

**REAADS von Willebrand Factor
Antigen Test Kit
For In Vitro Diagnostic Use**

**REAADS von Willebrand Factor
Antigen Test Kit**
Product #: 034-001
(96 well kit)

- **Convenient ELISA Procedure**
- **Objective, accurate and reproducible**
- **Reagent complete kit**
- **Total incubation time:
40 minutes**

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 Antigen (vWF:Ag) Test Kit is an enzyme linked immunosorbent assay for determining von Willebrand Factor levels in human plasma, expressed in relative percent (%) of normal. The assay is intended to be used as an aid in the diagnosis of von Willebrand Disease in patients with bleeding disorders, and to

help distinguish between vWD and classic Hemophilia A. REAADS vWF:Ag Test Kit will accurately detect antigen levels as low as 5% of normal.

Procedure

Diluted citrated patient plasma and controls are incubated in microwells coated with capture antibody specific for human vWF, 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:Ag 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

The clinical performance was determined by testing healthy blood donors and von Willebrand Disease plasma samples with REAADS vWF:Ag Test Kit and with a well established, commercially available von Willebrand Factor Antigen Rocket EIA method. The results correlated well, and were shown to be statistically similar by single factor Anova.

	REAADS	Rocket EIA
Healthy		
Mean	106%	103%
Range	47 - 197%	47 - 202%
vWF samples		
Mean	38.8%	37.4%
Range	26 - 59%	24 - 50%
Correlation (<i>r</i>) = 0.962; <i>P</i> value = 0.739		

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Technical Performance

Intra-assay precision of REAADS vWF:Ag Test Kit is 3.6%, while inter-assay precision is 5.0%. Linearity, expressed as the coefficient of determination (r^2) is 0.996, with a mean accuracy of 103.6%.

The REAADS vWF:Ag Test Kit is a rapid, convenient, highly accurate and precise method for the quantitative determination of vWF:Ag levels.



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