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LETTER TO THE EDITOR

Diagnostic Inconsistency in Molecular Viral Detection: Laboratory Diagnostic Case Study

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The precision and dependability of data published in academic literature are crucial in a time when molecular biology-based diagnostics of viral diseases, such as RT-PCR, isothermal amplification, and CRISPR-based diagnostics, are becoming more and more significant in the public health system. However, statistical metrics like sensitivity, specificity, and diagnostic accuracy are frequently found to be inconsistent in laboratory study results. This can be because of sample characteristics, methodological restrictions, or variable control. If these mistakes are not thoroughly considered or conveyed, they may have a direct impact on clinical and policy decisions in addition to affecting researchers' comprehension, particularly when it comes to respiratory infections, where prompt and precise diagnosis is essential for managing patients and controlling outbreaks.

We would like to emphasize this issue and provide insights into the context and methods for interpretation in clinical laboratories. The case study is a report that describes the use of RT-RPA with CRISPR-Cas12a to identify RSV-A and RSV-B [1]. The paper claims that the test has 100% specificity for both strains; however, it also reports lower accuracy numbers of 90.32% for RSV-A and 93.55% for RSV-B, indicating a considerable contradiction because 100% specificity implies no false positives. As a result, all errors that diminish accuracy must be caused by false negatives, indicating that the test's sensitivity is insufficient.

However, the study did not directly reveal the sensitivi-

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ty value, nor did it present a confusion matrix or sample-level comparative data, making it difficult to thoroughly evaluate the test kit's clinical performance. Alternative explanations to consider include: a) The amount of virus in the sample may be less than the detection limit of RT-RPA/CRISPR, but it can still be detected using RT-qPCR, b) The efficiency of RT-RPA may be inferior to amplifying small quantities of RNA, c) Variations in environmental variables and operator approaches in resource-constrained scenarios, and d) Inconsistencies between the technique and RT-qPCR, such as using different samples or performing RNA extraction stages.

Although these explanations may help to alleviate some concerns, the lack of transparent disclosure of data, particularly in terms of sensitivity and raw data structure, may also lead to misunderstandings about the tool's true performance and may influence decision-making in situations requiring accurate diagnosis. As a result, it is recommended that researchers and article reviewers prioritize transparent, comprehensive reporting and honest self-criticism to ensure the scientific integrity and safety of the public health system in general.

Declaration of Interest:
None.

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