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Development of an UKNEQAS external quality assessment scheme: galactomannan antigen detection in clinical specimens to aid in the diagnosis of invasive Aspergillosis

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Background Invasive Aspergillosis is initially an infection of the lower respiratory tract but can cause systemic dissemination, without antifungal intervention. *Aspergillus fumigatus species complex* is the most prevalent fungal pathogen responsible for fatal invasive aspergillosis and immuno compromised individuals (solid organ transplant, hematologic malignancies and neutropenic patients) are most susceptible.

Detection of the antigen galactomannan (GM), in serum and bronchoalveolar lavage (BAL) is recommended as a criterion in the early diagnosis of Invasive aspergillosis following EORTC/MSG guidelines (2008).

Several studies describe the variability in stability of GM in serum specimens during storage prior to testing. Some authors describe the GM as very stable at various temperatures but other studies state the antigen deteriorates during storage and recommend testing immediately after receipt of the clinical specimen, to determine the correct level of antigen present in the clinical specimen.

Material/methods A questionnaire sent out in 2015 to 300 laboratories worldwide (56% return of survey), all reported to the use of the Platelia Aspergillus ELISA kit (BioRad) and indicating following positive cut off index values, ranging from 0.5 to 1.5 index. The current recommended positive cut off value is 0.5 for serum specimens and 1.0 for BAL.

The variabilities in storage of specimens, stability of the antigen and interpretation of the results with the ELISA, warrants the need for an external quality assessment (EQA) scheme to assess the performance of laboratories providing a service in the detection of GM.

Factors contributing in the development of an EQA include the stability and homogeneity of GM. Spiked serum samples were prepared with an inoculation of a suspension of an NCPF strain of *Aspergillus fumigatus* species complex.

Simulated serum specimens with a galactomannan index of between 0.7-0.9 were prepared and stored at varying temperatures: +22°C, +4°C, -20°C and -80°C. The specimens were tested periodically over nine months for GM in duplicate, using the Platelia Aspergillus ELISA kit (figure 1).

Results: A two way ANOVA was applied on the two variables temperature and time of storage. There was statistical significance ($P<0.05$) with regards to temperature of storage. No statistical significance ($P>0.05$) was found for the period of storage. The T-Test and F-Test highlighted poor stability of GM at +4°C.

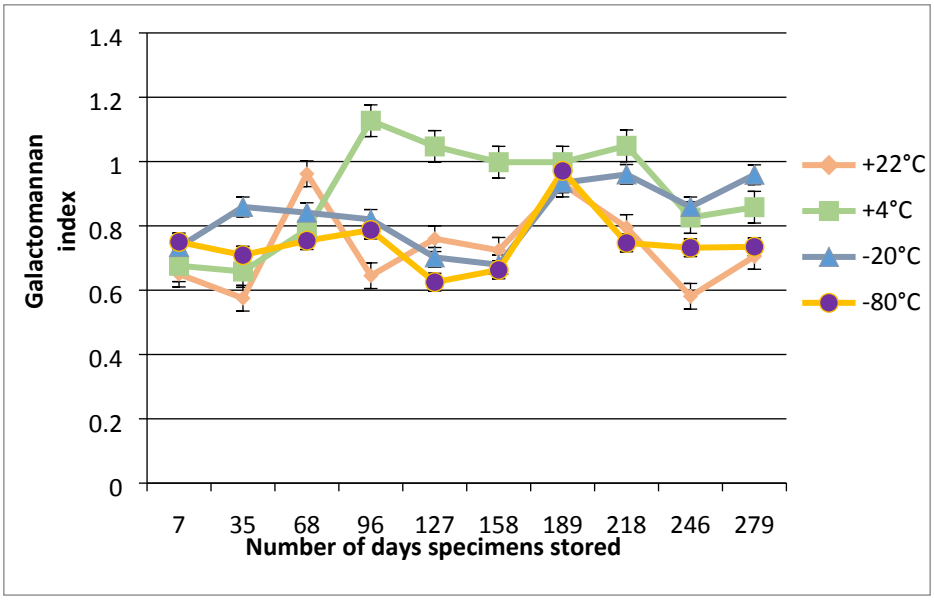

Figure 1: Stability of Galactomannan antigen (index 0.7-0.9) over a period of 9 months at various temperatures.

Conclusions: Data analysis confirms simulated specimens are homogenous and stable at ambient, -20°C and at -80°C. Storage at these temperatures does not affect the GM antigen concentration. Storage at +4°C prior to testing should be avoided, to reduce the probability of inconclusive results arising with true clinical specimens.

The first GM EQA scheme will be launched in April 2017, containing specimens in both simulated serum and BAL format.