ichroma™ hsCRP Control

INTENDED USE

ichroma™ hsCRP Control is intended for use in the clinical laboratory or doctor's office as a test sample of know concentration. Assay values are provided for ichroma™ system in the section of "CONTROL VALUE". The user can compare test results with expected ranges as means of assuring consistent performance of reagent and ichroma™ instrument.

FOR IN VITRO DIAGNOSTIC USE.

PRODUCT DESCRIPTION

ichroma™ hsCRP Control is a liquid stable control material prepared from human blood. Components of the controls which are derived from human source materials have been tested and found no-reactive for Hepatitis B Surface antigen (HBsAg), Hepatitis C(HCV), HIV-1 and HIV-2. However, no test method can offer complete assurance that products derived from human source are free of infectious agents.

INSTRUCTIONS FOR USE

Thoroughly mix the contents of the vial before each use by gently inverting for several times. Open the vial and pick up the control solution with the blood collecting capillary and assemble the capillary with then tube into one. After this step, follow the procedure according to the insert provided with the kit. The blood collecting capillary contains 10 ul of sample volume. (Please keep the control at a room temperature for 30 minutes, ahead of use.)

KIT COMPOSITION

REF CFPO-7

Reagents (Liquid)

ichroma™ hsCRP Control (Vial)	1 x 0.5 mL

STORAGE AND HANDLING

Control should be stored refrigerated (2-8°C). Return all reagents to 2-8°C promptly after use. Unopened vial of control is stable until the expiration date on the label. Opened vial of control can be used for 1 month if stored at 2-8°C.

CONTROL VALUE

The assigned ranges of this control are based on replicate assays of representative samples of the product by ichroma™ hsCRP and the reader**.** Expected values may vary slightly depending on users.

ichroma™ hsCRP Control	
LOT No.(EXP.)	CHCMH09 (2017.08)
Concentration (mg/L)	1.5
Range (mg/L)	1.2 ~ 1.8

For Technical Assistance call
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