

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

**REAADS Protein C
Antigen Test Kit**
Product #: 035-001
(96 well kit)

- **Convenient ELISA Procedure**
- **Objective, accurate and reproducible**
- **Reagent complete kit**
- **Total incubation time: 60 minutes**

Background

Protein C plays a key role in the naturally occurring anticoagulant pathway that regulates hemostasis. Through complex interactions with other components of the coagulation cascade, Protein C contributes to the maintenance of normal hemostasis by limiting clot formation and by promoting fibrinolysis. Deficiency of Protein C, either congenital or acquired, may lead to serious thrombotic events, such as thrombophlebitis, deep vein thrombosis, or pulmonary embolism. In congenital deficiency, decreased Protein C activity may result from low concentrations and/or abnormal function. Acquired deficiency, resulting from decreased levels of Protein C, may be seen in neonates, liver disease, and during oral anticoagulant therapy.

Principle

The REAADS Protein C Antigen Test Kit is a double antibody capture assay for measuring Protein C levels in human plasma, expressed in relative percent (%) of normal. The assay uses a six-point curve to determine levels of Protein C. The assay is intended to be used as an aid in the diagnosis of Protein C deficiency in patients with thrombotic disorders. The REAADS Protein C Antigen 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 Protein C. During an incubation period, patient Protein C is allowed to bind to the surface. Following a wash to remove any unbound plasma, horseradish peroxidase (HRP) conjugated anti-human Protein C detection antibody is added to the wells. After washing to remove unbound conjugate, a chromogenic substrate is added, resulting in a soluble colored product that is measured in a spectrophotometer at 450nm following the addition of a stop solution. Patient Protein C levels are determined from a six-point curve prepared from the reference plasma provided in the kit. 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 C ELISA with a well established, commercially available Protein C Antigen Rocket EID method. As shown in the table, the results correlated well, and were shown to be statistically similar by single factor Anova.

	REAADS	Rocket EID
Healthy:		
Mean	110%	100%
Range	72 – 160%	68 - 160%
Patients:		
Mean	57%	61%
Range	5 – 200%	8 – 240%
Correlation (<i>r</i>) = 0.949 <i>P</i> value = 0.838		

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Technical Performance

Intra-assay precision of REAADS Protein C ELISA is 7.0% while inter-assay precision is 7.5%. Linearity, expressed as the coefficient of determination (r^2) is 0.992 with a mean accuracy of 99.4%. REAADS Protein C ELISA is a rapid, convenient, highly accurate and precise method for the quantitative determination of Protein C levels in human plasma.



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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