H-FABP CONTROL LEVEL 1 (H-FABP CONTROL 1)

(Heart-Type Fatty Acid-Binding Protein Control Level 1)

CATALOGUE NO.	FB 4026
LOT NO.	228FB
EXPIRY:	2022-08-28
PRESENTATION:	Lyophilised
SIZE:	3 x 1 ml
GTIN:	05055273208696

INTENDED USE

The Randox H-FABP Control Level 1 is intended for use in the quality control of H-FABP on the RX **series** analysers, which includes the RX **daytona** and RX **imola**. The control contains heart-type fatty acid-binding protein (H-FABP).

DEVICE DESCRIPTION

The H-FABP Controls are supplied at 2 levels, Level 1 and Level 2.

SAFETY PRECAUTIONS AND WARNINGS

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 1, 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.

STORAGE AND STABILITY

Do not freeze.

Unopened: Store at +2°C to +8°C up to the expiration date.

Opened: Reconstituted controls 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.

MATERIALS PROVIDED

H-FABP Control Level 1	3 x 1 ml

MATERIALS REQUIRED BUT NOT PROVIDED

Volumetric pipette

PREPARATION FOR USE

The H-FABP controls are supplied lyophilised.

1. Open the vial very carefully, avoiding any loss of material.
2. Carefully reconstitute each vial with exactly 1 ml of distilled water at +15°C to +25°C.
3. Replace the rubber stopper, close vial and leave to roll for 30 minutes out of bright light.
4. Ensure that contents are completely dissolved.
5. Do not shake the vial.

The controls should only be reconstituted using this procedure.

LIMITATIONS

1. Do not use the product past the expiry date.
2. Do not use the product if there is evidence of contamination.

VALUE ASSIGNMENT

Due to the variation caused by test equipment, test reagents and laboratory technique, the quoted ranges are provided for guidance. It is recommended that these ranges are used until each laboratory has established its own ranges, based on individual laboratory requirements.

Each lot of H-FABP control is assayed immunoturbidimetrically by Randox Laboratories Limited, with reference to a Master Lot of H-FABP Calibrator.

VALUE

7.10 ng/ml	5.68 - 8.52 ng/ml

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