

Control Plasma Level 2

For In Vitro Diagnostic Use

**Control Plasma
Level 2****Art. No. 82 26 68****Batch No.:****CHROMOGENIX**

Chromogenix-
Instrumentation Laboratory SpA
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INTENDED USE OF THE KIT

For control of accuracy when using the Coatest APC Resistance and Coatest APC Resistance V kits.

REAGENT

Chromogenix Control Plasma Level 2 is a lyophilized preparation of citrated human plasma from selected donors.

CAUTION: Each donor unit used in the preparation of human source reagent has been tested by FDA approved methods for the presence of Hepatitis B surface antigen and antibodies to HIV 1 and 2 and Hepatitis C and found to be negative. However, since no test can completely rule out the presence of these blood borne diseases, the handling and disposal of human source reagents from this product should be made with care.

PROCEDURE

Reconstitute each vial with 1.0 mL deionized water, filtered through 0.22 μm or NCCLS type II water¹. Allow to stand at room temperature for 30 minutes. Swirl gently before use.

STABILITY

Stability after reconstitution is 6 hours at 2-25°C or 3 months at -20°C or below. The frozen reagent should be thawed at 37°C and gently mixed before use. Do not refreeze.

EXPECTED VALUES

Different clotting times will be obtained with different types of instruments depending on the clot detection principle. The following ranges cover the expected clotting times when performing analysis of Control Plasma Level 2 with the above batch number using the Coatest APC Resistance and Coatest APC Resistance V kits.

COATEST® APC™ RESISTANCE

Turbidimetric/photometric (e.g. ACL, MLA)

CaCl₂ (s)	APC/CaCl₂ (s)	APC ratio
28-36	56-76	1.7-2.4

Electro-mechanical (e.g. ST 4, KC, Fibrintimer)

CaCl₂ (s)	APC/CaCl₂ (s)	APC ratio
27-39	58-74	1.6-2.3

COATEST® APC™ RESISTANCE V

All instruments

CaCl₂ (s)	APC/CaCl₂ (s)	APC-V ratio
28-43	40-72	1.3-1.8

REFERENCE

- National Committee for Clinical Laboratory Standards. Specifications for reagent water used in the clinical laboratory, NCCLS Approved Standard: ASC-3