

K-ASSAY®

RF Calibrator

Lot G747, Exp. 2018-06-30

Cat. No. KAI-032C

INTENDED USE

The **K-ASSAY®** RF Calibrator is intended to be used to calibrate the **K-ASSAY®** RF immunoturbidimetric assay. The test uses human serum. The **K-ASSAY®** RF assay is used in the clinical diagnosis and prognosis of rheumatoid arthritis. *FOR IN VITRO* DIAGNOSTIC USE.

SUMMARY

The calibrators in this kit are human serum tested and found negative for HBsAg and HIV Ab. They contain known quantities of rheumatoid factor (RF). These are to be used as calibrators with the **K-ASSAY®** RF immunoturbidimetric assay.

KIT COMPOSITION**Calibrators (Liquid Stable)****MATERIALS PROVIDED**

Calibrators A-C	Human serum	3 x 2 mL
	Sodium azide	< 0.1%

Calibrators A-C contain pooled human serum with assigned values for rheumatoid factor.

WARNINGS AND PRECAUTIONS

FOR IN VITRO DIAGNOSTIC USE. Rx only.

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

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 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 calibrators from one test kit with those from a different lot number.

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

Calibrators in this kit contain sodium azide as a preservative. Sodium azide may form explosive compounds in metal drain lines. When disposing of calibrators 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.

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

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 for one year from the date of manufacturing as indicated on the expiration date 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 absorbance at 340 and 700 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

Materials Supplied

Calibrators should be used as specified in the **K-ASSAY**® RF assay package insert.

Calibrator A	1 x 2 mL
Calibrator B	1 x 2 mL
Calibrator C	1 x 2 mL

Materials Required But Not Supplied

K-ASSAY® RF Immunoturbidimetric Assay

Two-reagent clinical chemistry analyzer capable of accurate absorbance reading at 340 and 700 nm, accurately dispensing the required volumes, and maintaining 37°C.

Details of Procedure

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

K-ASSAY® RF Calibrators are assayed using the same procedure as the patient test samples run in the test procedure. See package insert from the **K-ASSAY**® RF immunoturbidimetric assay.

CALIBRATOR VALUES











Lot G747

	<u>RF (U/mL)</u>	<u>RF (WHO IU/mL)*</u>
A	65	67
B	166	171
C	323	333

* WHO IU/mL values are standardized to the WHO International Reference Preparation of Rheumatoid Arthritis Serum.

The expected values for the **K-ASSAY**® RF Calibrator 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.

LABELING SYMBOLS

	Lot Number
	Calibrator
	Expiration or "Use By" Date
	Catalog Number
	For <i>In Vitro</i> Diagnostic Use
	2-8°C Temperature Limitation. Store between 2 and 8 degrees C
	Potential Human Biohazard
	Manufacturer
	Consult Package Insert for Instructions for Use
	Authorized Representative in the European Community

EU AUTHORIZED REPRESENTATIVE





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