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.: 71851 Exp. Date: 07/11	
Method	**Units**	**Mean**	**Expected Range**
Gas Chromatography	mg/dL	79.2	70.7 – 87.6

REFERENCE

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

TECHNICAL ASSISTANCE

For technical assistance and ordering information call Clinical Controls Int'l/Central Coast Diagnostics, 888-534-0911, 805-534-0111, or FAX 805-534-1348

Mfg. by Clinical Controls Int'l/Central Coast Diagnostics Inc. Los Osos, CA 93402

CATALOG NUMBERS:

501-1 6X5 mL LEVEL 1
501-2 6X5 mL LEVEL 2
501-3 6X5 mL LEVEL 3

Rev 7/11/07

WHOLE BLOOD ETHANOL CONTROL

For *in vitro* diagnostic use
Cat. No. 501, Levels 1, 2 or 3

INTENDED USE

Clinical Controls **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.

REAGENT DESCRIPTION

Clinical Controls **LiquiSP$_x$** Whole Blood Ethanol 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.

STORAGE AND STABILITY

Whole Blood Ethanol Control is stable until the expiration date on the package 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

This product is from human source material. Each unit of raw material used in its manufacture was tested by an FDA approved method and found to be negative by tests for antibodies to HIV, HVC, HBc, HTLV-I/II and non-reactive for HBsAg, STS, HCV RNA AND HIV-1 RNA. These methods, however, cannot offer total assurance that human source products will not transmit these diseases. Therefore, handle this product as potentially infectious in accordance with Good Laboratory Practices (GLP) and precautions.

This product contains small amounts of sodium azide, which may react with copper or lead plumbing to form explosive azides. Flush drain with copious amounts of water to prevent azide build up when disposing of residual product.

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.

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. If the values obtained do not fall within the expected range, call for technical assistance immediately.

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 Clinical Controls, the reagent/instrument manufacturer and/or independent laboratories in accordance with an established protocol. Individual laboratory means should fall within the corresponding expected range.