

Intended Use

The Pointe Rheumatoid Factor (RF) Calibrator Set is intended to be used for the calibration of the Pointe Rheumatoid Factor 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 Rheumatoid Factor. These calibrators are to be used with the Pointe Rheumatoid Factor Reagent Set.

Kit Composition

Calibrators (Liquid Stable)

Materials Provided

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

Pointe RF Calibrator Levels B through F contain pooled human serum with assigned values for rheumatoid factor.

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.

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 contain pooled human serum from RF-positive 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, 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.

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.

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 until the expiration date indicated on the package and bottle labels.

Calibrator Stability

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

Instrument

Measurements of absorbance are to be made with a clinical chemistry analyzer able to accurately read absorbances. 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

Materials Supplied

Calibrators should be used as specified in the Pointe RF assay package insert.

Calibrator A	1 x 1 mL
Calibrator B	1 x 1 mL
Calibrator C	1 x 1 mL
Calibrator D	1 x 1 mL
Calibrator E	1 x 1 mL
Calibrator F	1 x 1 mL

Materials Required But Not Supplied

Pointe Rheumatoid Factor Assay (R7502)

Two-Reagent Clinical Chemistry Analyzer:

- Capable of accurate absorbance readings.
- 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 RF Calibrator is assayed using the same procedure as the patient test samples run in the test procedure. See package insert from the Pointe RF assay for details.

Calibrator Values

The values of the Pointe RF Calibrator set are traceable to the NIBSC Rheumatoid Arthritis Serum, 64/002. Based upon this standardization, results are reported in International Units (IU)/mL.

Data Tables

Lot: 333902 Exp. Date: 2024-10-31

Analyte	CAL A	CAL B	CAL C	CAL D	CAL E	CAL F
Rheumatoid Factor (IU/mL)	0	15	75	150	300	600

The expected values for the RF 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
<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

R7502-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. 12/23 P803-R7502-02