

K-ASSAY®

Multi-Analyte Calibrator

Lot D755, Exp. 2018-09-30

Cat. No. KAI-016C**INTENDED USE**

The **K-ASSAY®** Multi-Analyte Calibrator is intended to be used for the calibration of the **K-ASSAY®** α -1 AG, α -1 AT, C3, C4, Haptoglobin, IgA, IgG, IgM, and Transferrin immunoturbidimetric assays. *FOR IN VITRO* DIAGNOSTIC USE.

SUMMARY

The calibrators in this kit are human serum containing known quantities of α -1 AG, α -1 AT, C3, C4, Haptoglobin, IgA, IgG, IgM, and Transferrin. There is also a calibrator containing only diluent (150 mM sodium chloride). These calibrators are to be used with the **K-ASSAY®** α -1 AG, α -1 AT, C3, C4, Haptoglobin, IgA, IgG, IgM, and Transferrin immunoturbidimetric assays.

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

Calibrator A	Sodium Chloride	150 mM	1 x 1 mL
	Sodium Azide		< 0.1%
Calibrator B-F	Human Serum		5 x 1 mL
	Sodium Azide		< 0.1%

Calibrators B-F contain pooled human serum with assigned values for the specific serum proteins α -1 AG, α -1 AT, C3, C4, Haptoglobin, IgA, IgG, IgM, and Transferrin.

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. Each donor unit used in the preparation of this product has been tested by an FDA-approved method and found non-reactive for the presence of HBsAg and antibody to HIV. However, it is not possible to guarantee that they are free of hepatitis B, human immunodeficiency virus (HIV), or other infectious agents.

Therefore, all products which contain 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.

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

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 Guide Management No. CDC-22 issued by the Center for Disease Control, Atlanta, GA. 1976.

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 up to 18 months from the date of manufacture, as indicated by the expiration date on the package and bottle labels.

CALIBRATOR STABILITY

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

Calibrator transferred to the instrument sample cup may concentrate over time. Therefore, calibrators should be capped and stored at 2-8°C when not in use. Otherwise, fresh calibrators should be used for each calibration.

INSTRUMENT

Measurements of absorbance are to be made with a clinical chemistry analyzer able to accurately read absorbance at 340, 600, 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

Calibrators should be used as specified in the **K-ASSAY**® immunoturbidimetric assay package inserts for α -1 AG, α -1 AT, C3, C4, Haptoglobin, IgA, IgG, IgM, and Transferrin. It is recommended that the user determine calibration frequency as this depends on the instrument and number/type of other assays being performed. Initially, calibration should be performed each day. For each calibration, fresh calibrator reagent should be withdrawn from the **K-ASSAY**® Multi-Analyte Calibrator vials.

Materials Supplied

Calibrator A-F 6 x 1 mL

Materials Required But Not Supplied

K-ASSAY® α -1 AG, α -1 AT, C3, C4, Haptoglobin, IgA, IgG, IgM, and Transferrin immunoturbidimetric assay kits

Two Reagent Clinical Chemistry Analyzer:

- Capable of accurate absorbance reading at 340, 600, and 700 nm
- 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 **K-ASSAY**® Multi-Analyte Calibrator 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 kit.

CALIBRATOR VALUES (Lot D755)

[FOR *IN VITRO* DIAGNOSTIC USE]:

	<u>IgA (mg/dL)*</u>	<u>IgG (mg/dL)*</u>	<u>IgM (mg/dL)*</u>
A	0	0	0
B	107	636	47
C	215	1273	95
D	358	2121	158
E	501	2969	221
F	715	4242	316

	<u>α1-AG (mg/dL)*</u>	<u>α1-AT (mg/dL)*</u>	<u>HP (mg/dL)*</u>
A	0	Call for values	0
B	35	Call for values	42
C	70	Call for values	83
D	116	Call for values	139
E	162	Call for values	194
F	232	Call for values	277











K-ASSAY® Multi-Analyte Calibrator

	<u>C3 (mg/dL)*</u>	<u>C4 (mg/dL)*</u>	<u>TF (mg/dL)*</u>
A	0	0	0
B	51	10	77
C	102	19	155
D	171	32	258
E	239	45	361
F	341	64	516

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

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

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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