# Analytical performance of the LumiraDX Point of care Method for the Measurement of C-Reactive Protein

Adamantidou Christina, Jacques Vanderlinden Gruson Damien
Cliniques Universitaires St-Luc, Bruxelles, Belgium.
Contact: christina.adamantidou@gmail.com

## BACKGROUND AND AIMS

- C-reactive protein (CRP) is a biomarker that is widely used to diagnose and monitor infection, inflammatory states, autoimmune diseases, or other chronic conditions such as heart disease or cancer.
- Point-of-care testing (POCT) methods for the measurement of CRP have the potential to provide rapid and convenient testing for clinical decision-making including primary care .
- The aim of this study is to assess the analytical performance of the LumiraDX® POCT method for the measurement of CRP by evaluating the precision and comparison with a core laboratory reference method.

## METHODS

Precision was evaluated by analysing two pools of plasma from multiple patients at two different concentration levels of 20 mg/L and 70 mg/L twice per day, for five days.
The repeatability of the method was evaluated by measuring the same two pools of plasma.
A total of 40 patients' heparin plasma samples were collected and analysed using both the LumiraDX® method and the Cobas® 8000 platform. The samples were collected from a variety of patient populations and covered a wide range of CRP concentrations.
Correlation and agreement were tested using Bland Altman plot and Passing Bablok linear regression.

## RESULTS (1)

### Intermediate precision

| Sample size | 5 | 5 |
|---|---|---|
| Lowest value | 19,3 | 59 |
| Highest value | 21,3 | 65,1 |
| Arithmetic mean | 20,01 | 63,01 |
| 95% CI for the arithmetic mean | 19,54-20,7 | 60,99-65,05 |
| **CV (%)** | **3,28** | **3,42** |

**Figure 1**: The between-run imprecision coefficient of variation (CV) were 3.28 % and 3.42 % for the mean concentrations of 20,01 mg/L (95% CI for the mean 19,5 -20,7) and 63,01 mg/L (95% CI for the mean 60,9- 65,05) respectively.

## RESULTS (2)

### Repeatability

| Sample size | 5 | 5 |
|---|---|---|
| Lowest value | 46,7 | 43,3 |
| Highest value | 18,2 | 48 |
| Arithmetic mean | 17,64 | 44,98 |
| 95% CI for the Arithmetic mean | 16,9-18,35 | 42,68-47,27 |
| **CV (%)** | **3,27** | **4,11** |

**Figure 2:** The repeatability coefficient of variation (CV) were 3.27% and 4,11% for mean concentrations of 17,64 mg/L (95% CI for the mean 16,9 - 18,35) and 44,98 mg/L (95% CI for the mean 42,68- 47,27) respectively.

## RESULTS (3)

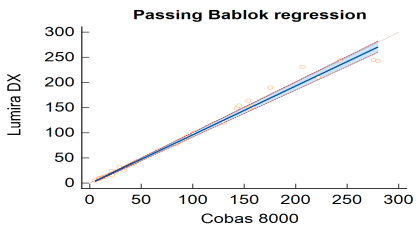


**Figure 3. 1:** The Passing and Bablok regression analysis showed a slope of 0,97 (95% CI: 0,9—1,0) an intercept of – 0,7 (95% CI: -2,1- -0,1) and no significant deviation from linearity. (p=0,07)

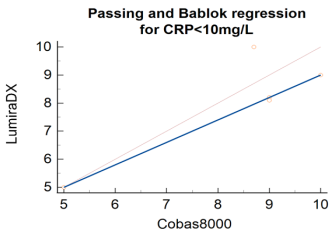


**Figure 3.2:** For CRP concentration <10mg/L the Passing and Bablok regression analysis showed a slope of 1,0 an intercept of 0,8 and no significant deviation from linearity . (p=0,5)

## RESULTS (4)

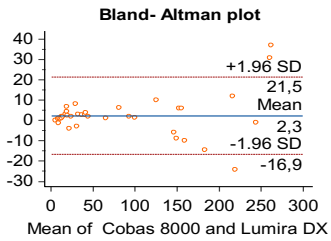


**Figure 4.1:** The Bland Altman Plot revealed a mean difference of 2,3 (95% CI :-22,0 - 11,3) between Cobas 8000 and LumiraDX. (p=0,14)

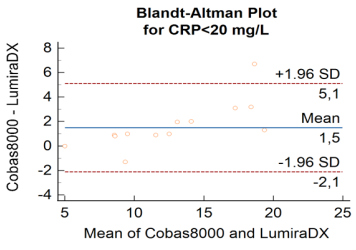


**Figure 4.2 :** For CRP concentration <10mg/L Bland Altman Plot revealed a mean difference of 1,5 between Cobas 8000 and LumiraDX. (p=0,07)

## REFERENCES

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## CONCLUSIONS

**Our study revealed excellent analytical and clinical performance for the LumiraDX® assay :**

- **the imprecision evaluation showed a decent CV**
- The agreement and correlation with the established method was **satisfactory with a limited bias .**

**The results indicate that the LumiraDX® method for the measurement of CRP has a good precision and demonstrate good agreement and correlation with the reference method. This new POCT device can help clinicians to reduce uncertainty at the time of diagnosis.**