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WIESLAB® Classical pathway assay – optimal for functional assessment

Felicia Andersson, Fredrik Karlsson and Yngve Sommarin
Euro Diagnostica AB, Malmö, Sweden

Aim

The objective of this study was to ensure that the performance of the test was not affected by the redesign of WIESLAB® Classical pathway ELISA.

Background

WIESLAB® Classical pathway ELISA (Euro Diagnostica AB, Sweden) has until now been on the market as a qualitative test for measuring the activity of the classical pathway. However, due to an increased awareness and interest in the complement system, the assay has now been redesigned. The redesign includes a possibility to dilute a six point calibrator and an external activity control to meet the needs for a simple and objective quantitative method to assess the function of classical complement activity.

Materials and Methods

The positive control (PC) in the kit is used to prepare the six point calibrator by dilution, using supplied dilution buffer. The reference range was estimated by analyzing 120 normal samples and the sensitivity was determined by analyzing 18 deficient complement samples. To analyze the impact of the performance of the new application, analytical comparison with the new semi-quantitative and existing qualitative application was done using 37 normal samples.

Analytical comparison was done with IMTEC Complement activity (Human) and Quidel CH50Eq EIA to verify the function of the new application to independent methods.

Results

Example of a standard curve

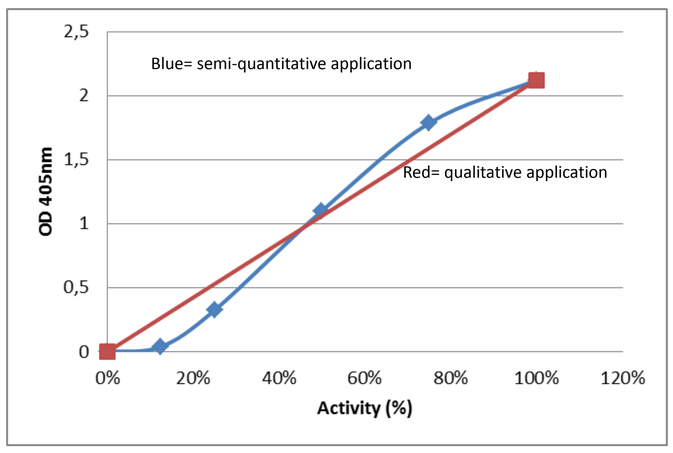


Figure 1. *Example of a standard curve. The 0%-calibrator is subtracted from all values before calculations of activity. Calibrator measurement range is 12.5%-100%, Limit of detection (LOD) is 8 %.[1]*

Application	n	Mean (%)	±2 SD (%)	Median (%)
Semi-quantitative	120	89	66-113	92
Qualitative	120	99	69-129	100

Table 1. *Normal reference range calculated from 120 normal serum samples. The normal reference range for these set of samples were 66-113 %. The mean value was 89%. Non of the blood donors were below 40%. Samples above the curve were diluted 1/201 to end up on the curve.[1] The qualitative application is shown for comparison.*

WIESLAB® COMPL CP310 semi-quant. vs. WIESLAB®COMPL CP310 qual.

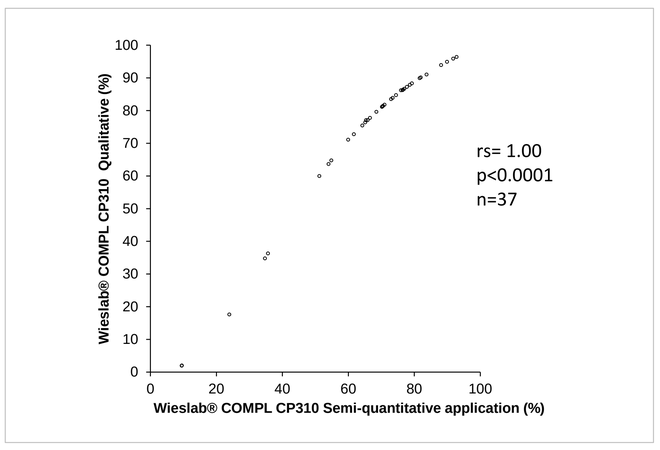


Figure 2. *Spearman correlation between the new semi-quantitative application and the qualitative application of WIESLAB® COMPL CP310.*

