K-*ASSAY*®

ASO / RF / CRP Control

Lot A123/B456, Exp. 2024-02-29

Cat. No. K55C-4M

INTENDED USE

The **K-*ASSAY*®** ASO/RF/CRP Control is intended to be used as a consistent test sample of known concentrations for monitoring the **K-*ASSAY*®** Anti-Streptolysin O (ASO), Rheumatoid Factor (RF), and C-Reactive Protein (CRP) immunoturbidimetric assays.

FOR *IN VITRO* DIAGNOSTIC USE.

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, RF, and CRP. These controls are to be used as controls with the **K-*ASSAY*®** Anti-Streptolysin O, Rheumatoid Factor, and C-Reactive Protein immunoturbidimetric assays.

SET COMPOSITION

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

ASO/RF/CRP Control Levels 1 and 2 contain pooled human serum with assigned values for ASO, RF, and CRP.

WARNINGS AND PRECAUTIONS

For *In Vitro* Diagnostic Use Only. ℞ only.

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

Controls contain pooled human serum from ASO, RF, and CRP positive human serum. The serum has been tested and found non-reactive for the presence of HBsAg, HCV Ab, and HIV antibody by an FDA approved 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.

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

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, GA.

CONTROL PREPARATION

1. Carefully and slowly remove rubber stopper and let air enter vacuum-sealed bottle.
2. Carefully add exactly 2 mL purified water (at room temperature) to bottle. 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 and reconstituted controls at 2-8°C. Return all controls to 2-8°C promptly after use. Unopened controls 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.

CONTROL STABILITY

Reconstituted controls can be used for 2 weeks if 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 cause 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

K-*ASSAY*® ASO (KAI-078), CRP (KAI-026), CRP(3) (KAI-082), or RF (Ver.2) (KAI-230) Immunoturbidimetric Assay kits

K-*ASSAY*® ASO Calibrator (KAI-079C), CRP Calibrator (KAI-012C), CRP(3) Calibrator Set E (KAI-084C), CRP(3) Calibrator Set F (KAI-086C), or RF Calibrator (Ver.2) (KAI-231C)

Two-reagent clinical chemistry analyzer

Purified water

Assay Procedure

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

K-ASSAY® ASO/RF/CRP Controls are assayed using the same procedure as the patient test samples run in the test procedure. See package insert from the ***K-ASSAY®*** ASO, RF (Ver.2), CRP, and CRP(3) immunoturbidimetric assay kits.

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, reconstitution inaccuracies, and technical errors associated with assay procedures.

This product is intended for use as an assayed control for quantitative assays of listed constituents in human serum. This product is not intended for use as a calibrator.

EXPECTED RESULTS

KAMIYA BIOMEDICAL COMPANY has established the expected values using ***K-ASSAY®*** reagents 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/CRP Control correspond to the lot numbers listed for the Assay 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

LEVEL 1, LOT A123, EXP. 2024-02-29		
ASSAY	**MEAN**	**RANGE**
ASO *	258 IU/mL	232 - 284 IU/mL
RF (Ver.2) **	31 IU/mL	22 - 40 IU/mL
CRP ***	1.1 mg/dL	0.8 - 1.4 mg/dL
CRP(3) Cal E ***	10.72 mg/L	8.58 - 12.87 mg/L
CRP(3) Cal F ***	11.0 mg/L	8.8 - 13.3 mg/L

LEVEL 2, LOT B456, EXP. 2024-05-31		
ASSAY	**MEAN**	**RANGE**
ASO *	427 IU/mL	384 - 470 IU/mL
RF (Ver.2) **	82 IU/mL	66 - 98 IU/mL
CRP ***	3.8 mg/dL	3.3 - 4.3 mg/dL
CRP(3) Cal E ***	35.56 mg/L	28.45 - 42.67 mg/L
CRP(3) Cal F ***	35.9 mg/L	28.7 - 43.1 mg/L

* Standardized against the WHO NIBSC Anti-Streptolysin-O standard material.

** Standardized against the WHO International Reference Preparation of Rheumatoid Arthritis Serum.

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

The expected values for the ***K-ASSAY®*** ASO/RF/CRP Control are continually being revised through ongoing quality assurance. Please refer to the package insert included with each control set for the most 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.

LABELING SYMBOLS

REF	Catalog Number
	Expiration or “Use By” Date
LOT	Lot Number
CONTROL	Control
	Consult Package Insert for Instructions for Use
IVD	For *In Vitro* Diagnostic Use
CE	CE Mark Registered
℞	For Prescription Use Only
	Potential Human Biohazard
2°C 8°C	Temperature Limitation. Store between 2 and 8 degrees C
	Manufacturer
EC REP	Authorized Representative in the European Community

EU AUTHORIZED REPRESENTATIVE

CE

EC REP

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Printed August 2022