Phoenix Police Department
Laboratory Services Bureau

IN HOUSE WHOLE BLOOD CONTROL

Lot #: **041323RB**

Target value: **0.200**

Acceptable Range (+/- 5%): **0.1900 to 0.2100**

This whole blood control was tested against a five point calibration constructed from five NIST traceable calibrators.
The method of Headspace Gas Chromatography, Flame Ionization Detector (HS/GC/FID) was used to determine the target value and acceptable range (a minimum of 40 tests).

Number of tests:	**59**
Average:	**0.20067**
Minimum Value:	**0.1949**
Maximum Value:	**0.2062**
Standard Deviation:	**0.00191**
Coefficient of Variation:	**0.951%**

Phoenix Police Department Laboratory Services Bureau	**IN HOUSE WHOLE BLOOD CONTROL**

Lot #: **092421JM**

Target value: **0.199**

Acceptable Range (+/- 5%): **0.1891 to 0.2090**

This whole blood control was tested against a five point calibration constructed from five NIST traceable calibrators.
The method of Headspace Gas Chromatography, Flame Ionization Detector (HS/GC/FID) was used to determine the target value and acceptable range (a minimum of 40 tests).

Number of tests: **49**

Average: **0.19924**

Minimum Value: **0.1954**

Maximum Value: **0.2021**

Standard Deviation: **0.00136**

Coefficient of Variation: **0.681%**

Phoenix Police Department Laboratory Services Bureau	**IN HOUSE WHOLE BLOOD CONTROL**

Lot #: **052920JM**

Target value: **0.198**

Acceptable Range (+/- 5%): **0.1881 to 0.2079**

This whole blood control was tested against a five point calibration constructed from five NIST traceable calibrators.
The method of Headspace Gas Chromatography, Flame Ionization Detector (HS/GC/FID) was used to determine the target value and acceptable range (a minimum of 40 tests).

Number of tests: **50**

Average: **0.19877**

Minimum Value: **0.1965**

Maximum Value: **0.2036**

Standard Deviation: **0.00165**

Coefficient of Variation: **0.830%**

Phoenix Police Department Laboratory Services Bureau	**IN HOUSE WHOLE BLOOD CONTROL**

Lot #: **021419JM**

Target value: **0.201**

Acceptable Range (+/- 5%): **0.1910 to 0.2111**

This whole blood control was tested against a five point calibration constructed from five NIST traceable calibrators.
The method of Headspace Gas Chromatography, Flame Ionization Detector (HS/GC/FID) was used to determine the target value and acceptable range (a minimum of 40 tests).

Number of tests: **51**

Average: **0.20106**

Minimum Value: **0.1958**

Maximum Value: **0.2044**

Standard Deviation: **0.00237**

Coefficient of Variation: **1.180%**

Phoenix Police Department Laboratory Services Bureau	**IN HOUSE WHOLE BLOOD CONTROL**

Lot #: **120117JM**

Target value: **0.200**

Acceptable Range (+/- 5%): **0.1900 to 0.2100**

This whole blood control was tested against a five point calibration constructed from five NIST traceable calibrators.
The method of Headspace Gas Chromatography, Flame Ionization Detector (HS/GC/FID) was used to determine the target value and acceptable range (a minimum of 40 tests).

Number of tests: **47**

Average: **0.20016**

Minimum Value: **0.1972**

Maximum Value: **0.2028**

Standard Deviation: **0.00140**

Coefficient of Variation: **0.701%**

Phoenix Police Department
Laboratory Services Bureau

IN HOUSE WHOLE BLOOD CONTROL

Lot #: **120116JM**

Target value: **0.197**

Acceptable Range (+/- 5%): **0.1872 to 0.2069**

This whole blood control was tested against a five point calibration constructed from five NIST traceable calibrators.
The method of Headspace Gas Chromatography, Flame Ionization Detector (HS/GC/FID) was used to determine the target value and acceptable range (a minimum of 40 tests).

Number of tests:	**48**
Average:	**0.19723**
Minimum Value:	**0.1950**
Maximum Value:	**0.1994**
Standard Deviation:	**0.00115**
Coefficient of Variation:	**0.582%**

Phoenix Police Department Laboratory Services Bureau	**IN HOUSE WHOLE BLOOD CONTROL**

Lot #: **122915JM**

Target value: **0.199**

Acceptable Range (+/- 5%): **0.1891 to 0.2090**

This whole blood control was tested against a five point calibration constructed from five NIST traceable calibrators.
The method of Headspace Gas Chromatography, Flame Ionization Detector (HS/GC/FID) was used to determine the target value and acceptable range (a minimum of 40 tests).

