

Fe Standard

REF 12146401 216

1 x 75 mL Calibrator

English

System information

For use on Roche/Hitachi MODULAR analyzers the calibrator code is 505.

For use on **cobas c** analyzers the calibrator code is 566.

For use on COBAS INTEGRA analyzers the system-ID is 07 7560 6.

Intended use

Fe Standard (Iron Standard) is for use in the calibration of quantitative Unsaturated Iron Binding Capacity (UIBC) assays on Roche clinical chemistry analyzers.

Summary

Fe Standard (Fe STD) is a ready-for-use calibrator based on an aqueous solution.

The concentrations of the calibrator components have been adjusted to ensure optimal calibration of the appropriate Roche methods on clinical chemistry analyzers.

Some methods specified in the relevant value sheet may not be available in all countries.

Reagents – working solutions

Reactive components:

0.09 mmol/L ferrous ammonium sulfate

Non-reactive components:

Diluted sulfuric acid

For the **cobas c** analyzers (except for the **cobas c 111** analyzer) the values are encoded in electronic files sent via the **cobas** link to the analyzers.

Calibrator values

Fe Standard is a gravimetrically prepared product containing iron at a concentration of 500 µg/dL (89.5 µmol/L).

Traceability information is given in the relevant Method Sheets for the system reagents.

Precautions and warnings

For in vitro diagnostic use.

Exercise the normal precautions required for handling all laboratory reagents.

Disposal of all waste material should be in accordance with local guidelines. Safety data sheet available for professional user on request.

Handling

The product is ready-for-use. Mix carefully before use. Avoid the formation of foam.

The enclosed barcoded labels are intended exclusively for Roche/Hitachi MODULAR automated analyzers and **cobas c** systems to identify the calibrator. Attach the barcoded labels to the tubes carrying the sample cups containing the calibrator material.

Storage and stability

Store at 15-25 °C.

Criterion for stability data stated by Roche:

Recovery within ± 5 % of initial value.

Stability:

Unopened: Up to the stated expiration date at 15-25 °C.

After opening: Up to the stated expiration date at 15-25 °C.

Store calibrator tightly capped when not in use.

Materials provided

- See "Reagents – working solutions" section
- Barcoded labels

Materials required (but not provided)

- Roche system reagents and clinical chemistry analyzers
- General laboratory equipment

Assay

Use Fe Standard as specified in the relevant Method Sheet for the system reagents.

A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard.

	Contents of kit
	Calibrator
	Volume after reconstitution or mixing

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Roche Diagnostics warrants that this product will meet the specifications stated in the labeling when used in accordance with such labeling and will be free from defects in material and workmanship until the expiration date printed on the label. THIS LIMITED WARRANTY IS IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR PARTICULAR PURPOSE. IN NO EVENT SHALL ROCHE DIAGNOSTICS BE LIABLE FOR INCIDENTAL, INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES.

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Significant additions or changes are indicated by a change bar in the margin.

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Roche Diagnostics GmbH, Sandhofer Strasse 116, D-68305 Mannheim
www.roche.com

Distribution in USA by:
Roche Diagnostics, Indianapolis, IN
US Customer Technical Support 1-800-428-2336

