

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE**

A. 510(k) Number:

K040987

B. Purpose for Submission:

To obtain clearance for a new assay.

C. Analyte:

Protein C

D. Type of Test:

Clotting

E. Applicant:

Precision Biologic INC.

F. Proprietary and Established Names:

CryoCheck Clot C

G. Regulatory Information:

1. Regulation section:
21 CFR 864.7290
2. Classification:
II
3. Product Code:
GGP
4. Panel:
81 Hematology

H. Intended Use:

1. Intended use(s):
The Precision Biologic Cro
Check C is a clot-based assay intended for the quantitative determination of protein C activity in citrated human plasma.

2. Indication(s) for use:

Protein C is a vitamin K dependent coagulation plasma protein that is activated by thrombin in presence of thrombomodulin; Protein C deficiency has both congenital and acquired etiologies. Acquired deficiencies are associated with hepatic disorders, oral anticoagulant therapy and disseminated intravascular coagulation. Congenital deficiencies are commonly associated with an increased risk of venous thrombosis.

3. Special condition for use statement(s):

4. Special instrument Requirements:

I. Device Description:

CryoCheck Clot C consists of Protein C Deficient Plasma-citrated pooled normal human plasma that has been depleted of protein C by immunoadsorption; Clot C Activator-protein isolated from the venom of *Agkistrodon contortrix* capable of activating protein C in human plasma, Russell's viper venom, phospholipids, heparin neutralizing agents, buffers and stabilizers; and CS diluent

J. Substantial Equivalence Information:

1. Predicate device name(s):

Diagnostica Stago STA-StacLOT Protein C

2. Predicate K number(s):

K861079

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	A clot-based assay intended for use in the quantitative determination of protein C activity in citrated human plasma.	For the quantitative measurement of the functional protein C level based on the prolongation of the activated partial thromboplastin time (APTT)
Differences		
Item	Device	Predicate
Format	Frozen	Lyophilized

K. Standard/Guidance Document Referenced (if applicable):

L. Test Principle:

CryoCheck Clot C™ functions by direct activation of protein C in the patient sample using protein C activator. The Common pathway of coagulation is initiated with a Russell's viper venom (RVV-X) reagent to convert factor X to Xa and by passing all factors above the common pathway. Patients with a protein C deficiency will have shortened clotting times relative to patients with normal levels of protein C. The clotting time is proportional to the amount of protein C in the patient's plasma, and can be quantified using a calibration curve.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Intra-assay: One normal sample and one sample close to the clinical critical decision point were tested 20 times each, one calibration curve. Normal = 6.0% CV, Boderline = 8.5%

Inter-assay: 25 normal and 25 samples from patients with abnormal low protein C levels were tested on two separate calibration curves, with different operators performing each run. Results obtained on curve 1 were compared to results obtained on curve 2, and presented as a linear regression curve ($y=0.975X + 7.4719$, $r=0.9899$).

Results were also presented in %CV for clotting times in sec and % protein C. All results were acceptable.

b. Linearity/assay reportable range:

Linearity was determined by running a 14 point calibration curve demonstrating linearity of 5- 150% protein C activity

c. Traceability (controls, calibrators, or method):

n/a

d. Detection limit:

n/a

e. Analytical specificity:

CryoCheck Clot CTM is unaffected by:

Factor VIII: c activity levels up to 600%

Unfractionated heparin (UFH) up to 1.2 IU/ml

Low molecular weight heparin (LMWH) up to 1.2 IU/ml

Heterozygous for the factor V_{LEIDEN} mutation

Lupus Anticoagulant: Interference by lupus anticoagulants (LA) has not been observed with CryoCheck Clot CTM. However, since LA are heterogeneous, the possibility that some could influence CryoCheck Clot CTM can not be ruled out.

Activated Protein C Resistance: CryoCheck Clot CTM is unaffected by samples from patients heterozygous for the factor V_{Leiden} mutation. CryoCheck Clot CTM may be affected by samples homozygous for this mutation.

f. Assay cut-off:

n/a

2. Comparison studies:

a. Method comparison with predicate device:

2 sites: Site 1: 119 samples tested on the STA instrument

$$y=1.1337X - 5.3861, r= 0.9142$$

Site 2: 99 samples tested on the STA-Compact

$$y=0.9494X +12.0754, r=0.8948$$

b. Matrix comparison:

n/a

3. Clinical studies:

a. Clinical sensitivity:

n/a

b. Clinical specificity:

n/a

c. Other clinical supportive data (when a and b are not applicable):

4. Clinical cut-off:

n/a

5. Expected values/Reference range:

126 normal (non-medicated, normal PT, APTT, & Fibrinogen, Negative APC and LA) ages 18-70.

$$\text{Mean} = 126\% \pm 2(32.6)$$

N. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.