

**REAADS Protein S
Antigen Test Kit**
For In Vitro Diagnostic Use

**REAADS Protein S
Antigen Test Kit**
Product #: 036-001
(96 well kit)

- **TOTAL and FREE Protein S**
- **Convenient ELISA Procedure**
- **Reagent complete kit**
- **Six point reference curve**
- **Total incubation time: 60 minutes**

Background

Protein S is a vitamin K dependent plasma protein synthesized in the liver, vascular endothelium and megakaryocytes, which plays an important role along with Protein C in the regulation of hemostasis. Protein S serves as a cofactor for the anticoagulant and fibrinolytic effects of activated Protein C. Approximately 40% of the Protein S circulates in the functionally active free form, while 60% is complexed to C4b-binding protein and is inactive. Protein S deficiency, either congenital or acquired, may lead to serious thrombotic events, such as thrombophlebitis, deep vein thrombosis, or pulmonary embolism. While susceptibility to thrombosis has been related to changes in the level of free Protein S, the measurement of both total and free Protein S is useful in classifying patients with congenital Protein S deficiency.

Principle

The REAADS Protein S Antigen Test kit is a double antibody capture assay for measuring total and free Protein S levels in human plasma, expressed in relative percent (%) of normal. The assay is intended to be used as an aid in the

diagnosis of Protein S deficiency in patients with thrombotic disorders. The REAADS Protein S Antigen Test Kit will accurately detect antigen levels as low as 5% of normal.

Procedure

Diluted citrated patient plasma is incubated in microwells coated with capture antibody specific for human Protein S, allowing patient Protein S to bind to the surface. The wells are washed, and HRP-conjugated anti-human Protein S 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 Protein S levels are determined from a six-point curve prepared from the reference plasma provided in the kit. Free Protein S levels can be measured simultaneously by testing patient, control, and reference plasma samples that have been pretreated with PEG, following the same assay procedure. Total incubation time is 60 minutes.

Clinical Performance

Plasma samples from healthy blood donors and from patients with a history of thrombosis were tested to define and compare the clinical performance of REAADS Protein S ELISA with a well established, commercially available Protein S Antigen Rocket EID method. As shown in the table, the results correlated well, and were shown to be statistically similar by single factor Anova.

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Technical Performance

Intra-assay precision is 10.1% for REAADS Total Protein S, and 6.6% for the Free Protein S assay. Inter-assay precision is 11.0% for Total, and 10.5% for Free Protein S. Linearity, expressed as the coefficient of determination (r^2) is 0.985 for Total, and 0.992 for Free Protein S. Mean accuracy is 101% for Total, and 98% for Free Protein S assays.

REAADS Protein S ELISA is a rapid, convenient, highly accurate and precise method for the quantitative determination of Protein S levels in human plasma.

	REAADS	Rocket EID
Total Protein S		
Healthy:		
Mean	105%	98%
Range	64 – 150%	65 - 143%
Patients:		
Mean	59%	58%
Range	23 – 140%	23 – 148%
Correlation (r) = 0.924; P value = 0.494		
Free Protein S		
Healthy:		
Mean	97%	102%
Range	61 – 162%	62 – 160%
Patients:		
Mean	47%	52%
Range	12 – 115%	20 – 127%
Correlation (r) = 0.934; P value = 0.346		



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