

Intended Use

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

Summary

The calibrators provided are human serum, tested and found negative for HBsAb and HIV Ab. The calibrators contain known quantities of Ferritin. These calibrators are to be used with the Pointe Ferritin Reagent Set.

Kit composition

Calibrators (Liquid Stable)

MATERIALS PROVIDED

Calibrator Levels 1-4 Human Ferritin 4 x 1 mL

Pointe Ferritin Calibrator Level 1 through 4 contain pooled human serum with assigned values for ferritin.

Materials Required But Not Supplied

Saline (0.9% NaCl) as 0.0 ng/mL (Blank)

Warnings and Precautions

For *In Vitro* Use Only. Rx only.

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

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 set 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.

Calibrators contain purified human serum. Each donor unit used in the preparation of this product has been tested and found non-reactive for the presence of HBsAg and antibody to HCV and HIV by an FDA accepted method. However, it is not possible to guarantee that any human source material is free of these 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.

Calibrator Preparation

Calibrators are liquid and ready to use.

Storage and Handling

Store calibrators at 2-8°C and protected from light. Return all calibrators to 2-8°C promptly after use. When stored at 2-8°C, unopened controls are stable up to 24 months from the date of manufacture, as indicated on the package and bottle labels. Opened bottles of ferritin calibrators are stable for two months when tightly capped and stored at 2-8°C.

Calibrator Stability

Discard calibrators if they become contaminated. Evidence of turbidity or particulate material in solution is reason to discard.

Instrument

Measurements of absorbance are to be made with a clinical chemistry analyzer able to accurately read absorbance at 570 and 800 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 Pointe Ferritin assay package insert.

Materials Supplied

Calibrator 1 1 x 1 mL
 Calibrator 2 1 x 1 mL
 Calibrator 3 1 x 1 mL
 Calibrator 4 1 x 1 mL

Materials Required But Not Supplied

Pointe Ferritin assay
 Saline (0.9% NaCl) as 0 ng/mL (blank) calibrator

Clinical chemistry analyzer: capable of accurate absorbance readings at 570 and 800 nm with appropriate cuvettes, capable of accurately dispensing the required volumes, and 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 Ferritin Calibrator set is assayed using the same procedure as the patient test samples run in the test procedure. See the package insert for the Pointe Ferritin Reagent Set (F7505) for details. It is recommended that the user determine calibration frequency as this depends on the instrument and number/type of other assays being performed.

Calibrator Values

There are two sets of values which can be used with our Ferritin Assay, please choose one set of calibration standards:

Calibrator Values Lot: 319302 Exp. Date: 2025-02-28

Standardization	Blank*	Level 1	Level 2	Level 3	Level 4
1 st I.S. values (ng/mL)	0	100	200	500	1000
3 rd I.S. values (ng/mL)	0	119	238	595	1190

* An additional saline blank (0 ng/mL ferritin) is required for best results.










The "1st I.S." Values are traceable to the world Health Organization 1st International Standards for Ferritin, lot 80/602 (NIBSC). These are the values that have traditionally been used for our assay. Use of these calibrator values will ensure that values for newly tested samples are aligned with sample values previously obtained.





The "3rd I.S." Values are traceable to the world Health Organization 3rd International Standards for Ferritin, lot 94/572 (NIBSC). This is the current international standard. Use of these values will help ensure good correlation with other ferritin assays that are using this standardization.




The needs of individual labs can differ. However, if possible, it is suggested to use the “3rd I.S.” values to ensure best correlation to the current international standards.

The values for the Ferritin Calibrators are continually being revised through ongoing quality assurance. 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
 <i>In vitro</i> diagnostic medical device	 Temperature limitation
 Consult instructions for use	Rx Only: Prescription Use Only
 CE mark	 Authorized representative in the European Community

 F7505-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.

Rev. 07/23 P803-F7505-02