DIRECT TIBC CALIBRATOR KIT

REF TS3000	LOT 209074	Exp. 2014-02			
CAL 1	LOT 209076	Exp. 2014-02	Assigned Value	66 µg/dL	
CAL 2	LOT 234075	Exp. 2014-02	Assigned Value	648 µg/dL	

PRODUCT SUMMARY

Stability	:	Until expiry at 2-8°C
Calibrator Preparaton	:	Reconstitute with 1.0 mL deionized water

SYMBOLS IN PRODUCT LABELLING

IVD	*In Vitro* Diagnostic Medical Device		Temperature Limitation
LOT	Lot Number		Use By
REF	Catalogue Number		Manufacturer
	Consult Instructions for Use		Biological risk

INTENDED USE

For calibrating the quantitative Direct Total Iron-Binding Capacity (dTIBC) assay on automated chemistry analyzer systems.

SUMMARY & EXPLANATION

Using the Direct TIBC reagent, 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 Kit consists of two (1 & 2) TIBC calibrators, of 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 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. Take 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.

STORAGE

- Lyophilized material, prior to reconstitution, is stable when stored at 2 – 8°C until the expiration date assigned for this lot, shown above.
- After reconstitution, the Calibrators are stable for: Ten (10) days stored at 2 – 8°C.
- 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

Order Information	
Cat No.	**Content**
TS3000	Cal. 1 3 x 1.0mL Cal. 2 3 x 1.0mL

840611 (R2)

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