



Phoenix Police Department
Laboratory Services Bureau

WHOLE BLOOD CONTROL

Lot #: ACQ lot 4130622206/9

Target value: 0.201

Acceptable Range (+/- 5%): 0.1910 to 0.2110

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: 0.20158

Minimum Value: 0.1986

Maximum Value: 0.2060

Standard Deviation: 0.00173

Coefficient of Variation: 0.859%

EtOH WH 2,0 g/L – In vitro diagnosticum

Ethanolkontrollen im Vollblut

Anwendung

Die Probe ist als Richtigkeitskontrolle oder Kalibrator für die Ethanolbestimmung einsetzbar.

Gebrauchsanweisung

Die Probe ist gebrauchsfertig und entsprechend der eigenen Laborvorschriften einzusetzen.

Zielwert

Die Zielwerte wurden unter der organisatorischen Leitung der ARVECON GmbH im Rahmen ihres Ringversuchsprogramms im Ringversuch EtB 2/24 B – Ethanol in Vollblut bestimmt. Die Analysen wurden von den Teilnehmern mit GC durchgeführt. Die Zielwerte wurden durch die Ringversuchsleitung der ARVECON freigegeben.

Lagerung und Haltbarkeit

Lagerung: + 2 °C bis + 8 °C

Haltbarkeit:

- Original verschlossen, lichtgeschützt: siehe Verfallsdatum auf der Packung.
- Dicht verschlossen, lichtgeschützt: siehe Verfallsdatum auf der Packung.

Vorsichtsmaßnahmen

Alle Materialien humanen Ursprungs sind grundsätzlich mit derselben Sorgfalt wie potentiell infektiöse Patientenproben zu behandeln. Jede zur Herstellung verwendete Bluteinheit wurde auf Antigen und Antikörper geprüft und für negativ befunden: HBsAG, anti-HIV-1, anti-HIV-2, anti-HBc und anti-HCV.

Ch.-B / Lotto: 4130622206
Best.-Nr. / Codice: WH20-015 (10 x 1,5 mL)
 WH20-115 (100 x 1,5 mL)
 WH20-030 (10 x 3,0 mL)
FG.Nr.: 24-08
Version / Versione: 2 – 202407

EtOH WH 2.0 g/L – For in vitro diagnostic use

Ethanol control in whole blood

Application

This material should be used in accordance with the laboratory's operating procedures for instrument calibration or as a control material

User guide

This ACQ Science EtOH WH requires no additional preparation and is ready for use.

Target value

This material was tested in the proficiency test EtB 2/24 B – Ethanol in whole blood, organized by ARVECON GmbH. The target values listed are the consensus values obtained from this trial. Quantitative analyses were performed by the participants using Gas Chromatography. The target values were released by the coordinator of proficiency testing of ARVECON.

Storage and stability

Storage: + 2 °C to + 8 °C

Stability:

- Sealed container, stored in the dark: see expiration date on the package.
- Stored in the dark tightly capped: see expiration date on package.

Precautions

All materials of human origin should be considered as potentially infectious and treated with the same care as patient specimens. Each individual blood unit used for the production of the control was tested for the following antigens and antibodies: HBsAG, anti-HIV-1, anti-HIV-2, anti-HBc and anti-HCV and found to be negative.

Lot / Lot: 4130622206
Best.-Nr. / Codice: WH20-015 (10 x 1,5 mL)
 WH20-115 (100 x 1,5 mL)
 WH20-030 (10 x 3,0 mL)
FG.Nr.: 24-08
Version / Versione: 2 – 202407

EtOH WH 2,0 g/L – Uso diagnostico in vitro

Controllo d'etanolo in sangue intero

Applicazione

Utilizzabile nelle procedure definite da ciascun laboratorio come calibratore o come materiale di controllo.

Utilizzo

Pronto all'uso.

Valori attesi

I valori attesi sono stati assegnati tramite l'attività di proficiency test della ARVECON: "EtB 2/24 B – Ethanol in sangue intero" sotto la direzione organizzativa di ARVECON GmbH. Le analisi sono state eseguite dai partecipanti tramite GC. I valori attesi sono stati forniti dal coordinatore dell'attività di proficiency test del ARVECON.

Conservazione e stabilità

Conservazione: + 2 °C fino a + 8 °C

Stabilità:

- Flacone non aperto: se conservato ben chiuso ed al riparo dalla luce fino alla data di scadenza.
- Flacone aperto: se conservato ben chiuso ed al riparo dalla luce fino alla data di scadenza in etichetta.

