

P1192 UK NEQAS EQA Scheme development: cryptococcal antigen detection in clinical specimens to help in the diagnosis of cryptococcosis

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Background: *Cryptococcus neoformans* is an opportunistic fungus causing systemic mycoses that exhibit high virulence in severely immunocompromised individuals. Globally, approximately one million cases of cryptococcosis occur every year, with a mortality rate of 1700 every day.

The detection of cryptococcal antigen (CrAg) from serum, cerebrospinal fluids (CSF) and broncho-alveolar lavage (BAL) specimens is the basis of diagnosing cryptococcosis in suspected patients. Latex agglutination (LAT) and Enzyme immunoassay (EIA) are commonly used in diagnostic and reference laboratories with a sensitivity of over 90%. Lateral flow assays (LFA) are used as point of care testing (POCT) with a sensitivity of over 95%.

AIM: To determine the stability and homogeneity of simulated respiratory, CSF and serum specimens containing different concentrations of cryptococcal antigen. Simulated specimens stored at ambient, +4°C and -20°C storage conditions, were tested for CrAg periodically over 12 months.

Materials/methods: An NCPF strain; *C. neoformans* was cultured onto Sabouraud dextrose agar (SAB) and incubated at 28°C for 48 hours in aerobic conditions.

A suspension (1McFarland standard) from the culture plates was prepared and inoculated into 10mL nutrient broth and incubated at 37°C for 24 hours in aerobic conditions.

Serum (screened negative for CrAg) and simulated CSF (laboratory base composition) were spiked with varying concentrations of the *C. neoformans* suspension and stored under the three different temperatures, to assess stability and homogeneity.

Results: From the first pilot study, specimens 3718 and 3719 tested with the LFA kit, detected the CrAg over a period of 12 months, stored at ambient, 4°C and -20°C.

However with LAT kit, did not detect the CrAg in both specimens after six months of storage at ambient temperature and levels were undetectable in the ninth month.

The first pilot distribution, distributed the two simulated serum specimens (3718 and 3719) positive for the CrAg. Excellent concordance with intended results 100% (46/46) and 97.8% (45/46) respectively, were achieved from the 47 laboratories returning results.

Conclusions: The result of this study has established that CrAg exhibits excellent stability and homogeneity over a period of time, stored at 4°C and -20°C, an important factor for developing an EQA scheme to laboratories worldwide.