

**REAADS von Willebrand Factor
Activity ELISA Test Kit**Product #: 10826
(96 well kit)

- **Utilizes a monoclonal antibody which recognizes a functional epitope on vWF molecule**
- **Total incubation time is 40 minutes**
- **Convenient ELISA Procedure**
- **Easy to use**

Background

von Willebrand Factor (vWF), a pro-coagulant protein, plays two important roles in hemostasis: 1) mediates platelet adhesion to sites of vascular injury; and 2) protects factor VIII from proteolytic cleavage in circulation. In von Willebrand Disease (vWD), which is caused by either quantitative (Type I) or qualitative (Type II) deficiencies in vWF, abnormal bleeding may result due to impaired platelet function and clotting factor inhibition. vWD is the most common inherited bleeding disorder, and is clinically characterized by easy bruising or prolonged bleeding from mucosal surfaces. While approximately 80% of vWD patients have Type I deficiency, both quantitative (antigenic) and qualitative (functional) assays may be required for a laboratory diagnosis of vWD.

Principle

The REAADS von Willebrand Factor Activity Test is an ELISA for the quantitative detection of vWF activity in citrated human plasma. The assay utilizes a purified murine anti-vWF monoclonal antibody which recognizes a functional epitope on the vWF molecule to assess vWF activity levels. Results are reported in percent (%) of normal, relative to a calibrator that has been standardized against the third International Standard for Factor VIII and von Willebrand Factor in Plasma (91/666).

Procedure

Diluted citrated patient plasma and controls are incubated in microwells coated with monoclonal capture antibody allowing patient vWF to bind to the surface. Following an incubation period, the wells are washed, and a horseradish peroxidase (HRP) conjugated anti-human vWF detection antibody is added. After incubation, the wells are washed, substrate is added, and color development is measured in a spectrophotometer at 450nm following the addition of a stop solution. Patient vWF:Act levels are determined from a six-point curve prepared from the reference plasma provided in the kit. Total incubation time is 40 minutes at room temperature.

Clinical Performance

100 citrated plasma samples from healthy individuals were assayed for von Willebrand Activity using the REAADS kit. 90% of the results for this population were $\geq 50\%$ activity. Comparable results are seen between the REAADS von Willebrand Factor Activity Test Kit, and another commercially available vWF activity ELISA kit when testing type 2 vWD samples. Using the REAADS von Willebrand Factor Activity Test Kit, the mean von Willebrand Factor Activity for the population is 26.5% with results ranging from 1.7-59.8%. Using

another commercially available kit, the population mean was 19.7%, with a range of 1.5-147.3%. When the results were compared, the values reported by the two methods are shown to be statistically similar.

Technical Performance

Precision within a lot was determined by testing 14 commercially prepared plasma samples, in duplicate dilutions, across three plate lots. The mean CV for duplicates over three plate lots was 5.2%. The precision between lots was determined by comparing the values recovered for eight different control samples on two lots. Each of the eight samples was tested in duplicate in each assay. The mean inter-assay CV was 8.3%. The lower limit of detection, as calculated from the reagent blank plus 3 standard deviations, using 3 kit lots, was 3.1%.



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