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TRANSFERRIN Control Set

REF R33300000071

CTRL 1 1x 1mL
CTRL 2 1x 1mL

Instructions for Use

Document Control:R33300000071_v1.0.A.E

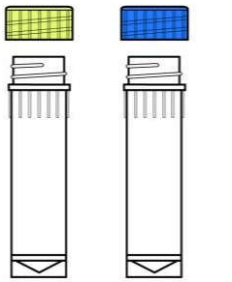
CE
IVD

LOT	T006		2020/03

Intended Use
The Transferrin Controls 1 and 2 are designed to be used exclusively with the ISE Transferrin detection in human stool samples;

REF R3330000060 - Transferrin detection kit – 100 test

KIT Components
The Transferrin control set is supplied ready to use with colour coded caps;



Control 1 *(Yellow Cap)* *Control* 2 *(Blue Cap)*

- CTRL 1 Control 1 1x 1mL
- CTRL 2 Control 2 1x 1mL

Instrument and Materials Required but no supplied
The TRANSFERRIN control set is designed to be used on the **Miura / Hemo One** family of systems.

Reagents Required:

REF R3330000060	TRANSFERRIN detection kit
REF R3330000067	Calibrator for TRANSFERRIN

Storage and Stability
Store at 2 to 8 °C. **Do not freeze.**
Note: Store control tightly capped when not in use.

Unopened vial: stability is up to the expiration date on label when stored at 2 to 8 °C.

Opened Vial: stability 30 days after opening, if control material is recapped and returned to 2-8°C immediately after use.

Disposal of reagent
Disposal of reagents must be performed in accordance with the EC regulations regarding waste, or the local national or regional legislation.

The product is in conformity with D.L: 8 September 2000, no. 332 "Actuation of the directive 98/79/EC regarding in vitro medical diagnostic devices".

Preparation
1. Allow Transferrin QC1 & QC2 to reach room temperature (15-30°C) prior to testing.
2. Extract/aliquot the volume necessary for the run into appropriate vials or tubes.
3. Recap the Transferrin controls and replace at 2 -8°C
4. Ensure the Instrument has been calibrated and run the extracted aliquots.
5. Discard the aliquots after use.

Precautions
1. For *in vitro* diagnostic use only.
2. For professional use only.
3. For use only on the Miura / Hemo One instruments
4. Package Insert instructions must be read and understood prior to use of all instruments and kits.
5. Do not use beyond expiry date.
6. Do not mix materials from different lot numbers.
7. Safety data sheets are available.
8. All materials have been tested but should be handled as potentially hazardous and good laboratory practice should be followed.

Assigned Values
The controls have been tested in accordance with standardised procedures and conditions, the values have been calculated from multiple determinations and instruments.

The assigned ranges for this lot:

LOT	T006		2020 / 03
ng/mL	Lower Limit	**Target**	Upper Limit
CTRL 1	13	**18**	24
CTRL 2	60	**86**	112

Symbols on labels and packaging

IVD	In vitro diagnostic medical device
REF	Catalog Number
LOT	Lot or batch number
	Manufacturer
	Expiry date
	Temperature limitation
	Consult Instructions for use

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