

**K-ASSAY**<sup>®</sup>

# Liquid Lipid Control

Lot 1612001C/1612002C, Exp. 2018-07-31

Cat. No. K110C-2M

**INTENDED USE**

The **K-ASSAY**<sup>®</sup> 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**<sup>®</sup> 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**<sup>®</sup> Liquid Lipid Control is provided at two levels to assist in the monitoring of analytical systems within the clinical range.

**PRODUCT DESCRIPTION**FOR *IN VITRO* DIAGNOSTIC USE. Rx only.

The **K-ASSAY**<sup>®</sup> 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**<sup>®</sup> 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**<sup>®</sup> 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**<sup>®</sup> 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**<sup>®</sup> 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**<sup>®</sup> 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**<sup>®</sup> Liquid Lipid Control requires storage and handling as detailed in STORAGE AND STABILITY. The **K-ASSAY**<sup>®</sup> 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 1612001C, Exp. 2018-07-31		Level 2, Lot 1612002C, Exp. 2018-07-31	
	Mean (mg/dL)	Expected Range (mg/dL)	Mean (mg/dL)	Expected Range (mg/dL)
<b>Apolipoprotein AI</b>				
KAMIYA BIOMEDICAL <b>K-ASSAY</b> <sup>®</sup> (as assayed on the Hitachi 917)	48	38 - 58	132	119 - 145
Other Assay Reagent Systems (not <b>K-ASSAY</b> <sup>®</sup> ) :				
Beckman Coulter / Olympus AU Systems	47.9	38.3 - 57.5	162	130 - 194
Beckman Coulter Immage	40.1	32.1 - 48.1	122	97.6 - 146
Roche Integra	47.0	37.6 - 56.4	139	111 - 167
<b>Apolipoprotein B</b>				
KAMIYA BIOMEDICAL <b>K-ASSAY</b> <sup>®</sup> (as assayed on the Hitachi 917)	97	87 - 107	169	152 - 186
Other Assay Reagent Systems (not <b>K-ASSAY</b> <sup>®</sup> ) :				
Beckman Coulter / Olympus AU Systems	104	83.2 - 125	171	137 - 205
Beckman Coulter Immage	79.8	63.8 - 95.8	145	116 - 174
Roche Integra	99.1	79.3 - 119	174	139 - 209
<b>Cholesterol, HDL</b>				
Beckman Coulter / Olympus AU Systems	24.2	19.4 - 29.0	55.0	44.0 - 66.0
Beckman Coulter Synchron LX / DxC	26.6	21.3 - 31.9	59.1	47.3 - 70.9
Ortho Vitros Systems	36.0	28.8 - 43.2	63.9	51.1 - 76.7
Roche Cobas C Series	29.7	23.8 - 35.6	58.2	46.6 - 69.8
Roche Integra	30.4	24.3 - 36.5	58.7	47.0 - 70.4
Siemens / Dade Behring Dimension	31.8	25.4 - 38.2	62.8	50.2 - 75.4
<b>Cholesterol, LDL</b>				
Beckman Coulter / Olympus AU Systems	81.7	65.4 - 98.0	144	115 - 173
Beckman Coulter Synchron LX / DxC	82.5	66.0 - 99.0	144	115 - 173
Ortho Vitros Systems	86.4	69.1 - 104	171	137 - 205
Roche Cobas C Series	93.8	75.0 - 113	158	126 - 190
Roche Integra	97.6	78.1 - 117	160	128 - 192
Siemens / Dade Behring Dimension	94.8	75.8 - 114	164	131 - 197
<b>Cholesterol (Total)</b>				
Beckman Coulter / Olympus AU Systems	145	116 - 174	265	212 - 318
Beckman Coulter Synchron LX / DxC	147	118 - 176	268	214 - 322
Ortho Vitros Systems	172	138 - 206	320	256 - 384
Roche Cobas C Series	157	126 - 188	280	224 - 336
Roche Integra	150	120 - 180	272	218 - 326
Siemens / Dade Behring Dimension	151	121 - 181	274	219 - 329
<b>Triglycerides</b>				
Beckman Coulter / Olympus AU Systems	110	88.0 - 132	417	334 - 500
Beckman Coulter Synchron LX / DxC	121	96.8 - 145	450	360 - 540
Ortho Vitros Systems	111	88.8 - 133	414	331 - 497
Roche Cobas C Series	116	92.8 - 139	433	346 - 520
Roche Integra	111	88.8 - 133	421	337 - 505
Siemens / Dade Behring Dimension	107	85.6 - 128	411	329 - 493

**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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Printed March 2017