

## COAGULATION CONTROL

**Lot No.** 215CG      **Cat. No.** N/A  
**Expiry:** 2018-11      **Size:** 12x1ml

### INTENDED USE

This product is intended for *in vitro* use, in the quality control of coagulation systems.

### SAFETY PRECAUTIONS AND WARNINGS

For *in vitro* use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents and controls.

Human source material, which has been added, has been tested at donor level for the Human Immunodeficiency Virus (HIV 1, HIV 2) antibody, Hepatitis B Surface Antigen (HbsAg), and Hepatitis C Virus (HCV) antibody and was found to be NON-REACTIVE. FDA approved methods have been used to conduct these tests.

However, since no method can offer complete assurance as to the absence of infectious agents, this material and all patient samples should be handled as though capable of transmitting infectious diseases and disposed of accordingly.

Health and Safety Data sheets are available on request.

### STORAGE AND STABILITY

**OPENED:** Store refrigerated (+2°C to +8°C). APTT, TT, PT and Fibrinogen in reconstituted serum are stable for 24 hours at +2°C to +8°C, if kept capped in original container and free from contamination. D-Dimer and Factors VIII and IX are stable for 8 hours at +2°C to +8°C. Only the required amount of product should be removed. After use, any residual product should NOT BE RETURNED to the original vial.

**UNOPENED:** The product is stable to the expiration date when stored at +2°C to +8°C.

### PREPARATION FOR USE

The Coagulation Controls are supplied lyophilised.

- Carefully reconstitute each vial of lyophilised control with exactly 1 ml of distilled water at +15°C to +25°C. Close the bottle and allow to stand for 30 minutes before use. Ensure contents are completely dissolved by swirling gently. Avoid the formation of foam. Do not shake the vial.
- Refrigerate any unused material. Prior to reuse, mix the contents of the vial thoroughly.

### MATERIALS PROVIDED

Coagulation Control      1 ml

### MATERIALS REQUIRED BUT NOT PROVIDED

Volumetric pipette

### ASSIGNED VALUES

Approximate values are assigned from results obtained from internal testing conducted at Randox Laboratories Ltd.

Analyte	Unit	Target	Method
Activated Partial Thromboplastin Time (APTT)	seconds	59.1	HemosIL Synthasil
D-Dimer	ng/ml	293	Hemosil D-Dimer
Factor VIII	%	25.1	HemosIL Synthasil
Factor IX	%	42.3	HemosIL Synthasil
Fibrinogen	mg/dl	153	HemosIL PT-Fibrinogen HS Plus
Prothrombin Time (PT)	seconds	21.8	HemosIL PT-Fibrinogen HS Plus
Prothrombin Time (PT) INR	INR	1.74	HemosIL PT-Fibrinogen HS Plus
Thrombin Time (TT)	seconds	14.7	HemosIL Thrombin Time 2ml

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