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Impact of Molecular Point-of-Care Testing on Respiratory Virus Management

Literature Review

The effectiveness of PCR point-of-care testing for SARS-CoV-2, flu, and RSV is well-supported by evidence.

- Improved Clinical Outcomes
- Multiple Targets for Accurate Detection
- Reduced Healthcare Associated Costs
- Appropriate Treatment Decisions
- Reduced Time to Results
- Improved Patient Flow and Shortened Isolation Time

PUBLICATIONS

1

Fragkou, P. C. et al. **Performance of point-of care molecular and antigen-based tests for SARS-CoV-2: a living systematic review and meta-analysis.** Clin. Microbiol. Infect. 29, 291–301 (2023)

- Molecular point-of-care tests (POCTs) showed higher sensitivity compared to antigen-based POCTs for detecting SARS-CoV-2 infection.
- The pooled sensitivity for molecular POCTs was 92.8%, while the pooled sensitivity for antigen based POCTs was 70.6%.
- The performance of molecular and antigen-based point-of-care tests (POCTs) for SARS-CoV-2 varies depending on the clinical status of the individuals being tested. Molecular POCTs showed higher sensitivity rates in symptomatic patients compared to antigen based POCTs, which had lower sensitivity rates overall.

2

Jørgensen R.L et al. **Emergence of circulating influenza A H3N2 viruses with genetic drift in the matrix gene: be alert of false-negative test results**. APMIS. 2022 Oct;130(10):612-617. doi: 10.1111/apm.13262. Epub 2022 Aug 10. PMID: 35836366; PMCID: PMC9544743.

- The study highlights the emergence of circulating Influenza A H3N2 viruses with genetic drift in the matrix gene, leading to potential false-negative test results.
- Commercial assay limitations: several commercially available influenza diagnostic assays showed decreased sensitivity in detecting the circulating A(H3N2) strain with genetic drift in the matrix gene. Caution is advised when using single-target matrix gene-based assays.
- Multiplex assays with multiple targets are recommended to ensure accurate detection influenza and avoid false-negative results.

3

Fistera D et al. **Point-of-care PCR testing of SARS-CoV-2 in the emergency department: Influence on workflow and efficiency.** PLoS One. 2023 Aug 3;18(8):e0288906. doi: 10.1371/journal.pone.0288906. PMID: 3753557; PMCID: PMC10399729.

- Rapid PCR testing reduced the time from admission to test result by an average of 14.46 hours compared to conventional PCR.
- Rapid PCR testing resulted in 90% of test results being available within 3 hours, whereas conventional PCR took up to 21 hours.
- The conventional PCR group experienced increased direct costs of €35.74 and lost revenues of €421.06 for each inpatient case compared to the rapid PCR group.

4

Davies, S. et al. **A cost-consequence analysis of the Xpert Xpress CoV-2/Flu/RSV *plus* test strategy for the diagnosis of influenza-like illnesses.** Journal of Medical Economics. 2024 March; 27(1), 430–441. https://doi.org/10.1080/13696998.2024.2313391

- The Xpert **Xpress** CoV-2/Flu/RSV ***plus*** test strategy resulted in cost savings and reduced healthcare resource utilization compared to other testing strategies for influenza-like illnesses (ILI).
- PCR strategies, such as the Xpert **Xpress** test, were more efficient due to improved diagnostic accuracy and reduced need for confirmatory testing.
- Decreased rates of hospitalizations, ICU admissions, mechanical ventilation, and mortality.

PUBLICATIONS

5

Jensen C.B. et al. **Evaluation of the analytical and clinical performance of two RT-PCR based point-of-care tests; Cepheid Xpert® Xpress CoV-2/Flu/RSV plus and SD BioSensor STANDARD™ M10 Flu/RSV/SARS-CoV-2.** Journal of Clinical Virology. 2024 (172). https://doi.org/10.1016/j.jcv.2024.105674.

- Xpert showed 100% clinical sensitivity across all Ct ranges for all four pathogens.
- This study demonstrated enhanced analytical and clinical performance of Xpert **Xpress** CoV-2/Flu/ RSV ***plus*** compared to STANDARD M10 Flu/RSV/SARS-CoV-2, which is crucial for maintaining diagnostic accuracy at every stage of a respiratory infection.
- The diagnostic safety of the Xpert **Xpress** CoV-2/Flu/RSV ***plus*** test is superior compared to the M10 Flu/RSV/SARS-CoV-2 test.

6

Nairz M, Todorovic T, Gehrer CM, et al. **Single-Center Experience in Detecting Influenza Virus, RSV and SARS-CoV-2 at the Emergency Department.** Viruses. 2023;15(2):470. Published 2023 Feb 8. doi:10.3390/v15020470

- Extensive use of the combined RT-PCR test enabled the monitoring of the re-emergence of influenza and RSV detections.
- PCR results for respiratory viruses from a real-life setting at an ED offer valuable insights into infection epidemiology, morbidity, hospital admissions, nosocomial risks, and the impact of preventive measures over several years.

7

Landry ML, Owen M. **Failure to Detect Influenza A H1N1 Highlights the Need for Multiple Gene Targets in Influenza Molecular Tests.** J Clin Microbiol. 2023;61(7): e0044823. doi:10.1128/jcm.00448-23

- Influenza virus can mutate at any time, so sensitivity should be monitored to prevent missed diagnoses that could affect patient care.
- Molecular tests targeting only one influenza A gene are at risk. Therefore, it is essential for all test manufacturers to include multiple gene targets for influenza A, following the approach used for SARS-CoV-2.
- Manufacturers should periodically evaluate their primers and probes against sequences from GISAID and other public genetic databases during flu season.

8

Garvey MI, 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 Jul 16; 8:120.

- POCT for influenza/RSV resulted in an increase in appropriate treatment with oseltamivir, shorter time to isolation, and reduction in nosocomial transmission.
- Recommended that routine POCT be introduced into diagnostic pathways for acute respiratory illness, especially at hospital entry points.

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