

K-ASSAY[®]

Liquid Lipid Control

Lot 1312050D/1403044D, Exp. 2015-10-31

Cat. No. K110C-2M

INTENDED USE

The **K-ASSAY**[®] Liquid Lipid Control is intended for use as an assayed quality control material for Apolipoprotein AI, Apolipoprotein B, Cholesterol (Total), High Density Lipoprotein, Low Density Lipoprotein, and Triglycerides. The **K-ASSAY**[®] Liquid Lipid Control is not intended for use as a standard.

FOR *IN VITRO* DIAGNOSTIC USE.**SUMMARY**

The use of quality control materials to objectively monitor the accuracy and precision of procedures is well established in clinical laboratories. The **K-ASSAY**[®] Liquid Lipid Control is provided at two levels to assist in the monitoring of analytical systems within the clinical range.

PRODUCT DESCRIPTION

The **K-ASSAY**[®] Liquid Lipid Control is human serum-based containing constituents of human origin. Preservatives and stabilizers have been added to maintain product integrity. The **K-ASSAY**[®] Liquid Lipid Control is a ready-to-use liquid control requiring no reconstitution or frozen storage.

SET COMPOSITION:K110C-2M

Level 1	1 x 3 mL
Level 2	1 x 3 mL

STORAGE AND STABILITY

The **K-ASSAY**[®] Liquid Lipid Control is stable until the expiration date on the vial label when stored unopened at 2-8°C. Once opened, the **K-ASSAY**[®] Liquid Lipid Control is stable for 30 days when stored tightly capped at 2-8°C and 7 days at 20-25°C.

PROCEDURE

The **K-ASSAY**[®] Liquid Lipid Control should be treated the same as patient specimens and run in accordance with the instructions accompanying the test system being used. Allow the product to reach room temperature prior to use. Gently mix the contents of each vial before sampling to ensure homogeneity. Replace cap immediately and store at 2-8°C.

QC materials should be used in accordance with local, state, and/or federal regulations or accreditation requirements.

LIMITATIONS OF PROCEDURE

The **K-ASSAY**[®] Liquid Lipid Control should not be used past the expiration date on the vial label. If there is evidence of microbial contamination or excessive turbidity in the product, discard the vial.

The **K-ASSAY**[®] Liquid Lipid Control requires storage and handling as detailed in STORAGE AND STABILITY. The **K-ASSAY**[®] Liquid Lipid Control is a stabilized liquid product. Accurate and reproducible results are dependent upon properly functioning instruments and reagents.

The published assay values were obtained using reagents and procedures available at the time of assay. In the event reagents or procedures are altered by the manufacturer, different assay values may be obtained.

ASSIGNMENT OF VALUES

The assigned mean values were derived from analyses of vials representative of the entire lot. Analyte values were obtained by in-house testing, from laboratories of the instrument manufacturer, manufacturers of instrument specific reagents, or from reference laboratories.

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.

The values are usually 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.










CAUTION**Human source material. Treat as potentially infectious.**

Each serum/plasma donor unit used in the manufacture of this product has been tested by FDA accepted methods and found non-reactive for the presence of HBsAg and antibody to HIV-1/2, HCV, and HIV-1 Ag. While these methods are highly accurate, they do not guarantee that all infected units will be detected. Because no known test method can offer complete assurance the hepatitis B virus, hepatitis C virus, human immunodeficiency virus (HIV), or other infectious agents are absent, all products containing human source material should be considered potentially infectious and handled with the same precautions used with patient specimens.

EXPECTED VALUES

Constituent and Method	Level 1, Lot 1312050D, Exp. 2015-10-31		Level 2, Lot 1403044D, Exp. 2015-10-31	
	Mean (mg/dL)	Expected Range (mg/dL)	Mean (mg/dL)	Expected Range (mg/dL)
Apolipoprotein AI				
KAMIYA BIOMEDICAL K-ASSAY® (as assayed on the Hitachi 917)	51	43 - 59	123	111 - 135
Other Assay Reagent Systems (not K-ASSAY®):				
Beckman Coulter / Olympus AU Systems	44.6	35.6 - 53.5	122	97.8 - 147
Beckman Coulter Immage	37.2	29.7 - 44.6	96.6	77.3 - 116
Roche Integra	47.2	37.8 - 56.7	114	91.2 - 137
Apolipoprotein B				
KAMIYA BIOMEDICAL K-ASSAY® (as assayed on the Hitachi 917)	87	78 - 96	168	151 - 185
Other Assay Reagent Systems (not K-ASSAY®):				
Beckman Coulter / Olympus AU Systems	100	80.3 - 120	184	147 - 221
Beckman Coulter Immage	77.8	62.3 - 93.4	140	112 - 168
Roche Integra	70.3	56.3 - 84.4	145	116 - 174
Cholesterol, HDL				
Beckman Coulter / Olympus AU Systems	25.6	20.5 - 30.8	57.5	46.0 - 69.0
Beckman Coulter Synchron CX	32.0	25.6 - 38.4	70.0	56.0 - 83.9
Ortho Vitros Systems	37.8	30.2 - 45.3	74.0	59.2 - 88.8
Roche Integra	29.0	23.2 - 34.8	57.5	46.0 - 68.9
Siemens Advia	12.7	10.1 - 15.2	33.3	26.6 - 39.9
Siemens / Dade Behring Dimension	28.7	22.9 - 34.4	58.3	46.6 - 69.9
Cholesterol, LDL				
Beckman Coulter / Olympus AU Systems	60.6	48.5 - 72.7	119	95.1 - 143
Beckman Coulter Synchron CX	67.8	54.2 - 81.3	133	106 - 159
Ortho Vitros Systems	67.5	54.0 - 81.0	143	115 - 172
Roche Integra	100	80.0 - 120	188	150 - 225
Siemens / Dade Behring Dimension	88.5	70.8 - 106	167	134 - 200
Cholesterol (Total)				
Beckman Coulter / Olympus AU Systems	141	113 - 170	276	221 - 331
Beckman Coulter Synchron CX	153	123 - 184	301	241 - 361
Ortho Vitros Systems	158	126 - 190	313	250 - 375
Roche Integra	144	116 - 173	279	224 - 335
Siemens Advia	144	115 - 173	278	222 - 334
Siemens / Dade Behring Dimension	144	115 - 172	280	224 - 336
Triglycerides				
Beckman Coulter / Olympus AU Systems	112	89.3 - 134	409	327 - 491
Beckman Coulter Synchron CX	129	103 - 154	437	349 - 524
Ortho Vitros Systems	118	94.4 - 142	446	357 - 535
Roche Integra	116	93.0 - 140	424	339 - 508
Siemens Advia	111	88.6 - 133	399	319 - 479
Siemens / Dade Behring Dimension	107	85.8 - 129	404	323 - 485

LABELING SYMBOLS

-  Lot Number
-  Control
-  Expiration or "Use By" Date
-  Catalog Number
-  For *In Vitro* 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

ORDERING / PRICING / TECHNICAL INFORMATION


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