

**P261** DEVELOPMENT OF AN EXTENDED SPECIFICITY MULTIPLEX IMMUNOASSAY USING HUMAN MONOCLONAL ANTIBODIES FOR DETECTION OF STREPTOCOCCUS PNEUMONIAE SEROTYPE-SPECIFIC ANTIGEN IN URINE

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**Streptococcus pneumoniae** (pneumococcus) is a major cause of morbidity and mortality worldwide. To date 93 capsular serotypes of pneumococcus have been described, but many of these are rarely found in disease. Currently vaccines are targeted at the 7 and 23 of the most common circulating serotypes. However, with the uptake of any pneumococcal serotype based vaccine the risk of serotype-replacement and an increase in disease caused by non-vaccine serotypes remains. This highlights the importance of determination of the serotype responsible for the infection. The diagnosis and subsequent serotype surveillance of pneumococcal infection relies heavily on culture techniques which are known to be insensitive, particularly in cases of non-invasive disease. There are, therefore, potentially many pneumococcal disease cases where an isolate for serotyping is never obtained. Urine antigen detection using methods such as BinaxNOW (Alere) can be used to confirm pneumococcal infection in the absence of an isolate, but does not give serotype information.

Previously described serotype-specific urine assays covering mainly conjugate vaccine serotypes, give no/very little information about circulating non-vaccine serotypes and are currently only available in one or two specialist laboratories.

Our laboratory has just completed initial development of an extended range antigen capture Luminex based assay to detect *S. pneumoniae* serotype specific antigen in urine samples using fully human human, full length monoclonal antibodies. The assay covers 24 different serotypes/groups plus C-polysaccharide, including all the currently available conjugate vaccine and 23-valent polysaccharide vaccine types plus some cross-reactive serotypes.

We have validated the assay for sensitivity, specificity and reproducibility using spiked urine samples and a panel of BinaxNOW tested clinical urine specimens, some of which were from patients from whom a pneumococcal isolate was also cultured. The results for the validation will be presented.

This assay can be extended to testing other clinical samples such as cerebrospinal and pleural fluids and with development has the potential to greatly improve serotype-specific surveillance in the many cases of pneumococcal disease from which a culture is never obtained.

**REFERENCE**