K-*ASSAY*®

Liquid ITA Control

(For K-*ASSAY*® Immunoturbidimetric Assays)

Lot A123, Exp. 2024-09-30

Cat. No. K49C-4M

INTENDED USE

The **K-*ASSAY*®** Liquid ITA Control is intended to be used as a consistent test sample of known concentration for monitoring the performance of **K-*ASSAY*®** immunoturbidimetric assays (ITA) for the listed constituents.

FOR *IN VITRO* DIAGNOSTIC USE.

SUMMARY

The controls in this set are human serum, tested and found negative for HBsAg and antibodies to HCV and HIV. They contain known quantities of the listed constituents. They are to be used as controls with the **K-*ASSAY*®** immunoturbidimetric assays.

SET COMPOSITION

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

Liquid ITA Control, Levels 1 and 2, contain pooled human serum with assigned values for the listed constituents.

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. 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.

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.

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.

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

CONTROL PREPARATION

Controls are liquid and ready to use.

STORAGE AND HANDLING

Store 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

Opened controls can be used for 1 month if stored at 2-8°C.

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*® Immunoturbidimetric Assay Kits
K-*ASSAY*® Calibrator

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

Assay Procedure

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

The **K-*ASSAY*®** Liquid ITA Control is assayed using the same procedure as the patient test samples run in the test procedure. See package insert from the **K-*ASSAY*®** 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 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.

The expected values for the **K-*ASSAY*®** Liquid ITA Control 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.

EXPECTED RESULTS

KAMIYA BIOMEDICAL COMPANY has established the expected values. Values listed were obtained using an Abbott Architect c8000 and **K-*ASSAY*®** reagents and calibrators. Subsequent modifications in instrument, reagent, or procedure may invalidate these results. 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 Liquid ITA 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

Lot A123, Exp. 2024-09-30

Values are standardized to the CAP/BCR/IFCC Reference Prep. for Proteins in Human Serum (RPPHS), lot 91/0619.

ASSAY	LEVEL 1		LEVEL 2	
	MEAN (mg/dL)	RANGE (mg/dL)	MEAN (mg/dL)	RANGE (mg/dL)
Alpha-1 Acid Glycoprotein	69	55 - 83	130	117 - 143
Alpha-1 Anti-Trypsin	115	92 - 138	224	202 - 246
C-Reactive Protein	1.1	0.8 - 1.4	3.8	3.3 - 4.3
Complement C3	98	78 - 118	243	219 - 267
Complement C4	19	15 - 23	45	40 - 50
Haptoglobin	96	77 - 115	203	183 - 223
IgA	176	141 - 211	427	384 - 470
IgG	855	684 - 1,026	2,149	1,934 - 2,364
IgM	77	62 - 92	185	166 - 204
Prealbumin	20	16 - 24	41	37 - 45
Transferrin	238	190 - 286	455	409 - 501

The expected values for the **K-*ASSAY*®** Liquid ITA 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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