Precauzioni

Tuttavia, poiché nessuna analisi può offrire sicurezza completa che gli agenti infettivi siano assenti, questo prodotto deve essere manipolato osservando le stesse precauzioni di sicurezza usate quando si manipola qualunque tipo di materiale potenzialmente infettivo. I componenti originari da cui questo prodotto è stato derivato, sono stati trovati negativi per HBsAg e per gli anticorpi contro HCV, HBc, HIV-1 e HIV-2 attraverso metodologie di analisi approvate.

EtOH WH 2,0 g/L – Usage in vitro

Contrôle d'éthanol dans le sang total

Application

Standard dédié à la calibration pour techniques analytiques de détermination de concentration d'éthanol ou à utiliser comme contrôle d'exactitude.

Utilisation

Ce contrôle est prêt à l'emploi.

Valeur cible

Les valeurs cibles ont été déterminées lors d'un test inter-laboratoire de ARVECON: "EtB 2/24 B – Ethanol dans le sang total", organisé par la société ARVECON GmbH. Les participants ont utilisé la méthode GC. Les valeurs cibles ont été validées par le responsable des tests inter-laboratoires de ARVECON.

Conservation et stabilité

Conservation: + 2 °C jusqu'à + 8 °C

Stabilité:

- Scellé (à l'origine), à l'abri de la lumière: voir la date d'expiration indiquée sur l'étiquette.
- à stocker hermétiquement à l'abri de la lumière: voir la date d'expiration indiquée sur l'étiquette.

Précautions

Tout matériel humain doit être considéré comme étant potentiellement infectieux et traité dans les mêmes conditions que des échantillons de patients. Chaque unité de sang utilisée pour la préparation de ce contrôle a été testée et trouvée négatif pour les antigènes et anticorps suivants: AgHBs, anti-HIV-1, anti-HIV-2, anti-HBc et anti-HCV.

EtOH WH 2,0 g/L – Lot: 4130622206 - For in vitro diagnostic use

Ethanol control in whole blood

EXP 05/2029

Messverfahren Method Metodo Méthode	Zielwert Target value Valori attesi Valeur cible	Konfidenzbereiche / Confidence ranges / Intervallo di fiducia / Intervalle de confiance			Einheit Unit Unità Unité
		statistisch / statistical ¹ statistico / statistique ¹	forensisch / forensic ² forense / médecine légale ²	klinisch / clinical ³ clinico / clinique ³	
GC	1,963	1,821– 2,105	1,865 – 2,061	1,786 – 2,140	g/L

1 Konfidenzbereich – Analysenwerte

Der Konfidenzbereich gibt den Bereich an, in dem der Zielwert mit einer Wahrscheinlichkeit von 95% liegt.

2 Konfidenzbereich – Deutsche forensische Richtlinie

[EtOH] ≤ 1,06 g/L → Konfidenzbereich ± 0,053 g/L von dem Zielwert
[EtOH] > 1,06 g/L → Konfidenzbereich ± 5% von dem Zielwert

Literatur:

Bundesgesundheitsamt (1966) - Richtlinie für die Blutalkoholbestimmung für forensische Zwecke.
Richtlinien zur Bestimmung der Blutalkoholkonzentration (BAK) für forensische Zwecke (aus der Deutschen Gesellschaft für Rechtsmedizin, der Gesellschaft für Toxikologische und Forensische Chemie und der Deutschen Gesellschaft für Verkehrsmedizin, publiziert in Blutalkohol (2011) 48: 137-143)

3 Konfidenzbereich – Richtlinie der deutschen Bundesärztekammer

Für 0,2 < [EtOH] ≤ 0,6 g/L → Konfidenzbereich ± 15% vom Zielwert
Für 0,6 < [EtOH] ≤ 5,0 g/L → Konfidenzbereich ± 9% vom Zielwert

Literatur:

Richtlinien der Bundesärztekammer zur Qualitätssicherung laboratoriumsmedizinischer Untersuchungen (14.04.2023)

1 Confidence ranges – measured values

The confidence interval indicates the range in which the target value is located with a significance level of 95%.

2 Confidence ranges – German forensic directives

[EtOH] ≤ 1.06 g/L → ± 0.053 g/L from the target value
[EtOH] > 1.06 g/L → ± 5% from the target value

References:

Bundesgesundheitsamt (1966) - Richtlinie für die Blutalkoholbestimmung für forensische Zwecke.
Richtlinien zur Bestimmung der Blutalkoholkonzentration (BAK) für forensische Zwecke (aus der Deutschen Gesellschaft für Rechtsmedizin, der Gesellschaft für Toxikologische und Forensische Chemie und der Deutschen Gesellschaft für Verkehrsmedizin, publiziert in Blutalkohol (2011) 48: 137-143)

3 Confidence ranges – Directive of the German Medical Association

0.2 < [EtOH] ≤ 0.6 g/L → ± 15% from the target value
0.6 < [EtOH] ≤ 5.0 g/L → ± 9% from the target value

References:

Richtlinien der Bundesärztekammer zur Qualitätssicherung laboratoriumsmedizinischer Untersuchungen (14.04.2023)

1 Intervallo di fiducia - Valori di analisi

L'intervallo di fiducia indica l'intervallo entro il quale si trova il valore atteso con un livello di significatività del 95%.

