

Technical Memorandum

To: Physicians, Clinical Staff and Clients

From: Wesley J. Kim, M.D. Ana Ortega-Lopez, M.D. Amy Powers, MD

DLS Medical Director Lab Director Lab Director

Date: September 29, 2025

Subject: Transition to New von Willebrand, Factor Assays and Introduction of von

Willebrand Activity Assay

1. Transition to New vWF Antigen and Factor Assays - Effective September 29, 2025

Starting September 29, 2025, Diagnostic Laboratory Services (DLS) will upgrade its coagulation testing platform from Stago to Werfen. This transition is designed to improve the accuracy of test results and reduce turnaround times, ultimately enhancing patient care.

Below are the revised reference ranges that will be implemented with the new system:

| Test Report Name | Reference range | | | |
|----------------------------------|--------------------------|----------------|-----------------------|----------------|
| | Current Range (Stago) | Reporting unit | New Range (Werfen) | Reporting unit |
| von Willebrand Antigen | 50-160 | % | 42.0-176.3 | % |
| Factor VIII | 50-200 | % | 50-150 | % |
| Factor IX | 50-200 | % | 65-150 | % |
| Factor VIII Inhibitor (Bethesda) | <0.3 | BU | <0.6 | BU |

2. Launch of von Willebrand Factor Activity Assay

DLS is introducing a fully automated von Willebrand Factor (vWF) activity assay using glycoprotein lb-binding (GPlbR) technology. This method replaces traditional platelet-based ristocetin cofactor (vWF:RCo) assays with latex beads coated in recombinant GPlb. The new assay will provide more precise and efficient diagnosis and monitoring of von Willebrand Disease (VWD).

3. Discontinuation of Factor IX Inhibitor Assay

Due to low testing volume, the Factor IX Inhibitor assay will be discontinued and transitioned to a send-out test.

For further information, please contact Client Services at 808-589-5101.