Clinical evaluation of the Hydragel 5 von Willebrand Multimers of Sebia

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Background

The von Willebrand disease (vWD) is the most common inherited bleeding disorder. The underlying cause is a quantitative (type 1 and type 3) or qualitative (type 2) defect of the von Willebrand factor (vWF). The vWF is secreted in the blood flow as a dimeric (Low Molecular Weight: LMW) to a multimeric (High Molecular Weight: HMW) structure. Absence or decreased levels of HMW (as seen in 2A and 2B vWD subtypes) are responsible for the bleeding symptoms.

The treatment of a patient must be adapted depending on its vWD's type/subtype. Different assays are available to type the disease. The electrophoresis of the vWF multimers is one of them and it allows the characterization of the distribution of vWF multimers in the plasma.

Until now, multimers assay was performed using home-made, time consuming and non-standardized methods (***Figure 1***). In 2016, Sebia has launched a new kit (Hydragel 5 von Willebrand Multimer) on the Hydrasis 2 Scan system. The purpose of this work is to evaluate it performances.

Figure 1. Home-made vWF electrophoresis

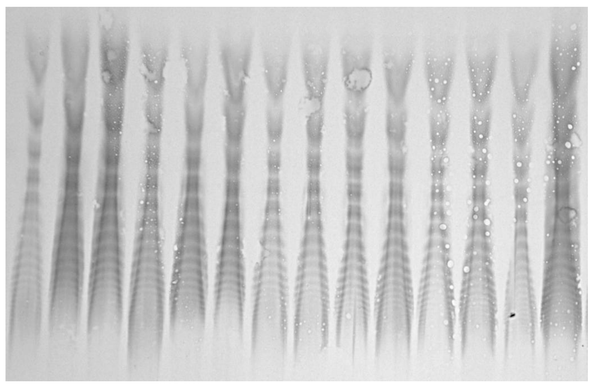

Figure 2. Sebia Hydrasis 2 vWF electrophoresis and electrophoregrams.
Intra-day reproductibility (**1-5**= **Normal Control**)

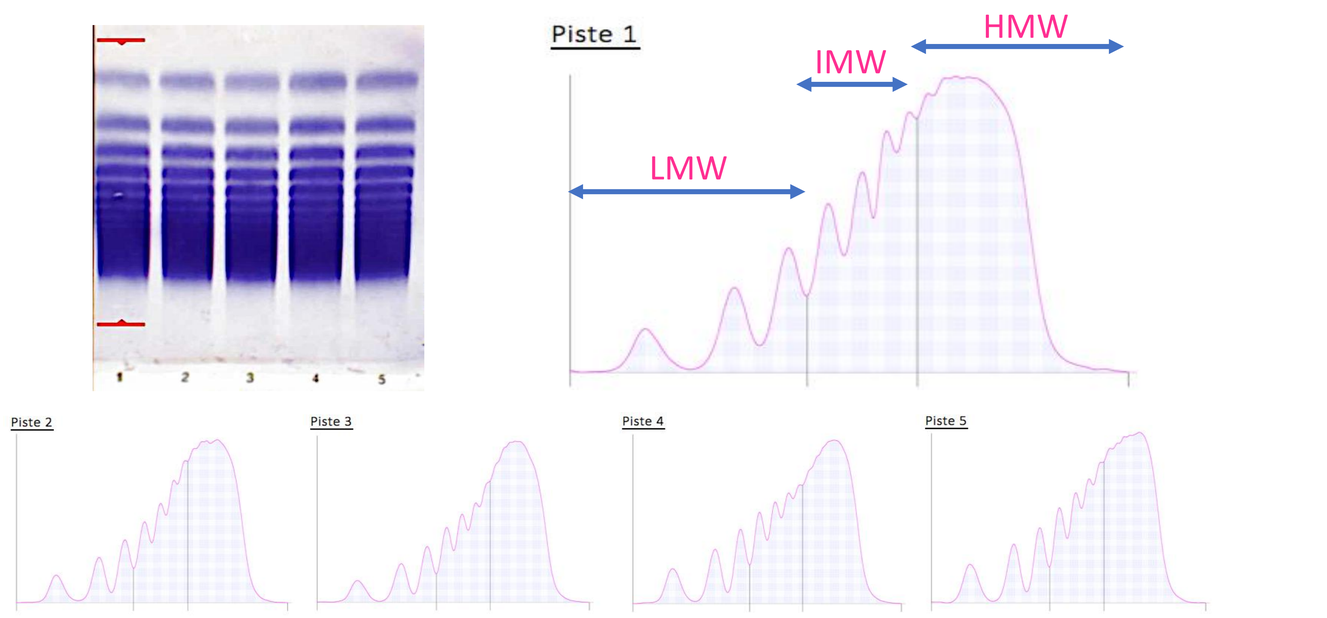

Figure 3. Inter-day reproductibility (n=3). **1**= **Type 1**; **2**= **Severe Type** 1; **3**= **Type 2A** (loss of HMW); **4**= **Type 2B** (loss of IMW and HMW); **5**=Normal Control. Day 1 electrophoregrams only