2 Intervallo di fiducia – Direttiva Forense Tedesca

[EtOH] ≤ 1,06 g/L → ± 0,053 g/L del valore atteso
[EtOH] > 1,06 g/L → ± 5% del valore atteso

Bibliografia:

Bundesgesundheitsamt (1966) - Richtlinie für die Blutalkoholbestimmung für forensische Zwecke.
Richtlinien zur Bestimmung der Blutalkoholkonzentration (BAK) für forensische Zwecke (aus der Deutschen Gesellschaft für Rechtsmedizin, der Gesellschaft für Toxikologische und Forensische Chemie und der Deutschen Gesellschaft für Verkehrsmedizin, publiziert in Blutalkohol (2011) 48: 137-143)

3 Intervallo di fiducia – Direttiva dell' Ordine Nazionale Tedesca dei Medici

0,2 < [EtOH] ≤ 0,6 g/L → ± 15% del valore atteso
0,6 < [EtOH] ≤ 5,0 g/L → ± 9% del valore atteso

Bibliografia:

Richtlinien der Bundesärztekammer zur Qualitätssicherung laboratoriumsmedizinischer Untersuchungen (14.04.2023)

1 Intervalle de confiance – Valeurs des analyses

La marge de confiance est la marge dans laquelle la valeur cible se trouve avec une probabilité de 95%.

2 Intervalle de confiance – Directives allemandes de la Médecine Légale

[EtOH] ≤ 1,06 g/L → ± 0,053 g/L de la valeur cible
[EtOH] > 1,06 g/L → ± 5% de la valeur cible

Littérature:

Bundesgesundheitsamt (1966) - Richtlinie für die Blutalkoholbestimmung für forensische Zwecke.
Richtlinien zur Bestimmung der Blutalkoholkonzentration (BAK) für forensische Zwecke (aus der Deutschen Gesellschaft für Rechtsmedizin, der Gesellschaft für Toxikologische und Forensische Chemie und der Deutschen Gesellschaft für Verkehrsmedizin, publiziert in Blutalkohol (2011) 48: 137-143)

3 Intervalle de confiance – Directives allemandes cliniques

0,2 < [EtOH] ≤ 0,6 g/L → ± 15% de la valeur cible
0,6 < [EtOH] ≤ 5,0 g/L → ± 9% de la valeur cible

Littérature:

Richtlinien der Bundesärztekammer zur Qualitätssicherung laboratoriumsmedizinischer Untersuchungen (14.04.2023)



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 printed only as guidelines.

ASSIGNED VALUES:

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

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

		Lot 50353 Exp. Date 02/09	
Level 3			
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.

LiquiSP_x is a Trademark of SP_x Systems, San Luis Obispo, CA, and is licensed to Clinical Controls.

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



*Redd
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-III 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.

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.

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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		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.

LiquiSP_x is a Trademark of SP_xSystems, San Luis Obispo, CA, and is licensed to Clinical Controls.

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



LiquiSP

WHOLE BLOOD ETHANOL CONTROL

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

INTENDED USE

Clinical Controls LiquiSPTM 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-III 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.

LiquiSP_x is a Trademark of SP_xSystems, San Luis Obispo, CA, and is licensed to Clinical Controls.

CATALOG NUMBERS:

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



LiquiSP

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 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.

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

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.

LiquiSP_x is a Trademark of SP_x Systems, San Luis Obispo, CA, and is licensed to Clinical Controls.

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 $\pm 5\%$ 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.



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 _____

71036 C_00 CO 7011 2/23/09

DATE _____

2/23/09

2/24/09 Recd LBV AG3330



Whole Blood Ethanol Control Level 2

INTENDED USE

FOR IN VITRO DIAGNOSTIC USE

Clinical Controls LiquiSP[™] 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[™] 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.

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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.

MANUFACTURED BY CLINIQA CORPORATION

288 Distribution St.
San Marcos, CA 92078
USA



SALES AND TECHNICAL SUPPORT

P: 800 728 5205
+1 760 744 1900
F: +1 760 891 3767
www.cliniqa.com

FOR ORDERS AND CUSTOMER SERVICE

P: 800 728 5205
+1 760 744 1900
F: +1 760 571 5197

EC RESPONSIBLE AUTHORITY

CEpartner4U
Esdooimlaan 13
3951 DB Maarn, The Netherlands
P: +31 343 442 524
F: +31 343 442 162



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

