

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

A. 510(k) Number:

K050448

B. Purpose for Submission:

To obtain a name change and manufacturer change from Chromocheck Protein C and Chromocheck Antithrombin to Chromopep Protein C and Chromopep Antithrombin.

C. Measurand:

Protein C and Antithrombin

D. Type of Test:

Chromogenic

E. Applicant:

Horiba ABX, Inc.

F. Proprietary and Established Names:

Chromopep PC 2.5 or Chromopep PC 5

Chromopep AT 2.5 or Chromopep AT 5

G. Regulatory Information:

1. Regulation section:

21CFR 864.7290 (Chromopep PC)

21 CFR 864.7060 (Chromopep AT)

2. Classification:

Class II

3. Product code:

GGP (Chromopep PC)

JBQ (Chromopep AT)

4. Panel:

81 Hematology

H. Intended Use:

1. Intended use(s):

Chromopep PC is intended for use as an *in vitro* chromogenic assay for the quantitative determination of Protein C activity in citrated human plasma.

Chromopep AT PC is intended for use as an *in vitro* chromogenic assay for the quantitative determination of antithrombin activity in citrated human plasma.

2. Indication(s) for use:

Chromopep PC is intended for use as an *in vitro* chromogenic assay for the quantitative determination of Protein C activity in citrated human plasma.

Chromopep AT PC is intended for use as an *in vitro* chromogenic assay for the quantitative determination of antithrombin activity in citrated human plasma.

3. Special conditions for use statement(s):

4. Special instrument requirements:

I. Device Description:

Chromopep Protein C is a chromogenic assay consisting of a synthetic substrate and Protein C activator.

Chromopep Antithrombin assay consists of a synthetic substrate, Factor Xa and a Tris Heparin buffer.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Chromocheck Protein C

Chromocheck Antithrombin

2. Predicate 510(k) number(s):

K023990 (Chromocheck Protein C)

K023991 (Chromocheck Antithrombin)

3. Comparison with predicate:

Similarities				
Item	Device		Predicate	
Component Reagents	Chromoep PC	Chromoep AT	Chromocheck PC	Chromocheck AT
	Same	Same	As provided in original 510(k)	As provided in original 510(k)
Controls & calibrators	All citrated human plasma (frozen or lyophilized) and validated against an international standard may be used.	Same	Same	Same

Differences				
Item	Device		Predicate	
	Chromoep PC	Chromoep AT	Chromocheck PC	Chromocheck AT
Labeling	Chormoep PC specific label	Chromoep AT specific label		

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

L. Test Principle:

Protein C in plasma is activated by a specific enzyme from Agkistrodon c. contortrix snake venom. The amount of activated protein C (APC) is determined by the rate of hydrolysis of the chromogenic substrate pNAPEP 1566TI. The pNA release measured at 405 nm is proportional to the protein C level in the range from 0-120% of normal plasma.

Chromoep Antithrombin is a kinetic assay based on competition between inhibition of factor Xa by the heparin-antithrombin complex and hydrolysis of a chromogenic

substrate by factor Xa which is present in excess. The amount of pNA released in the reaction measured at 405 nm is inversely proportional to the amount of antithrombin present and this can be quantified using a calibration curve.

M. Performance Characteristics (if/when applicable):

***Note:** The performance characteristics for Chromopep Protein C 2.5 and Chromopep Protein C 5 were established from the data provided in the original 510(k) K023990 ChromoCheck™ Protein C 25 and ChromoCheck™ Protein C 5 submitted by Precision Biologic, Inc., and cleared on March 19, 2003.

The performance characteristics for Chromopep Antithrombin and Chromopep Antithrombin 5 were established from the data provided in the original 510(k) K023991 ChromoCheck™ Antithrombin 2.5 and ChromoCheck™ Antithrombin 5 submitted by Precision Biologic, Inc., and cleared on April 28, 2003.

Both products are manufactured by Biopep, manguio, France. No product change has occurred since the original submission.

1. Analytical performance:

Refer to previously cleared 510(k) submissions – K023990 & K023991

- a. *Precision/Reproducibility:*
- b. *Linearity/assay reportable range:*
- c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
- d. *Detection limit:*
- e. *Analytical specificity:*
- f. *Assay cut-off:*

2. Comparison studies:

Refer to previously cleared 510(k) submissions – K023990 & K023991

- a. *Method comparison with predicate device:*
- b. *Matrix comparison:*

3. Clinical studies:

Refer to previously cleared 510(k) submissions – K023990 & K023991

a. Clinical Sensitivity:

b. Clinical specificity:

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

4. Clinical cut-off:

5. Expected values/Reference range:

The range of the Chromopep PC assay is 5% - 140% protein C activity.

The range of the Chromopep AT assay is 0% - 120% antithrombin activity.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

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