

Intended Use

The Pointe Transferrin Calibrator Set is intended to be used for the calibration of Pointe Transferrin immunoturbidimetric assay. For in vitro diagnostic use.

Product Description

These calibrators are human serum containing known quantities of Transferrin. There is also a calibrator containing only diluent (150 mM sodium chloride). These calibrators are to be used with the Pointe Transferrin Reagent Set.

Kit Composition

Calibrators (Liquid Stable)

MATERIALS PROVIDED

Level A	Sodium Chloride (150mM)	1 x 1mL
Level B-F	Human Serum (Liquid)	5 x 1mL

Pointe Transferrin Calibrators, levels B through F, contain pooled human serum with assigned values for transferrin.

Warnings and Precautions

For In Vitro Diagnostic Use Only. Rx Only.

Not to be used internally in humans or animals. Normal precautions in handling laboratory reagents should be followed.

Calibrators contain pooled human serum. Each donor unit used in the preparation of this product has been tested by an FDA approved method and found non-reactive for the presence of HBsAg and antibody to HIV. However, it is not possible to guarantee that they are free of hepatitis B, human immunodeficiency virus (HIV), or other infectious agents.

Therefore, all products containing human serum should be handled in accordance with good laboratory practices using appropriate precautions as described in the CDC/NIH Manual, "Biosafety in Microbiological and Biomedical Laboratories," 2nd ed., 1988, HHS Publication No. (CDC) 88-8395.

Do not mix or use calibrators from one test kit with those from a different lot.

Do not use calibrators past their expiration date stated on each control container label.

Do not pipette by mouth. Avoid ingestion and contact with skin.

Calibrators in this kit contain <0.1% w/v sodium azide as a preservative. Sodium azide may form explosive compounds in metal drain lines. When disposing of controls through plumbing fixtures, flush with copious amounts of water. For further information, refer to "Decontamination of Laboratory Sink Drains to remove Azide Salts," in the Manual Guide Safety Management No. CDC-22 issued by the Centers for Disease Control, Atlanta, Georgia.

Calibrator Preparation

The calibrators are ready to use and do not require reconstitution.

Storage and Handling

All calibrators should be stored refrigerated (2-8°C). Return all calibrators to 2-8°C promptly after use. Unopened calibrators can be used for up to 18 months from the date of manufacture, as indicated by the expiration date on the package and bottle labels.

Calibrator Stability

Opened bottles of calibrators may be used for 1 month if stored at 2-8°C. Discard calibrators if they become contaminated. Evidence of cloudiness or particulate material in solution is cause to discard.

Calibrator transferred to the instrument sample cup may concentrate over time. Therefore, calibrators should be capped and stored at 2-8°C when not in use. Otherwise, fresh calibrators should be used for each calibration.

Instrument

Measurements of absorbance are to be made with a clinical chemistry analyzer able to accurately read absorbance at 340, 600, and 700 nm. Refer to the instrument manual from the manufacturer regarding the following:

- Use or function
- Installation procedures and requirements
- Principles of operation
- Performance characteristics, operating instructions
- Calibration procedures including materials and / or equipment to be used
- Operational precautions, limitations, and hazards
- Service and maintenance information

Procedure

Calibrators should be used as specified in the Transferrin Reagent Set package insert. It is recommended that the user determine calibration frequency as this depends on the instrument and number/type of other assays being performed. Initially, calibration should be performed each day. For each calibration, fresh calibrator reagent should be withdrawn from the Pointe Transferrin Calibrator vials.

Materials Supplied

Calibrators A-F 6 x 1 mL

Materials Required but Not Supplied

Pointe Transferrin immunoturbidimetric assay kit (T7535)

Two Reagent Clinical Chemistry Analyzer:

Capable of accurate absorbance reading at 340, 600, and 700 nm

Capable of accurately dispensing the required volumes

Capable of maintaining 37°C

Details of Procedure

Note: Allow all reagents and specimens to come to room temperature. Mix all reagents gently before using.

The Pointe Transferrin Calibrator is assayed using the same procedure as the patient test samples run in the test procedure. See package insert from the Transferrin assay kit (T7535)

Calibrator Values

Lot 331302 Exp. 2025-03-31

Analyte	Level A	Level B	Level C	Level D	Level E	Level F
Transferrin (mg/dL)*	0	82	164	273	382	546

*Standardized against CAP/BCR/IFCC Reference Preparation for Proteins in Human Serum (RPPHS), lot 91/0619.

The expected values for the Transferrin Calibrators are continually being revised through ongoing quality control. As a result, the expected values may change from lot to lot. Please refer to the package insert for each lot for the exact calibrator values.

Symbol Key

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

T7535-CAL Manufactured for HORIBA Instruments Incorporated - Pointe Brand 5449 Research Drive Canton, MI 48188 2°C - 8°C

	Manufactured by Kamiya Biomedical Company 12779 Gateway Drive, Seattle, WA 98168 USA
	Advena Ltd. Tower Business Centre, 2 nd Flr., Tower Street, Swatar, BKR 4013 Malta

Certified to Perform Reagents

The Pointe reagents are certified to be manufactured according to specified parameters. Any Pointe reagent product not meeting specifications through its listed expiration date will be remedied immediately without charge.

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