Table 1 Accuracy and kappa statistic for IMMY CrAg LFA performed at point of care by direct application of finger-prick blood samples to the LFA strip and by transferring blood to diluent using a disposable pipette, compared to the reference standard of IMMY CrAg LFA performed on settled plasma in the laboratory in a) a case-control diagnostic accuracy study and b) a clinic-based implementation study

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|  | No. tested | Sensitivity %, (no.), 95% CI | Specificity %, (no.), 95% CI | Kappa value (95% CI) |
| 1. Case-control Diagnostic Accuracy Study | | | | |
| *IMMY CrAg LFA strip applied to finger-prick blood sample (July 2015 – June 2017)* | | | | |
| 10 minutes | 176 | 82% (40/49), 68% – 91% | 100% (127/127), 97% - 100% | 0.87 (0.78 – 0.95) |
| 20 minutes | 74 | 100% (14/14), 77%-100% | 100% (60/60), 94%-100% | 1.0 (1.0 – 1.0) |
| *IMMY CrAg LFA performed on finger-prick blood sample added to diluent with a disposable pipette (July 2017 – February 2018)* | | | | |
| 10 minutes | 27 | 95% (14/15\*), 68% - 100% | 100% (25/25), 86% - 100% | 0.9 (0.8 – 1.0) |
| 20 minutes | 27 | 100% (15/15), 78% - 100% | 100% (24/24), 86% - 100% | 1. (1.0 – 1.0) |
| 1. Clinic-based POC CrAg Screening Implementation Study | | | | |
| *POC IMMY CrAg LFA strip applied to finger-prick blood sample (September 2016 – June 2017)* | | | | |
| 10 minutes | 420 | 20% (1/5), 0.5% - 72% | 100% (415/415), 99% - 100% | 0.33 (-0.15 – 0.82) |
| 20 minutes | 420 | 20% (1/5), 0.5% - 72% | 100% (414/414), 99%-100% | 0.33 (-0.15 – 0.82) |
| *POC IMMY CrAg LFA performed on finger-prick blood sample added to diluent with a disposable pipette (July 2017 – February 2018)* | | | | |
| 10 minutes | 235 | 100% (4/4), 40% – 100%) | 100% (230/231†), 98% - 100% | 0.89 (0.7 – 1.0) |
| 20 minutes | 235 | 100% (4/4), 40% – 100% | 100% (230/231†), 98% - 100%) | 0.89 (0.7 – 1.0) |

Abbreviations: CI = confidence interval; POC = point of care; IMMY = Immunomycologics; CrAg = cryptococcal anigen; LFA = lateral flow assay. Exact binomial 95% confidence intervals are given.m

\*CrAg titer for the false negative CrAg tests when using a pipette to transfer finger-prick blood to diluent, and read after 10 minutes was 10. This was read as positive at 20 minutes.

†No reason was found for the false positive result at point of care. A repeat POC test three days later was negative.