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Short Communication

Galactomannan VirClia® Monotest (Vircell): Benefits and Critical Points

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Abstract

Vircell Company proposes a new kit that allows for the partial automation of the galactommanan test. This system, in monotest format, theoretically allows samples to be tested when required during the day. Nevertheless, several critical points need to be taken into account with regards to the analytical and post-analytical part.

Keywords: Invasive aspergillosis; Galactomannan; VirClia®; Chemiluminescence Immunoassay (CLIA)

Short Communication

Vircell Company (Granada, Spain) proposes a new CE-IVD test for the detection and determination of galactomannan in serum or plasma of patients at risk of invasive aspergillosis, as well as in bronchoalveolar lavages.

This new test, partly automated, is based on a sandwich-type chemiluminescence immunoassay (CLIA) [1] for the detection of galactomannan antigen.

This test represents a potentially interesting alternative to the classical manual test, ELISA, which can be considered as a "gold standard" for the detection and determination of galactomannan.

In 2020, our laboratory tested the Galactomannan VirClia® Monotest on the VirClia®Lotus automated system from Vircell (provided by BMD - BioMedical Diagnostics, Antwerp, Belgium), in order to evaluate its analytical advantages and disadvantages.

This unitary test allows, throughout the day, to measure individually each sample arriving at the laboratory, thus allowing in principle an optimal management of the flow of requests, as well as a fast return of the results. Furthermore, the result is given in quantitative form, which is an important advantage for this assay test.

The VirClia® Monotest Galactomannan, packed in monotest blocks, allows the analysis to be performed in one hour on the VirClia®Lotus, a fully automated chemiluminescence system for the serology of various infectious diseases [2-4]. Control and calibration reagents are included in each monotest. As with the manual test, ELISA, sample pre-treatment is required making the test on the VirClia®Lotus. This pre-treatment step, allowing the extraction of galactomannan, involves the same steps as for ELISA tests, and requires ≈15 minutes of technical time.

Despite its simple principle of use, the VirClia® Galactomannan Monotest presents a certain number of sensitive points. These issues are important to consider in order to limit the risk of analytical and post-analytical errors.

At the analytical level, several issues arise during sample analysis.

The supplier information (www.vircell.com) is clear, but at the start of our tests, additional technical data were sent to us by the BMD Company in order to limit the risk of analytical errors. It should be noted that these additional recommendations were not present in the initial product data sheet from the supplier. Therefore, an update of the data sheet might be necessary, including these recommendations.

Several important points are indeed specified, to ensure a correct rendering of the results, but an important point is underlined concerning the use of the Virclia®Lotus automated system for this test. In fact, one of the main risks for this test is the environmental contamination of the samples during the analysis, which can lead to false positive results. To limit this risk, the BMD Company recommends using new consumables (distilled water, wash buffer) before each series of tests, and to completely decontaminate the Virclia®Lotus with Mucocit® 4%. These technical constraints greatly limit the use of this test with the flow of daily requests. Thus, it seems preferable to plan the realization of this test in series, in order to limit the use of consumables by the Virclia®Lotus.

Another sensitive point concerns the sample pre-treatment step. Indeed, for this step, no control is planned in parallel with the patient samples, contrarily to manual ELISA tests, which generally provide positive and negative control samples to be pre-treated in parallel with a series of patient samples. Thus, even if the Galactomannan VirClia® Monotest contains control reagents, these controls only allow to verify the proper functioning of the chemiluminescence test on the automated system. The kit does not allow to control the pre-treatment step, which is a critical point for this analysis. It should be noted that this lack of risk control at this critical step is difficult to oppose to the ISO 15189:2012 standard regarding the quality requirements for medical laboratory analysis.

A final critical point concerns the interpretation of the test results. This is not to question the performance of the test itself (one Spanish multicenter study comparing this test with the Platelia™ Bio-Rad ELISA shows rather encouraging results; these results were presented to ECCMID in 2020 [5]). Here, the Galactomannan VirClia® Monotest proposes a positivity index of 0.2. For ELISA tests, the proposed positivity index is generally 0.5. This difference in threshold can be explained mainly by the fact that the chemiluminescence measurement method is different from the ELISA test, which is based

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on an optical density measurement.

This difference in threshold must be explained to clinicians, especially for those who have been working with ELISA tests for several years. Indeed, the threshold of 0.5 is commonly accepted in the medical community, due to the fact that ELISA tests are the most widely used. The 2017 ESCMID recommendations are also in line with this, as they include this 0.5 threshold in their recommendations [6]. Clinician education and awareness is therefore essential to avoid misinterpretation of results.

The Galactomannan VirClia® Monotest (Vircell), which can be used on the Virclia®Lotus automated system, is an interesting alternative for the automation of galactomannan detection. Nevertheless, certain critical points must be taken into consideration in order to avoid any error in the rendering of results, as well as misinterpretation of results by clinicians.

Highlights

- Vircell Company offers an automated test for the detection of galactomannan.
- This test can be performed in serum, plasma or bronchoalveolar lavage.
- The automation of this test requires a high degree of technical rigor.
- The positivity threshold of 0.2 requires a relevant education level of clinicians.

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