

Intended Use

For calibrating the quantitative Direct Total Iron-Binding Capacity (TIBC) assay on automated chemistry analyzer systems. **Rx Only**

Summary & Explanation

Using the Direct TIBC reagents, measurement of the total iron-binding capacity of serum occurs in a fully automated manner, without the need for any off-line separation. Since the entire reaction process is monitored by the chemistry analyzer, it is necessary to calibrate the assay with serum-based calibrators which are carried through the same reaction process as the patient specimens.

Characteristics

The Calibrator Set is a set of two (Level 1 & Level 2) TIBC calibrators, set at a low and high TIBC concentration. The calibrators are serum based, lyophilized preparations which contain nonreactive stabilizers and additives. When using with automated chemistry analyzers, follow the manufacturer's recommended protocol to insure accuracy.

Assigned Value

Assigned values for each calibrator lot were derived from multiple occasion replicate analyses. Variations in calibration may be caused by differences in instrumentation, reagent, or test method employed in the laboratory.

Precautions

For *in vitro* diagnostic use.

POTENTIAL BIOHAZARDOUS MATERIAL

The calibrators contain human plasma donor units of which have been tested and found to be non-reactive for HBsAg, HIV 1/2 AB, HIV-1 RNA, HCV Ab, HCV RNA, and STS. Nevertheless, this product should be handled as if it is capable of transmitting an infectious disease.

Contains 0.05% sodium azide as a preservative.

Reconstitution

1. Remove cap and stopper from each bottle, taking care to avoid loss of any lyophilized material.
2. Using a volumetric pipet, add 1.0 ml of deionized water to the bottle.
3. Replace the rubber stopper and allow 30 minutes at room temperature for lyophilized material to completely dissolve. Gently invert the vial three times and swirl, avoiding foam formation, and inspect for complete dissolution of solids.

Lot Specific Information:

Calibrator	1	2
Lot Number	319202	319202
Expiry Date (Lyophilized)	2024-11-30	2024-11-30
Assigned Value (ug/dL)	105	728

Storage

1. Lyophilized material, prior to reconstitution, is stable when stored at 2-8°C until the expiration date assigned for this lot, shown above.
2. After reconstitution, the Calibrator is stable for: Ten (10) days stored at 2-8°C.
3. The reconstituted Calibrator should be brought to room temperature (18-26°C) before assaying.

Limitations

Erroneous results may occur if reconstituted incorrectly. Quality control samples should be run to verify proper calibration.

References

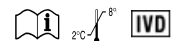
1. Department of Labor, Occupational Safety and Health Administration, 29 CFR Part 1910 1030. Occupational Exposure to Bloodborne Pathogens; Final Rule. Federal Register 1991, 56:64175-64182

Symbol Key

840611(R2)

Use by (YYYY-MM-DD)	LOT Lot and batch code
REF Catalog number	Manufacturer
IVD <i>In vitro</i> diagnostic medical device	Temperature limitation
Consult instructions for use	Rx Only: Prescription Use Only
CE CE mark	EC REP Authorized representative in the European Community

REF 17517-CAL

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Certified Performance Guarantee

HORIBA certifies that all of our products are manufactured according to specified parameters. Any product not meeting specifications through their listed expiration date will be remedied immediately without charge.

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