



Evaluation of the new Dynamiker cryptococcal antigen Lateral Flow Assay (LFA) in comparison with IMMY LFA and Meridian latex agglutination test

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Background

Cryptococcal meningitis is a serious condition with high morbidity and mortality. Nearly one million cases of cryptococcal meningitis occur each year world-wide, with more than 500,000 deaths, the majority being in sub-Saharan Africa (1). Antigen test can diagnose the condition fast, which is decisive for survival. Recently, two lateral flow assays (LFA), IMMY and Dynamiker have been marketed, one of which has not been published in the literature. Our purpose was to compare the performance of latex agglutination (LA) with that of the two LFA devices.

Materials/methods

We included 25 historical serum and CSF samples (11/14 each). The samples were received for *Cryptococcus* antigen LA testing (CALAS, Meridian, UK). The sample were tested in parallel using the Dynamiker (SSI, Diagnostika, DK) and the IMMY (IMMY, US) LFA devices as recommended by the manufacturer. The LFA results were scored as strongly (+++), moderately (++), weakly (+), and doubtfully positive ((+)) or negative (-) and scores were compared to the LA titre.

Results

For the Dynamiker LFA kit a 100%/100% sensitivity/specificity was achieved when classifying – and (+) as negative and ++++ as positive using the LA as gold standard. If accepting (+) as positive the sensitivity/specificity parameters were 100%/90%. Similarly, for the IMMY test the sensitivity/specificity parameters were 87%/100% when classifying – and (+) as negative and ++++ as positive, but 100%/100% when accepting (+) as positive.

Figure 1 shows the distribution of band intensity of IMMY and Dynamiker LFA (y-axis) compared with the latex agglutinations titre for LA positive samples (x-axis).

As there is no quantitative relation between band intensities of the to LFA and latex agglutination titre, it is not possible to monitor the fluctuation of titre when serum samples for the same patient were observed over time, as in Figure 2. Thus neither Dynamiker nor IMMY LFA can monitor the disease progress. The lines in Figure 2 are based on 4 samples from the same patient.

Figure 1. Band intensity for positive samples using two *Cryptococcus* LFA

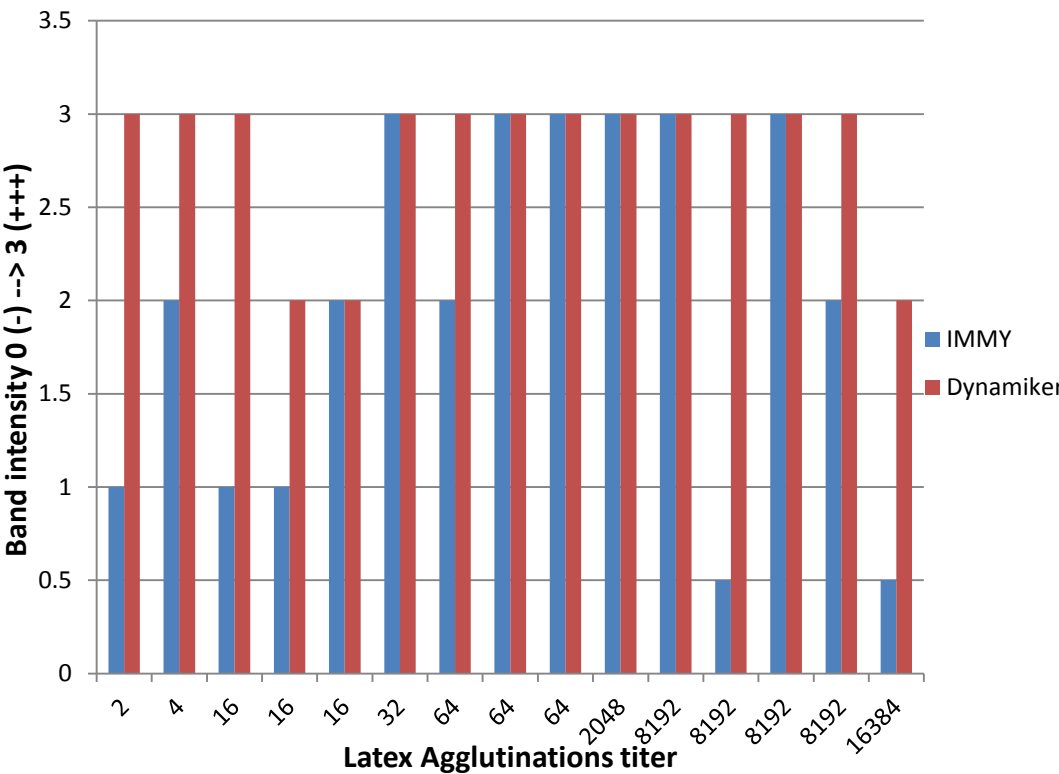
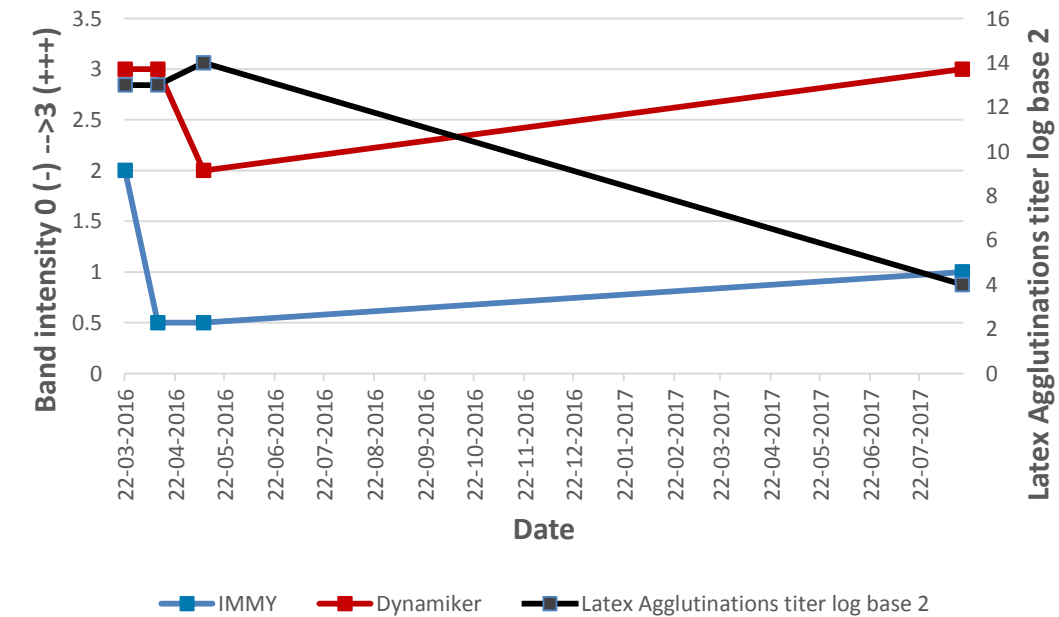


Figure 2. *Cryptococcus* LFA over time for a patient



Conclusions

- Both LFA tests performed excellently when compared to the LA test
- No direct quantitative correlation between strength of band intensity and LA titter was observed.
- Band intensity was in general stronger for the Dynamiker LFA for which a (+) should be regarded negative in order not to compromise specificity.
- The contrary was true for the IMMY test, which accordingly may be more difficult to read ensuring optimal sensitivity.

References

Park BJ, Wannemuehler KA, Marston BJ et al., Estimation of the current global burden of cryptococcal meningitis among persons living with HIV/AIDS, AIDS 2009 20;23(4):525-30