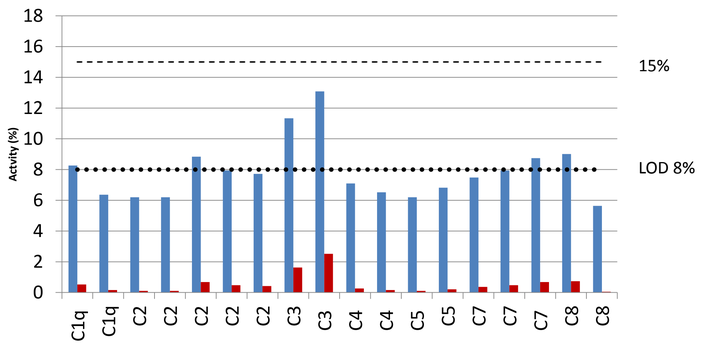
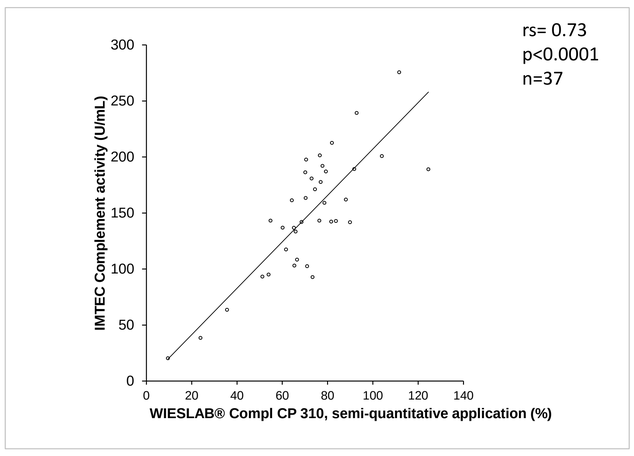


Table 2. *18 known deficient complement samples were analyzed in the semi - quantitative WIESLAB® COMPL CP310 (blue). All samples were below lower reference range limit (66%) and non of the samples had an activity above 15 %.[1] Deficient and low activity samples will get a higher activity value compared to the qualitative application of WIESLAB® COMPL CP310 (red), due to the shape of the calibrator. OD-values for the samples varied between 0.048 and 0.001.*

WIESLAB® COMPL CP310 semi-quant. vs. IMTEC



WIESLAB® COMPL CP310 semi-quant. vs. Quidel CH50

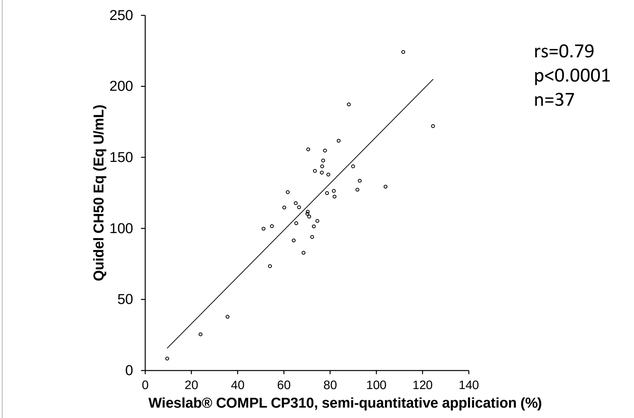


Figure 3. *Spearman correlations between WIESLAB® COMPL CP310 and IMTEC respective WIESLAB® COMPL CP310 and Quidel CH50 is satisfied, rs= 0.73 resp rs= 0.79. Spearman correlation between the two tests and the qualitative application of WIESLAB® COMPL CP310 shows the same results, data not shown.*

Discussion & Conclusions

The performance of WIESLAB® COMPL CP310 kit is still the same after the redesign:

- **Spearman correlation, rs= 1.00 between the two applications of the WIESLAB® COMPL CP310**
- **Spearman correlation between WIESLAB® COMPL CP310 semi-quantitative application vs IMTEC and vs Quidel CH50 shows the same results as for the qualitative application of WIESLAB® COMPL CP310**

References

1. **Instruction for use** WIESLAB® Complement System Classical Pathway, Doc No: E-23-0162-10
Reference website:
http://www.eurodiagnostica.com/index.php?headId=3&pageId=3&productId=80

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