K-*ASSAY*®

RF / ASO Liquid Control

Lot 1234567/7654321, Exp. 2019-08-31

Cat. No. K125C-2M and K125C-4M

INTENDED USE

The **K-*ASSAY*®** RF / ASO Liquid Control is intended for use as an assayed quality control material for serum protein analysis of Rheumatoid Factor and Anti-Streptolysin O.

FOR *IN VITRO* DIAGNOSTIC USE.

SUMMARY

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

PRODUCT DESCRIPTION

The **K-*ASSAY*®** RF / ASO Liquid Control is prepared from human plasma and human plasma proteins. Preservatives and stabilizers have been added to maintain product integrity. The **K-*ASSAY*®** RF / ASO Liquid Control is a ready-to-use liquid control requiring no reconstitution or frozen storage.

SET COMPOSITION:

K125C-2M

Level 1	Human serum (liquid)	1 x 3 mL
Level 2	Human serum (liquid)	1 x 3 mL

K125C-4M

Level 1	Human serum (liquid)	2 x 3 mL
Level 2	Human serum (liquid)	2 x 3 mL

STORAGE AND STABILITY

The **K-*ASSAY*®** RF / ASO Liquid Control is stable until the expiration date on the vial label when stored unopened at 2-8℃. Once opened, the **K-*ASSAY*®** RF / ASO Liquid Control is stable for 60 days when stored tightly capped at 2-8℃.

PROCEDURE

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℃.

The **K-*ASSAY*®** RF / ASO Liquid Control should be treated the same as patient specimens and run in accordance with the instructions accompanying the test system being used. QC materials should be used in accordance with local, state, and/or federal regulations or accreditation requirements.

LIMITATIONS OF PROCEDURE

The **K-*ASSAY*®** RF / ASO Liquid 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*®** RF / ASO Liquid Control is a stabilized liquid product. To obtain consistent assay values, the **K-*ASSAY*®** RF / ASO Liquid Control requires storage and handling as detailed in STORAGE AND STABILITY. 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. Analyte values for some methods may have been obtained using dilutions according to the manufacturer's instructions. The Expected Range of the Mean for each analyte value is calculated using the appropriate factors and may exceed the linearity for that method.

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.

This product contains 0.09% sodium azide as a preservative. Sodium azide may react with lead and copper plumbing to form potentially explosive compounds. Flush with excess water upon disposal.

EXPECTED VALUES

Constituent and Method	Level 1, Lot 1234567, Exp. 2019-08-31		Level 2, Lot 7654321, Exp. 2019-08-31	
	Mean (IU/mL)	Expected Range (IU/mL)	Mean (IU/mL)	Expected Range (IU/mL)
Anti-Streptolysin O				
KAMIYA BIOMEDICAL K-*ASSAY*® ASO (as assayed on the Hitachi 911) Standardized against the WHO NIBSC Anti-Streptolysin-O standard material.	**103**	**82 - 124**	**295**	**236 - 355**
Rheumatoid Factor				
KAMIYA BIOMEDICAL K-*ASSAY*® RF (as assayed on the Beckman CX7) Standardized against the WHO International Reference Preparation of Rheumatoid Arthritis Serum	**24**	**19 - 29**	**55**	**44 - 66**
KAMIYA BIOMEDICAL K-*ASSAY*® RF (as assayed on the Hitachi 911) Standardized against the WHO International Reference Preparation of Rheumatoid Arthritis Serum	**27**	**22 - 33**	**72**	**57 - 86**

The expected values for the **K-*ASSAY*®** RF / ASO Liquid 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

LOT	Lot Number
CONTROL	Control
	Expiration or "Use By" Date
REF	Catalog Number
IVD	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
EC REP	Authorized Representative in the European Community

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ORDERING / PRICING / TECHNICAL INFORMATION

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