

# ichroma™ iFOB Control

## INTENDED USE

**ichroma™ iFOB Control** is intended for use in the clinical laboratory or doctor's office as a test sample of known 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™ iFOB Control** is a liquid stable control material human hemoglobin A0. 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

1. Thoroughly mix the contents of the vial before each use by gently inverting for several times.
2. Remove the upper cap with sampling stick from the Sample Collection Tube.
3. Take 10 µl from viral, put into the Sample Collection Tube and return the upper cap. Tighten the upper cap and then shake the up and down mix well.
4. After this step, follow the procedure according to the insert provided with the kit. (Please keep the control at a room temperature for 30 minutes, ahead of use.)

## KIT COMPOSITION

**REF** CFPO-14

Reagents (Liquid)

ichroma™ iFOB Control	L	1 x 200ul
ichroma™ iFOB Control	H	1 x 200ul

## 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 using ichroma™ iFOB and the reader. Expected values may vary slightly depending on users.

ichroma™ iFOB Control		
LOT No.(EXP.)	FOCNK31 (2018.11)	
Low	Concentration (ng/mL)	90
	Range (ng/mL)	67.5-113
High	Concentration (ng/mL)	500
	Range (ng/mL)	375-625

For Technical Assistance call

**Boditech Med Inc.'s Technical Services at**

Tel: +82 (33) 243-1400

E-mail: sales@boditech.co.kr



**Boditech Med Incorporated**

43, Geodudanji 1-gil, Dongnae-myeon,

Chuncheon-si, Gang-won-do, 24398

Republic of Korea

Tel: +82 -33-243-1400

Fax: +82 -33-243-9373

www.boditech.co.kr



**Obelis s.a**

Bd. Général Wahis 53,

1030 Brussels, BELGIUM

Tel: +(32) -2-732-59-54

Fax: +(32) -2-732-60-03

E-Mail: mail@obelis.net

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