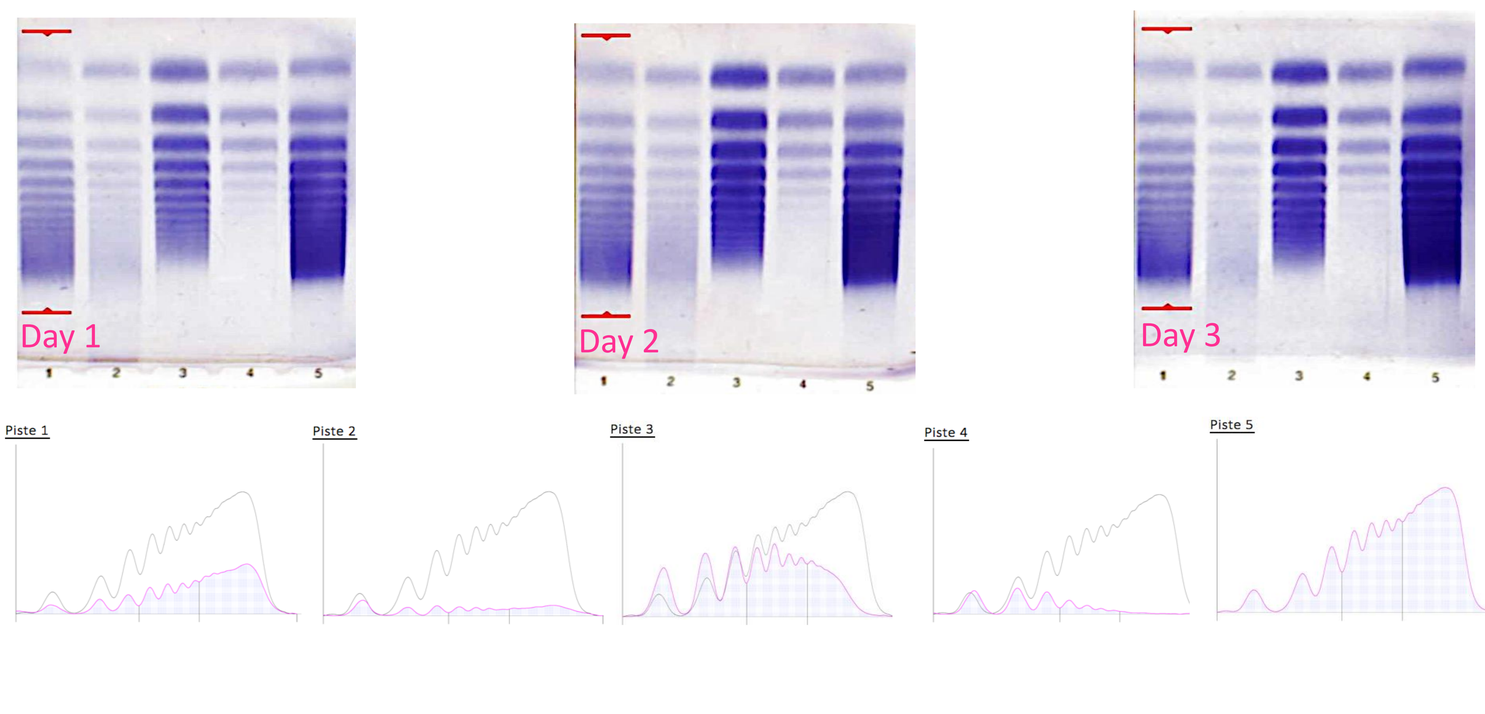

Figure 4. Inter-sample contamination
1,2,3= low vWF (**Type 1**); **4**= no vWF (**Type 3**); **5**= Normal Control

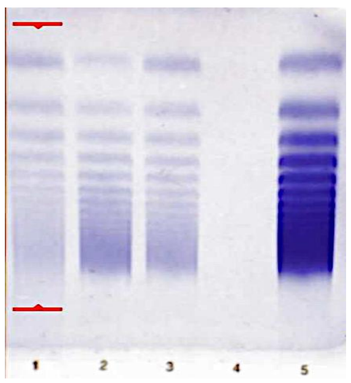

Figure 5. Accuracy. 2= ECAT 15.101 (**Type 2A**); 3= ECAT15.135 (**Type 1**); 4= ECAT16.24 (Normal Sample); 5= Normal Control

Results

Results showed a complete and partial loss of HMW for the type 2A and type 2B patients (Figures 3 and 4). No multimers were detected in the plasma of type 3 patient.

Our results also showed that the method of Sebia is reproducible (Figure 2 and 4) and accurate (Figure 5). We did not observe any inter-sample contaminations (Figure 3).

Conclusions

The Hydragel 5 von Willebrand multimers kit of Sebia allows the discrimination of the different subtypes of the vW disease in regards to the distribution of the different multimers of the protein. The method is simple, accurate and fast. It has been ISO15189 accredited in our lab in June 2016.

Method

The electrophoresis of vWF has been performed on a Sebia Hydrasis 2 Scan following the recommendations of the manufacturer. Intra-day and inter-day reproducibility have been tested using a normal control and plasma samples from patients presenting different type of vWD. Accuracy of the method has been evaluated using samples from external quality control surveys (ECAT, 3 different surveys). A plasma sample from a type 3 patient has been used to evaluate the inter-sample contamination. Plasma samples from patients presenting the different type of vWD have been analyzed to test the specificity of the assay.