

Summary / qLabs ElectroMeter Q-3 Plus Owren (dry) for measurement of prothrombin time



Producer: Micropoint Bioscience, Inc.

Supplier: LumiraDx in Denmark, Norway and Sweden

Summary of an evaluation provided by SKUP

Conclusion

- **The quality goal for repeatability was fulfilled by the intended users**
- **The quality goal for accuracy was not fulfilled by the intended users**
- **The quality goal for user-friendliness was not fulfilled**

Background

The qLabs Q-3 Plus PT (INR) Owren (dry) system is an in vitro diagnostic device for quantitative measurement of Prothrombin Time International Normalized Ratio (PT (INR)). The product is intended for professional use. The sample material is fresh capillary blood. The system is produced by Micropoint Bioscience, Inc. The system was launched into the Scandinavian market September 2019. The SKUP evaluation was carried out late September 2020 to early February 2021 at the request of Micropoint Bioscience, Inc. in USA.

The aim of the evaluation

The aim of the evaluation was to assess the analytical quality and user-friendliness of qLabs Q-3 Plus PT (INR) Owren (dry), when used under real-life conditions by intended users in primary health care.

Materials and methods

In four primary health care centres (PHCCs), fresh capillary blood samples from a total of 186 patients, all stable on vitamin-K-antagonist treatment, were measured on qLabs Q-3 Plus PT (INR) Owren (dry) (modified Owren method). Citrate plasma samples from the same patients were analysed on a comparison method (Equalis calibrated Owren's method with Owren's PT reagent from Medirox AB on Sysmex CS5100, Siemens Healthineers). The analytical results and user-friendliness were assessed according to pre-set quality goals. The quality goal for precision was a repeatability (coefficient of variation, CV) $\leq 5,0$ % and for accuracy that ≥ 95 % of the results should be within $\pm 20,0$ % of the results from the comparison method. The user-friendliness was assessed using a questionnaire with three given ratings; satisfactory, intermediate and unsatisfactory, and with the quality goal of a total rating of "satisfactory".

Results

At PT (INR) level $< 2,5$ the CV achieved in the different PHCCs varied between 4,1 and 5,7 %, and at PT (INR) level $\geq 2,5$ the CV varied between 3,6 and 5,1 %. When the results from all PHCCs were merged per level, the CV achieved at PT (INR) level $< 2,5$ was 4,9 % and at PT (INR) level $\geq 2,5$ it was 4,5 %. An average bias of 0,2 INR was shown between qLabs Q-3 Plus PT (INR) Owren (dry) and the comparison method. For accuracy, 90 % of the results were within the allowable deviation limits. Of the 178 results included, seven deviated more than 25 % from the results of the comparison method, which corresponds to 4 %. The user-friendliness was rated as satisfactory for all topics but the instrument itself, which was rated as intermediate.

Comments from Micropoint Bioscience, Inc.

A letter with comments from Micropoint Bioscience, Inc. is attached to the report.

This summary is also published in Danish, Norwegian and Swedish at www.skup.org.