase Chain Reaction. *Clin Infect Dis*. 2005;41(3):345-51.
92. Timbrook TT, Morton JB, McConeghy KW, Caffrey AR, Mylonakis E, LaPlante KL. The Effect of Molecular Rapid Diagnostic Testing on Clinical Outcomes in Bloodstream Infections: A Systematic Review and Meta-analysis. *Clin Infect Dis*. 2017;64(1):15-23. doi:10.1093/cid/ciw649
93. U.S. Food and Drug Administration (FDA) website device approvals, denials and clearances (2020).
94. Uyeki TM, Bernstein HH, Bradley JS, et al. Clinical Practice Guidelines by the Infectious Diseases Society of America: 2018 Update on Diagnosis, Treatment, Chemoprophylaxis, and Institutional Outbreak Management of Seasonal Influenza. *Clin Infect Dis*. 2018:1-47.
95. Vila J. New molecular diagnostic tools in traveller's diarrhea. *J Travel Med*. 2017;24(1):S23-S28.
96. Vos LM, Bruning AHL, Reitsma JB, et al. Rapid Molecular Tests for Influenza, Respiratory Syncytial Virus, and Other Respiratory Viruses: A Systematic Review of Diagnostic Accuracy and Clinical Impact Studies. *Clin Infect Dis*. 2019;69:1243-1253.
97. Wagner K, Springer B, Imkamp F, Opota O, Greub G, Keller PM. Detection of respiratory bacterial pathogens causing atypical pneumonia by multiplex Lightmix® RT-PCR. *Int J Med Microbiol*. 2018;308(3):317-323. doi:10.1016/j.ijmm.2018.01.010
98. Walker DH. Principles of Diagnosis of Infectious Diseases. Pathobiology of Human Disease. 2014:222-5. doi: 10.1016/B978-0-12-386456-7.01713-5. Epub 2014 Aug 21. PMCID: PMC7149376.
99. Woods GL, Walker DH. Detection of infection or infectious agents by use of cytologic and histologic stains. *Clin Microbiol Rev*. 1996 Jul;9(3):382-404. doi: 10.1128/CMR.9.3.382. PMID: 8809467; PMCID: PMC172900.
100. Zhang H, Morrison S, Tang YW. Multiplex polymerase chain reaction tests for detection of pathogens associated with gastroenteritis. *Clin Lab Med*. 2015;35(2):461-486. doi:10.1016/j.cll.2015.02.006