

## Intended Use

The Pointe Ferritin Control Set is intended for use as a consistent test sample of known concentration for monitoring the performance of the Pointe Ferritin immunoturbidimetric assay with serum or plasma samples. For *in vitro* diagnostic use only.

## Summary

The use of quality control materials to objectively monitor the precision of procedures has been well established. The Pointe Ferritin Control is provided at two levels.

## Set Composition

Level 1 (Lyophilized) 1 x 3mL  
Level 2 (Lyophilized) 1 x 3mL

## 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.

Controls contain ferritin from human serum. The serum has been tested and found non-reactive for the presence of HBsAg and antibody to HCV and HIV by an FDA accepted method. However, all products containing human source material should be handled in accordance with good laboratory practices using appropriate control. Refer to the NIH Manual, "Biosafety in Microbiological and Biomedical Laboratories," 2nd ed., 1988, HHS Publication No. (CDC) 88-8395.

Do not mix or use controls from one test set with those from a different lot.

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

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

## Control Preparation

1. Allow all reagents and specimens to come to room temperature. Remove cap carefully.
2. Add 3.0 mL of deionized water. Let stand for 20 minutes.
3. Invert gently until fully dissolved.

## Storage and Handling

Store controls at 2-8°C. Return all controls to 2-8°C promptly after use. Unopened controls are stable until the date indicated on the package or bottle labels when stored at 2-8°C.

## Control Stability

Opened, reconstituted Ferritin Controls are stable for two weeks when stored at 2-8°C.

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

## PROCEDURE

### Materials Supplied

Level 1 Ferritin - Serum / Plasma Control: 1 x 3 mL  
Level 2 Ferritin - Serum / Plasma Control: 1 x 3 mL

## Materials Required But Not Supplied

Pointe Ferritin assay (F7505)  
Pointe Ferritin Calibrator (F7505-CAL)  
Two Reagent Clinical Chemistry Analyzer Capable of:  
Accurate absorbance readings  
Accurately dispensing the required volumes  
Maintaining 37°C

## Assay Procedure

NOTE: Allow all reagents and specimens to come to room temperature. The Pointe Ferritin - Serum / Plasma Controls are assayed using the same procedure as the samples run in the test procedure. See package insert from the Pointe Ferritin immunoturbidimetric assay kit.

## Limitations of Procedure

Accurate and reproducible results are dependent upon properly functioning instruments, reagents, and good laboratory technique. Erroneous results can occur from improper storage and technical errors associated with assay procedures.

This product is intended for use as an assayed control for the Pointe Ferritin Assay (F7505) in human serum or plasma. This product is not intended for use as a calibrator.

## Expected Values

Expected values were established using Pointe Ferritin Reagent and Calibrators. The assignment of mean values was derived from analysis of vials representative of the entire lot.

Values listed are specific for each lot only. Verify that the lot numbers on the vials of Ferritin Control correspond to the lot numbers listed for the assayed data.

The expected range of the mean is provided to assist the laboratory until it has established its own mean and standard deviation. It is considered good laboratory practice for each laboratory to establish its own mean and standard deviation for its test methods. The indicated mean and expected range of the mean should serve as a guide in assessing the performance of each test method.

## Assay Data Table

Lot: 319303 Exp. Date: 2024-05-31










Standardization	Unit	Ferritin Control Level 1		Ferritin Control Level 2	
		Mean	Range	Mean	Range
1 <sup>st</sup> I.S. Values	ng/mL	101	86-116	396	337-455
3 <sup>rd</sup> I.S. Values	ng/mL	120	102-138	471	400-542





Ferritin values are provided with two options: 1<sup>st</sup> or 3<sup>rd</sup> I.S. (International Standard) Values. It is recommended to use the same standardized system as was chosen when selecting values for the Pointe Ferritin Calibrators (F7505-CAL).




The expected values for the Pointe Ferritin Control Set 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 appropriate control values.

Recovered values may be method dependent. The variations which can occur over time and between laboratories may be attributed to differences in laboratory technique, instrumentation, reagent lot, method modifications, and other systematic errors including random errors.

## 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	<b>Rx Only:</b> Prescription Use Only
 CE mark	 Authorized representative in the European Community

 F7505-CTL 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 <sup>nd</sup> 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-F7505-03