Pointe ASO/Rheumatoid Factor (RF) Control Set

HORIBA Instruments Incorporated
5449 Research Drive, Canton, MI 48188
Phone: 734-487-8300; (800) 445-9853

Intended Use
The Pointe Anti-Streptolysin O (ASO) / Rheumatoid Factor (RF) Control Set is intended for use as a consistent test sample of known concentration for monitoring the performance of the Pointe Anti-streptolysin O (ASO) and Rheumatoid Factor (RF) immunoturbidimetric assays. For *in vitro* diagnostic use only.

Summary
The controls in this set are human serum tested and found negative for HBsAg, HCV Ab, and HIV Ab. They contain known quantities of ASO and RF. These controls are to be used as controls with the Pointe ASO and Rheumatoid Factor Immunoturbidimetric assay.

Set Composition

Level 1 (Human serum, lyophilized)	2 x 2 mL
Level 2 (Human serum, lyophilized)	2 x 2 mL

Pointe ASO/RF Controls contain pooled human serum with assigned values for ASO and 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.

Controls contain pooled human serum from ASO and 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 from these infectious agents.

Therefore, 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.

Controls 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.

Control Preparation
1. Carefully and slowly remove rubber stopper and let air enter vacuum-sealed bottle.
2. Carefully add 2.0 mL of deionized water at room temperature. DO NOT MIX.
3. Replace rubber stopper.
4. Let bottle sit at room temperature for 10 minutes.
5. Mix by slowly swirling bottle numerous times. Do not shake or induce foaming.
6. Continue to mix until all contents have dissolved completely.
7. Before each subsequent use, be sure to mix bottle by slowly swirling.

Storage and Handling
Store lyophilized or reconstituted controls at 2-8°C. Return all controls to 2-8°C promptly after use. Unopened controls can be used up to 18 months from the date of manufacture, as indicated by the expiration date on the package or bottle labels.

Control Stability
Reconstituted controls are stable for two weeks when stored at 2-8°C.

Reconstituted Controls can also be frozen immediately after reconstitution at -20°C for 2 months and then thawed ONE TIME ONLY.

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

Procedure

Materials Supplied
Level 1 Human serum 2 x 2 mL
Level 2 Human serum 2 x 2 mL

Materials Required But Not Supplied

Pointe ASO (A7567) or RF (R7502) Immunoturbidimetric Assay kits
Pointe ASO Calibrator (A7567-CAL) or RF Calibrator (R7502-CAL)
Two-reagent clinical chemistry analyzer
Purified water

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 both the Pointe ASO Assay (A7567) and Rheumatoid Factor Assay (R7502). This product is not intended for use as a calibrator.

Assay Procedure
NOTE: Allow all reagents and specimens to come to room temperature. Mix all reagents gently before using.

Pointe ASO/RF Controls are assayed using the same procedure as the patient test samples run in the test procedure. See the package insert from the Pointe ASO or Rheumatoid Factor immunoturbidimetric assay kits.

Expected Values
Expected values have been established using Pointe ASO and Rheumatoid Factor Reagent and Calibrators. Actual values recovered depend on the instrument and reagent used. 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 ASO/RF 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.

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Assay Data

Level 1	Lot 319305	Exp. 2024-01-31
Assay	**Mean**	**Range**
ASO* (IU/mL)	251	226-276
RF** (IU/mL)	29	20-38

Level 2	Lot 319305	Exp. 2024-01-31
Assay	**Mean**	**Range**
ASO* (IU/mL)	419	377-461
RF** (IU/mL)	81	65-97

*Standardized against the WHO NIBSC Anti-streptolysin O standard material.
**Standardized against the WHO International Reference Preparation of Rheumatoid Arthritis Serum.

The expected values for the Pointe ASO/RF 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 modification, and other systemic errors including random errors.

Symbol Key

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

REF RA502-CTL

Manufactured for HORIBA Instruments Incorporated - Pointe Brand
5449 Research Drive Canton, MI 48188

2°C 8°C

IVD

Manufactured by Kamiya Biomedical Company
12779 Gateway Drive, Seattle, WA 98168 USA

EC REP Advena Ltd.
Tower Business Centre, 2nd Flr.,
Tower Street, Swatar, BKR 4013 Malta

CE

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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