Number of tests: **48**

Average: **0.19931**

Minimum Value: **0.1956**

Maximum Value: **0.2023**

Standard Deviation: **0.00161**

Coefficient of Variation: **0.806%**

Phoenix Police Department Laboratory Services Bureau	**IN HOUSE WHOLE BLOOD CONTROL**

Lot #: **011615JM**

Target value: **0.197**

Acceptable Range (+/- 5%): **0.1872 to 0.2069**

This whole blood control was tested against a five point calibration constructed from five NIST traceable calibrators.
The method of Headspace Gas Chromatography, Flame Ionization Detector (HS/GC/FID) was used to determine the target value and acceptable range (a minimum of 40 tests).

Number of tests: **62**

Average: **0.19780**

Minimum Value: **0.1952**

Maximum Value: **0.2022**

Standard Deviation: **0.00186**

Coefficient of Variation: **0.939%**

Phoenix Police Department
Laboratory Services Bureau

IN HOUSE WHOLE BLOOD CONTROL

Lot #: **030714JM**

Target value: **0.198**

Acceptable Range (+/- 5%): **0.1881 to 0.2079**

This whole blood control was tested against a five point calibration constructed from five NIST traceable calibrators.
The method of Headspace Gas Chromatography, Flame Ionization Detector (HS/GC/FID) was used to determine the target value and acceptable range (a minimum of 40 tests).

Number of tests:	**47**
Average:	**0.19803**
Minimum Value:	**0.1950**
Maximum Value:	**0.2012**
Standard Deviation:	**0.00177**
Coefficient of Variation:	**0.892%**

Phoenix Police Department Laboratory Services Bureau	**IN HOUSE WHOLE BLOOD CONTROL**

Lot #: **042413JM**

Target value: **0.198**

Acceptable Range (+/- 5%): **0.1881 to 0.2079**

This whole blood control was tested against a five point calibration constructed from five NIST traceable calibrators.
The method of Headspace Gas Chromatography, Flame Ionization Detector (HS/GC/FID) was used to determine the target value and acceptable range (a minimum of 40 tests).

Number of tests:	**51**
Average:	**0.19806**
Minimum Value:	**0.1941**
Maximum Value:	**0.2020**
Standard Deviation:	**0.00168**
Coefficient of Variation:	**0.847%**

Phoenix Police Department
Laboratory Services Bureau

IN HOUSE WHOLE BLOOD CONTROL

Lot #: **071012JM**

Target value: **0.196**

Acceptable Range (+/- 5%): **0.1865 to 0.2061**

This whole blood control was tested against a five point calibration constructed from five NIST traceable calibrators.
The method of Headspace Gas Chromatography, Flame Ionization Detector (HS/GC/FID) was used to determine the target value and acceptable range (a minimum of 40 tests).

Number of tests:	**52**
Average:	**0.19626**
Minimum Value:	**0.1925**
Maximum Value:	**0.1986**
Standard Deviation:	**0.00130**
Coefficient of Variation:	**0.661%**

Phoenix Police Department Laboratory Services Bureau	**IN HOUSE WHOLE BLOOD CONTROL**

Lot #: **091611JM**

Target value: **0.199**

Acceptable Range (+/- 5%): **0.1898 to 0.2097**

This whole blood control was tested against a five point calibration constructed from five NIST traceable calibrators.
The method of Headspace Gas Chromatography, Flame Ionization Detector (HS/GC/FID) was used to determine the target value and acceptable range (a minimum of 40 tests).

Number of tests: **40**

Average: **0.19976**

Minimum Value: **0.1973**

Maximum Value: **0.2023**

Standard Deviation: **0.00099**

Coefficient of Variation: **0.494%**

Phoenix Police Department
Laboratory Services Bureau

IN HOUSE WHOLE BLOOD CONTROL

Lot #: **012711JM**

Target value: **0.196**

Acceptable Range (+/- 5%): **0.1862 to 0.2058**

This whole blood control was tested against a five point calibration constructed from five NIST traceable calibrators.
The method of Headspace Gas Chromatography, Flame Ionization Detector (HS/GC/FID) was used to determine the target value and acceptable range (a minimum of 40 tests).

