Whole Blood Ethanol Control Level 1

CE

INTENDED USE

FOR IN VITRO DIAGNOSTIC USE

LiquiSP$_x$™ Whole Blood Ethanol Control is an assayed quality control material intended for use in monitoring the accuracy and precision of the quantitative determination of ethanol in whole blood.

SUMMARY AND PRINCIPLE

This product is to be used exactly as directed for the patient sample in order to monitor, and thus minimize the potential for technical and performance errors in routine testing.

PRODUCT DESCRIPTION

LiquiSP$_x$ Whole Blood Ethanol Control is prepared from stabilized normal human whole blood with the addition of ethanol. This product has been assigned lot-specific ethanol values using quantitative analytical methods. This product is packaged 5.0 mL per vial.

2°C – 8°C

STORAGE AND STABILITY

LiquiSP$_x$ Whole Blood Ethanol Control is stable until the expiration date on the package when stored unopened at 2-8° C and 45 days after opening when stored at 2-8° C. Discard any contaminated material. Microbial contamination is evidenced by an increase in turbidity and/or a characteristic odor.

⚠ PRECAUTIONS

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.

PROCEDURE

Allow the refrigerated controls to warm to room temperature (18-25° C) and gently swirl the control material prior to use in order to ensure product homogeneity. QC materials should be used in accordance with local, state, and/or federal regulations or accreditation requirements.

LIMITATIONS

This material is a control for methods listed in the ASSIGNED VALUES section; it is not to be used as a calibrator. Accurate and reproducible results are dependent upon properly functioning instruments, reagents, standardization, and proper laboratory techniques. Individual laboratories may not obtain the mean assigned value as listed.

VALUE ASSIGNMENT

The mean values and expected ranges printed in this insert were derived from extensive replicate analyses and are specific for this lot.

Values listed below were generated by Cliniqa, the reagent/instrument manufacturer and/or independent laboratories in accordance with an established protocol.

Procedural or assay modifications may alter the mean value obtained. Each laboratory should establish its own parameters of precision; use the mean assigned values and expected ranges provided only as guidelines.

ASSIGNED VALUES

Level 1		Lot No.: 1212090 Exp. Date: 2016-12	
Method	**Units**	**Mean**	**Expected Range**
Gas Chromatography	mg/dL	77.3	61.8 - 92.7

REFERENCES

Baselt, R.C. Analytical Procedures for Therapeutic Drug Monitoring and Emergency Toxicology. Littleton, MA, PSG Publishing, 1987.

IVD **For in vitro diagnostic use**

See package insert for proper use

CLINIQA CORPORATION
288 Distribution St.
San Marcos, CA 92078
USA

SALES AND TECHNICAL SUPPORT
P: 800 728 5205
+1 760 744 1900
F: +1 760 571 5198
www.cliniqa.com

FOR ORDERS AND CUSTOMER SERVICE
P: 800 728 5205
+1 760 744 1900
F: +1 760 571 5197
csgroup@cliniqa.com

EC REP
CEpartner4U
Esdoornlaan 13
3951 DB Maarn, The Netherlands
P: +31 (0)6 516 536 26

RE-ORDER INFORMATION
Whole Blood Ethanol Control

Catalog No.	Catalog No.	Catalog No.
REF 93211	REF 93212	REF 93213
Level 1, 6 x 5 mL	Level 2, 6 x 5 mL	Level 3, 6 x 5 mL

CLINIQA®

33100_04 12/6/10

© 2008 Cliniqa Corporation. All rights reserved.