Traceability and method groups of C-reactive protein results

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Introduction

C-reactive protein (CRP) is the most sensitive of the acute phase reactants and its concentration increases rapidly in inflammatory reactions. According to the manufacturers CRP results are traceable to the three certified reference materials (CRM): ERM® - DA470, ERM® - DA472/IFCC and ERM® - DA474/IFCC which all are traceable to SI via ERM® - DA470 (1). The traceability of results enables the use of common biological reference intervals in laboratories worldwide. Patient results can also be compared over time and between hospitals and countries.

Labquality has organized external quality assurance schemes (EQA) for CRP measurements since 1983. In these schemes results are processed in method groups and the method group mean is used as the assigned value. The idea of this poster was to investigate whether it would be possible to handle the results in one group since traceability of all the results is to the same ERM® - DA470. In theory no differences exist between measurement methods. Moreover, we wanted to examine the usage of different assigned values i.e. method group mean and transferred reference value from ERM® - DA474/IFCC and their influence on the evaluation of the performance of the laboratories.

Material and Methods

The results of the CRP EQA round 3, 2017 for clinical laboratories were used (Table 1). The sample materials consisted of two human serum pools with added human purified CRP and no additives.

Transfered reference values for EQA samples were obtained as follows. The samples were analysed together with the ERM® - DA474/IFCC 10 times at random in one analytical run. The transferred reference values for both EQA samples were calculated using the obtained certified value of the CRM. Measurements were performed on a Roche cobas c702 device with the immunoturbidimetric assay C-Reactive Protein Gen.3. The transferred reference value traceable to the ERM® - DA474/IFCC was reported to the participants.

The assigned value (method group mean) was calculated for Immunoturbidimetry, Roche cobas & Tina-quant and Vitros separately. The acceptance criteria (target limits) in Labquality’s CRP schemes is the assigned value ± total allowable error 12%.

Results

- The variation of the results is lower when method grouping is used compared to all results in one group, except Vitros results of Sample 2 (Table 1)
- Immunoturbidimetry group: no difference in fulfilling the acceptance criteria was noticed whether the transferred reference value or method group mean was used as the assigned value (Figures 1 and 2)
- Roche cobas & Tina-quant group: more results did not fulfill the acceptance criteria (below acceptance limits) when the transferred reference value was used as the assigned value vs. method group mean (Figures 1 and 2)

![Figure 1. Method group mean as the assigned value, Sample 1](image1)

![Figure 2. Transferred value as the assigned value, Sample 1](image2)

Table 1. Results of the CRP for analysers, round 3, 2017

<table>
<thead>
<tr>
<th>Sample 1</th>
<th>Immuno-turbidimetry</th>
<th>Roche cobas &amp; Tina-quant</th>
<th>Vitros</th>
<th>All results</th>
<th>Transferred value**</th>
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<tbody>
<tr>
<td>SD</td>
<td>1.7</td>
<td>0.6</td>
<td>2.2</td>
<td>2.1</td>
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<tr>
<td>CV%</td>
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<td>3.7</td>
<td>9.6</td>
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<tr>
<td>N</td>
<td>200</td>
<td>94</td>
<td>9</td>
<td>369</td>
<td>133 ± 0.1 (k2)</td>
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<tr>
<td>Sample 2</td>
<td>mean*</td>
<td>54 ± 0.2</td>
<td>50.1 ± 0.3</td>
<td>57.5 ± 1.6</td>
<td>52.9 ± 0.2</td>
</tr>
<tr>
<td>SD</td>
<td>3.5</td>
<td>2.8</td>
<td>4.7</td>
<td>3.9</td>
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<tr>
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<td>5.6</td>
<td>8.2</td>
<td>7.3</td>
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<tr>
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<td>96</td>
<td>9</td>
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<td>10</td>
</tr>
</tbody>
</table>

* mean ± SEM as standard uncertainty
** Transferred value from ERM® - DA474 / IFCC

Conclusion

From the data it can be seen that although the CRP results are traceable to the same ERM® - DA470, the uniform result level is not reached. If the transferred reference value from ERM® - DA474/IFCC is used as the assigned value, Roche Tinaquant and Vitros laboratories receive poor performance evaluation which does not necessarily indicate laboratory’s error. Other factors in measurement methods i.e. manufacturers’ in-house calibration and measuring platform, have an additional influence on CRP results. Our results show that there are differences between different measurement methods thus there is a need for harmonization. Using method group means as the assigned value in the CRP EQA scheme should only be used for harmonization within own method group and does not aid to overall harmonization. To be able to evaluate on method trueness and to aim for better traceability and overall harmonization traceable reference values should be used as the assigned value.

References


![Image 1](image1)

![Image 2](image2)