Number of tests:	**48**
Average:	**0.19667**
Minimum Value:	**0.1934**
Maximum Value:	**0.1995**
Standard Deviation:	**0.00135**
Coefficient of Variation:	**0.686%**

Phoenix Police Department Laboratory Services Bureau	**IN HOUSE WHOLE BLOOD CONTROL**

Lot #: **081710JM**

Target value: **0.200**

Acceptable Range (+/- 5%): **0.1900 to 0.2100**

This whole blood control was tested against a five point calibration constructed from five NIST traceable calibrators.
The method of Headspace Gas Chromatography, Flame Ionization Detector (HS/GC/FID) was used to determine the above results (a minimum of 40 tests).

Number of tests:	**52**
Average:	**0.20069**
Minimum Value:	**0.1973**
Maximum Value:	**0.2030**
Standard Deviation:	**0.00143**
Coefficient of Variation:	**0.715%**

Phoenix Police Department Laboratory Services Bureau	**IN HOUSE WHOLE BLOOD CONTROL**

Lot #: **031810JM**

Target value: **0.198**

Acceptable Range (+/- 5%): **0.1881 to 0.2079**

This whole blood control was tested against a five point calibration constructed from five NIST traceable calibrators.
The method of Headspace Gas Chromatography, Flame Ionization Detector (HS/GC/FID) was used to determine the above results (a minimum of 40 tests).

Number of tests:	**48**
Average:	**0.19834**
Minimum Value:	**0.1947**
Maximum Value:	**0.2010**
Standard Deviation:	**0.00145**
Coefficient of Correlation:	**0.732%**

Phoenix Police Department Laboratory Services Bureau	**IN HOUSE WHOLE BLOOD CONTROL**

Lot #: **082009JM**

Target value: **0.193**

Acceptable Range (+/- 5%): **0.1834 to 0.2026**

This whole blood control was tested against a five point calibration constructed from five NIST traceable calibrators.
The method of Headspace Gas Chromatography, Flame Ionization Detector (HS/GC/FID) was used to determine the above results (a minimum of 40 tests).

Number of tests: **47**

Average: **0.19333**

Minimum Value: **0.1892**

Maximum Value: **0.1972**

Standard Deviation: **0.00177**

Coefficient of Correlation: **0.917%**

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 pr d only as guidelines.

ASSIGNED VALUES:

Level 1		Lot 50351 Exp. Date 02/09	
Method	Units	Mean	Expected Range
Gas Chromatography	mg/dL	82.5	74.3 – 90.8

Level 2		Lot 50352 Exp. Date 02/09	
Method	Units	Mean	Expected Range
Gas Chromatography	mg/dL	189	170 - 208

Level 3		Lot 50353 Exp. Date 02/09	
Method	Units	Mean	Expected Range
Gas Chromatography	mg/dL	285	256 - 314

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 Central Coast Diagnostics, 888-534-0911, 805-534-0111, or FAX 805-534-1348

Mfg. by Clinical Controls Int'l, Los Osos, CA 93402.

CATALOG NUMBERS:

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

Rev 02/05

LiquiSP$_x$

Ped 7/5/05

WHOLE BLOOD ETHANOL CONTROL

For *In vitro* diagnostic use
Cat. No. 501, Levels 1, 2 & 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.

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. This product may be stored frozen; however, it may be frozen and thawed one time only. 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.

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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 2	[redacted]	Lot 60742 Exp. Date 03/10	
Method	**Units**	**Mean**	**Expected Range**
Gas Chromatography	mg/dL	196	180 – 212

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 Central Coast Diagnostics, 888-534-0911, 805-534-0111, or FAX 805-534-1348

Mfg. by Clinical Controls Int'l, Los Osos, CA 93402.

CATALOG NUMBERS:

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

Proven stable in liquid format for four years.

Rev 06/06

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. This product may be stored frozen; however, it may be frozen and thawed one time only. 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 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 results should fall within the corresponding expected range.

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 2		Lot 70932 Exp. Date 04/11	
Method	**Units**	**Mean**	**Expected Range**
Gas Chromatography	g/dL	0.182	0.166 – 0.198

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 Central Coast Diagnostics, 888-534-0911, 805-534-0111, or FAX 805-534-1348

Mfg. by Clinical Controls Int'l, Los Osos, CA 93402.

