

# LumiraDx® Case Study

## Product Evaluation of the LumiraDx Platform and INR Test at the medical practice Dres. Schreiber, Steinbauer & Dechant

The results shown here are specific to one health care facility and may differ from those achieved by other institutions

### Introduction

Patients on vitamin K antagonist (VKA) therapy, have a narrow therapeutic window and require regular international normalised ratio (INR) monitoring to maintain optimal coagulation. The LumiraDx Platform INR test is a novel, point of care in vitro diagnostic system that can be used for INR testing using fingerstick blood samples by healthcare professionals. It is used to measure the INR in capillary blood samples in patients who are stabilized on oral anticoagulation therapy with VKAs.

A post launch evaluation was completed for the LumiraDx Platform and INR Test at the medical practice Dres. Schreiber, Steinbauer & Dechant. Results were compared to the site reference method and the practice team has filled in a healthcare professional questionnaire on ease of use of device and test in clinical practice.

### Overview of medical practice Dres. Schreiber, Steinbauer & Dechant

The medical practice for general medicine and emergency medicine Dres. Schreiber, Steinbauer & Dechant comprises 6 physicians and is located in the center of Burglengenfeld in the Oberpfalz region of Germany. The practice is equally committed to general and emergency medicine and always has focus on high-level medical treatment, the latest technologies and optimal training for staff. The practice is also part of a regional education program (in collaboration with Asklepios Clinic Burglengenfeld) to offer physicians a consistent and high level of education with a clearly structured curriculum and a broad range of medical services in the settings of acute hospitals and large regional specialist medical practices.



**“Results from the LumiraDx Platform INR Test were very consistent with those obtained by our site reference method, with a strong correlation ( $r=0.979$ ),” over the evaluation period.**

Dr. med. Wolfgang Schreiber,  
Facharzt für Allgemeinmedizin,  
Notfallmedizin



## Methodology

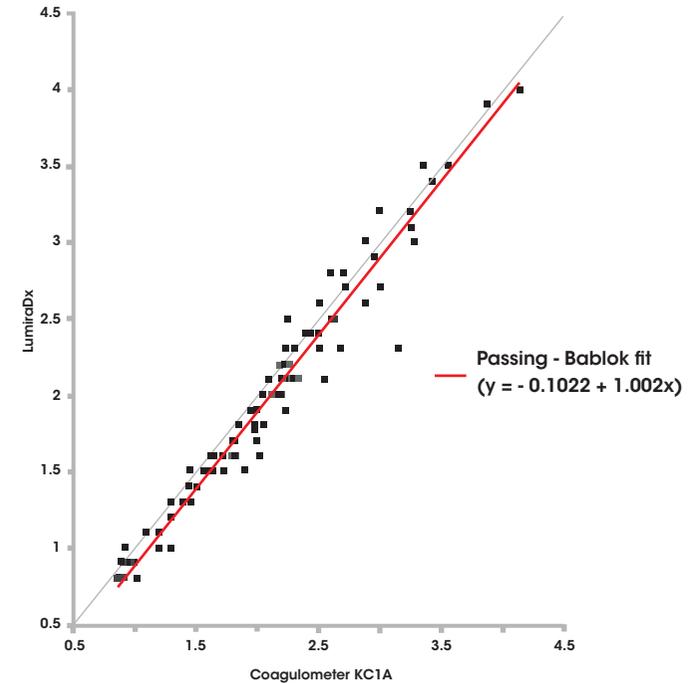
A post launch evaluation was completed for the LumiraDx INR Test at the medical practice Dres. Schreiber, Steinbauer & Dechant from 15.1.-12.2.2019. Data collection included capillary finger stick INR Test results from the LumiraDx INR Test and the site reference method (Coagulometer KC1A). The site tested a total of 97 patient samples on both the LumiraDx INR Test and on the site reference analyser. Sample collection and application was performed with a transfer pipette. The practice team also completed a questionnaire on ease of use of the CE marked LumiraDx Platform and INR Test within the intended use. Method comparison analysis was conducted using Passing-Bablok regression.

## Results

Results showed a strong correlation of 0.979 (95% confidence interval: 0.967 to 0.986) between the LumiraDx INR Test with the site reference method, the Coagulometer KC1A. The analysis of the LumiraDx INR Test showed that the system provided a rapid and reliable INR analysis at the point of care over the evaluation period. Healthcare professionals indicated that the system was easy to prepare, follow instructions, had an easy to use interface, gave clear, easy to read results and was simple to clean.

Reference: Post-CE Evaluation Data Management and Analysis Report. LumiraDx Internal Report.

The LumiraDx INR Test is subject to the intended use and limitations as set out in the LumiraDx INR Test Strip Product Insert.



Test	N	Slope	Intercept	r
LumiraDx INR Test	89	1.002	-0.102	0.979

“The LumiraDx Platform provided a convenient and appropriate method for point of care measurement of INR when evaluated in our medical practice”

Ingrid Fuchs,  
Medizinische Fachangestellte  
(MFA)

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Product not available in all countries and regions. Not available in the USA.