

H-FABP CALIBRATOR SERIES (H-FABP CAL) (Heart-Type Fatty Acid-Binding Protein Calibrator Series)

CAT. NO. FB 3134
PRESENTATION: Lyophilised
SIZE: 6 x l ml

GTIN: 05055273208672

INTENDED USE

The Randox H-FABP Calibrator Series is intended for use in the calibration of H-FABP on the RX series analysers, which includes the RX daytona and RX imola.

SAFETY PRECAUTIONS

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

Human source material from which this product has been derived has been tested for the Human Immunodeficiency Virus (HIV I, HIV 2) antibody, and Hepatitis B Surface Antigen (HbsAg) and 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.

The reagents must be used only for the purpose intended by suitably qualified laboratory personnel, under appropriate laboratory conditions.

REAGENT COMPOSITION

Lyophilised 19 mM Tris buffered saline, pH 7.2 containing a protein matrix, stabilisers, preservatives and H-FABP.

SAMPLE PREPARATION

- 1. Open vial very carefully, avoiding any loss of material.
- 2. Reconstitute each vial with I ml of double deionised water.
- 3. Replace stopper, close vial and mix carefully for 30 minutes.
- 4. Ensure contents are completely dissolved before use.

STORAGE AND STABILITY

Do not freeze.

UNOPENED: Store at $+2^{\circ}C$ to $+8^{\circ}C$ up to the expiration date.

OPENED: Reconstituted vials are stable for 35 days at +2°C to +8°C when stored in the original vial. Only the required amount

of product should be removed. After use, any residual product should NOT BE RETURNED to the original vial.

Reconstituted vials are stable for 8 weeks at -20°C, when frozen once.

VALUE ASSIGNMENT

Assignment of H-FABP Calibrators has been performed at Randox Laboratories by latex enhanced immunoturbidimetry. The assigned values for the H-FABP Calibrators are listed below.

Std. No	Lot. No	CONCENTRATION	EXPIRY DATE
1	207FB	0 ng/ml	2021-03-28
2	206FB	6.31 ng/ml	2021-03-28
3	205FB	12.09 ng/ml	2021-03-28
4	204FB	26.65 ng/ml	2021-03-28
5	203FB	55.33 ng/ml	2021-03-28
6	202FB	I I 3.38 ng/ml	2021-03-28

31 Mar 20 ml



THIS PAGE IS INTENTIONALLY BLANK