CATALOG NUMBERS:

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

Proven stable in liquid format for four years.

REVISED 02/08

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 **E**thanol 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 2-8º C. This product may be stored frozen; however, it may be frozen and thawed one time only. 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 (18-25º C) and gently swirl the control material prior to use in order to ensure product homogeneity.

LIMITATIONS

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 2		Lot 81692 Exp. Date 11/12	
Method	**Units**	**Mean**	**Expected Range**
Gas Chromatography	g/dL	0.190	0.184 – 0.195

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 Central Coast Diagnostics, 888-534-0911, 805-534-0111, or FAX 805-534-1348

Mfg. by Clinical Controls Int'l, Los Osos, CA 93402.

CATALOG NUMBERS:

501-1 6X5 mL LEVEL 1

501-2 6X5 mL LEVEL 2

501-3 6X5 mL LEVEL 3

Proven stable in liquid format for four years.

Cliniqa	New Lot 0902159c
NI022709	0.2034
	0.2037
	0.2043
	0.2031
	0.2045
	0.2027
	0.2034
abg030509	0.2029
	0.2063
	0.2057
	0.2065
	0.2091
	0.2067
	0.2053
	0.2059
	0.2053
jsh033009	0.2023
	0.2031
	0.1993
	0.2014
	0.2028
	0.2022
	0.2001
	0.2015
	0.2009
jsh040809	0.2003
	0.201
	0.2018
	0.2024
	0.2023
	0.2018
	0.2013
	0.2018
	0.2011
jm041409	0.1994
	0.199
	0.199
	0.1975
	0.1997
	0.2006
	0.1992
	0.1975
Target (average)	0.202
sd	0.002607009
cv%	1.3
Range ±5% of Target	0.1919 to 0.2121

This whole blood control was tested against a five point calibration using five NIST traceable calibrators. The Phoenix Crime Laboratory uses the method of Headspace-Gas Chromatography, Flame Ionization Detector (HS/GC/FID) to determine the target concentration using a minimum of 40 results.

CLINIQA

CERTIFICATE OF ANALYSIS

Whole Blood Ethanol Control, Level 2, Labeled Vial

CATALOG NUMBER: 71036

LOT NUMBER: 0902159C

EXPIRATION DATE: February 28, 2013

SOURCE: Human Whole Blood

FORM: Liquid, 1 mL fill

PRESERVATIVE: < 0.1% Sodium Azide

CONCENTRATIONS:

ANALYTE	METHOD	UOM
Ethanol	Gas Chromatography	194.2 mg/dL

HBsAg, anti-HIV 1/2, anti-HCV and HIV-1 Ag: Nonreactive when tested on a single/pooled donor unit basis by FDA accepted methods.

STORAGE TEMPERATURE: 2-8°C

SHIPPING TEMPERATURE: 2-8°C

SAFETY: Because no test method can offer complete assurance that products derived from human source will not transmit infectious disease agents, it is recommended that this product be handled with the same precautions used for patient specimens.

QUALITY ASSURANCE APPROVAL _____ **DATE** 2/23/09

71036 C_00 CO 7011 2/23/09

2/24/09 Recd UBV A53326

Toll Free • 800.728.5205 Phone • 760.744.1900 Fax • 760.571.5197 Web • www.cliniqa.com
Cliniqa Corporation • 288 Distribution St. • San Marcos, CA 92078 USA

Whole Blood Ethanol Control Level 2

CE

INTENDED USE

FOR IN VITRO DIAGNOSTIC 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.

PRODUCT 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. This product may be stored frozen; however, it may be frozen and thawed one time only. 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.

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. Individual laboratory means should fall within the corresponding expected range.

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 2		Lot No.: XR2829 Exp. Date: 2013/01	
Method	**Units**	**Mean**	**Expected Range**
Gas Chromatography	mg/dL	197.5	190-205

REFERENCES

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

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RE-ORDER INFORMATION
Whole Blood Ethanol Control

Catalog No.
REF 93211
Level 1, 6 x 5 mL

Catalog No.
REF 93212
Level 2, 6 x 5 mL

Catalog No.
REF 93213
Level 3, 6 x 5 mL

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