

Summary

LabPad Evolution Ksmart CRP

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| Manufacturer | Biosynex SA |
| Supplier in Scandinavia | Biosynex Nordic A/S |
| Launched in Scandinavia | November 2022 |



Aim

To assess the analytical performance and user-friendliness of CRP measurements with LabPad Evolution when used by the intended users, i.e. health care professionals, in primary health care.

| Performance specifications | Conclusion and results |
|--|---|
| Repeatability CV ≤ 10 % | Not fulfilled when used by the intended users. (CV 18,6 – 24,8 %) |
| Accuracy ≥ 95 % of the results within the specified limits compared to the average result of the comparison method ± 2 mg/L at CRP concentration < 10 mg/L ± 15 % at CRP concentration ≥ 10 mg/L | Not fulfilled when used by the intended users. (80,6 %) |
| User-friendliness A total rating of “Satisfactory” | Not fulfilled. The user-friendliness was rated <i>intermediate</i> . |

Additional information

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|--------------------------|--|
| Participants | 186 participants from five primary health care centres, coming in with symptoms of infection where the general practitioner requested a CRP measurement. |
| Evaluated method | LabPad Evolution Ksmart CRP (immunofluorescence) on fresh capillary whole blood using three lots of test kits. Intended for professional use. |
| Comparison method | Cobas 8000, c 702 (particle-enhanced immunoturbidimetric assay) on venous serum samples. |
| Bias | An average small positive bias of 0,29 mg/L between LabPad Evolution and the comparison method was shown. |
| Technical error | 0,38 %. The SKUP recommendation of a fraction of ≤ 2 % was achieved. |

A letter with comments from Biosynex Nordic A/S is attached to the report.

Further information about the evaluation and the organisation of SKUP can be found on www.skup.org. This summary is also published in Danish, Norwegian and Swedish at SKUPs website.