

**REAADS Monoclonal Free
Protein S Test Kit**
For In Vitro Diagnostic Use

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Protein S Test Kit**

Product #: 051-001
(96 well kit)

- **Utilizes a monoclonal antibody specific for Free Protein S**
- **Convenient ELISA Procedure**
- **Objective, accurate and reproducible**
- **Reagent complete kit**
- **Total incubation time: 60 minutes at room temperature**

Protein S is a vitamin K dependent plasma protein which plays an important role along with Protein C in the regulation of coagulation. Protein S functions as a cofactor for activated Protein C on the vascular membrane to facilitate the degradation of factors Va and VIIIa, down-regulating clot formation and promoting fibrinolysis. Approximately 40% of 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 the type of deficiency in congenital Protein S deficient patients.

Principle

REAADS Monoclonal Free Protein S ELISA uses a monoclonal antibody specific for free Protein S to measure free Protein S levels in citrated human plasma. No pretreatment of samples with polyethylene glycol (PEG) is

required. Results are reported in percent (%) of normal, relative to a reference plasma that has been standardized against the Secondary Standard for Coagulation/ International Society on Thrombosis and Haemostasis (SSC/ISTH) preparation, which is calibrated to World Health Organization (WHO) standards.

Procedure

Diluted citrated patient plasma is incubated in microwells coated with a monoclonal capture antibody specific for free Protein S, allowing patient free Protein S to bind to the surface. After washing to remove unbound plasma proteins, HRP-conjugated polyclonal anti-human Protein S detection antibody is added, which attaches to the surface bound free Protein S antigen during a second incubation. The wells are washed, and a chromogenic substrate is added, resulting in a soluble colored product that is measured in a spectrophotometer at 450 nm after the addition of stop solution. The concentration of free Protein S in the test sample is determined from a standard curve prepared from the reference plasma provided in the kit. Total assay incubation time is 60 minutes at room temperature.

Clinical Performance

The clinical performance was determined by testing plasma samples from 35 healthy individuals and 20 patients with known Protein S deficiency with REAADS Monoclonal Free Protein S assay and REAADS Protein S Antigen Test Kit (PEG method). As shown in the table, a good correlation was seen between the two methods for the combined test population ($r = 0.980$), with a P value of 0.739 by single factor Anova.

Technical Performance

Intra-assay precision, expressed in %CV, was 4.7% when samples ranging in value from 6 - 150% were tested in duplicate with

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REAADS Monoclonal Free Protein S assay. Inter-assay precision was shown to be 5.2%. Accuracy was demonstrated by testing the recovery of plasma samples spiked with known levels of free Protein S; the mean % recovery was 101.2% across three production lots. Linearity was determined by linear regression of the log-log curve generated from the reference plasma, and expressed as the coefficient of determination (r^2) = 0.994.

REAADS Monoclonal Free Protein S Assay is a rapid, accurate and precise method for the determination of free Protein S levels in human plasma, offering improved specificity, convenience and significant time savings over traditional methods that require PEG precipitation.

	REAADS Monoclonal Free Protein S	REAADS Protein S Assay (PEG Method)
Normals:		
Mean	105%	100%
Range	65 - 144%	61 - 130%
Deficients:		
Mean	20%	22%
Range	8 - 40%	12 - 34%
Correlation (r) = 0.980; P value = 0.739		



Corgenix, Inc.

12061 Tejon Street
Westminster, Colorado 80234
Toll Free: 800-729-5661
Telephone: 303-457-4345
Fax: 303-457-4519
Email: techsupport@corgenix.com
www.corgenixonline.com

Corgenix (UK) Ltd.

75 Broadway
Peterborough, PE1 1SY UK
Telephone: +44 (0) 1733 296800
Fax: +44 (0) 1733 296809
Email: sales@corgenix.co.uk
www.corgenix.co.uk

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