Clinical correlation of an automated encapsulated liposome assay for the investigation of complement activity

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Introduction
Complement function testing has been in routine use across diagnostic laboratories for a number of years, with the radial immunodiffusion (RID) the most common method of testing the function of the classical complement pathway.
The Immunology laboratory at the Royal London Hospital (RLH) has traditionally employed this method but due to the advancement in equipment and technologies, newer methods have emerged which provide improved turn-around times, are more reliable, just as sensitive and specific, automated, non-subjective and improve patient treatment pathway times as a result.
This investigation will explore a different method, the CH50 assay on the SPA Plus® to determine if it can improve turnaround times, reduce test costs, is less labour intensive and provide a better service to users and improving patient care as a result.

Method
102 patient samples with a result from the RID method were tested on the SPA Plus® using the CH50 assay to determine the classical pathway functional activity.

Samples were selected so the full measuring range of the assay could be tested, along with the intra-, inter-assay variation and linearity. Samples with results beyond the upper and lower limit measuring range of the RID assay were tested to determine if the CH50 is more sensitive

Results
The CH50 assay demonstrated good performance, with the intra-assay coefficient of variations (CVs) of 1.26% and 1.50%. The inter-assay CVs ranged from 0.68% to 14.43% and the average linearity of y=1.0935x - 7.82, r=0.9981, which is comparable to the Binding Site® linearity results.

The CH50 assay was able to produce results for 9 of 23 samples for which the RID method was unable to produce a result (beyond upper and lower detecting limits). The comparison of results for both methods produced a coefficient of determination (R2) value of 0.441.

Discussion
The automated CH50 assay provides improved turnaround times as the assay is completed within half a working day, repeat testing can be achieved on the same day. Results are able to be transferred automatically from analyser to LIMS. Reagent kits are more stable and have a longer shelf-life. Result subjectivity of the RID is also removed. The reagent cost of the assay and labour are reduced, making it more feasible to introduce this new method. Patients and service users will get an improved, more timely service to allow for investigations into immunological disorders to progress at quicker rate than if the RID method was continued.

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References