

# Summary



## **Summary of an evaluation provided by SKUP**

microINR for measurement of PT (INR)

**Manufacturer:** iLine Microsystems S.L.

**Supplier:** Orion Diagnostica A/S in Denmark/Orion Diagnostica as in Norway/Orion Diagnostica AB in Sweden

### **Conclusion**

The quality goal for repeatability at PT (INR) level  $<2,5$  was most likely fulfilled. At PT (INR) level  $\geq 2,5$  the quality goal for the repeatability was not fulfilled. The quality goal for accuracy was fulfilled. The quality goal for user-friendliness was not fulfilled.

### **Background**

The microINR portable coagulometer is an in vitro diagnostic device for the quantitative measurement of prothrombin time, PT (INR). The system is intended for professional use, self-testing and self-management of patients on oral vitamin K antagonist therapy. The sample material is fresh capillary whole blood. The system is produced by iLine Microsystems S.L. and was launched into the Scandinavian market December 2012. The SKUP evaluation was carried out from March to August 2015 at the request of iLine Microsystems S.L. in Spain.

### **The aim of the evaluation**

The aim of the evaluation was to determine the analytical quality and user-friendliness of the microINR system, both when used under optimal conditions in a hospital laboratory and by intended users in primary health care. The analytical results were assessed according to the quality goals set for the evaluation.

### **Materials and methods**

In a hospital laboratory, capillary samples from 98 patients were measured with the microINR system. In two primary health care centres, capillary samples from 40 and 48 patients respectively were measured with the microINR system. Venous samples from the same patients were analysed on the comparison method implemented on STA-R Evolution. The quality goal was a repeatability (CV)  $\leq 5,0\%$  and for accuracy that  $\geq 95\%$  of the results should be within  $\pm 20\%$  from the results of the comparison method. The quality goal for the user-friendliness was a total rating of “satisfactory” including an incident of tests wasted due to technical errors  $\leq 2\%$ . The microINR system was tested in stationary mode, i.e. not moved during sample application or measurement.

### **Results**

For PT (INR) results  $< 2,5$  the repeatability was estimated to be just below 5,0% at all evaluation sites. For PT (INR) results  $\geq 2,5$  the repeatability was 6,0% under optimal conditions and between 6,1% and 6,3% achieved by the intended users. At PT (INR) level  $< 2,5$  there was a statistically significant bias of +0,06 INR under optimal conditions. For PT (INR) level  $\geq 2,5$  there was no statistically significant bias. Under optimal conditions, 97% of the results were within the quality goal for accuracy, and when handled by the intended users 95% of the samples were within the quality goal for accuracy. The user-friendliness was rated as intermediate and the incident of tests wasted due to technical errors was 1,6%.

### **Comments from iLine Microsystems S.L.**

A letter with comment from iLine Microsystems S.L. is attached to the report.