

# Mission CliniCheck Assayed Chemistry Control

## Level 1 and Level 2



DD-93001D Level 1  
 DD-93002D Level 2  
 DD-93012 Multi Level



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R0K112 - EU

Level 1 R0F113-EU  
 Level 2 R0G111-EU

English

### INTENDED USE

Mission CliniCheck Assayed Chemistry Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the following analytes Acid Phosphatase (Total), Alanine Aminotransferase (ALT/SGPT), Albumin, Alkaline Phosphatase (ALP), Amylase, Aspartate Aminotransferase (AST/SGOT), Bicarbonate (CO<sub>2</sub>), Bilirubin (Direct), Bilirubin (Total), Calcium, Chloride, Cholesterol (Total), Cholesterol (HDL), Cholesterol (LDL), Cholinesterase, Creatine Kinase (CK), Creatinine, Gamma Glutamyltransferase (GGT), Glucose, Iron, Iron (UIBC), Lactate (Lactic acid), Lactate Dehydrogenase (LDH), Lipase, Lithium, Magnesium, Phosphorus, Potassium, Protein-Total, Sodium, Triglycerides, Urea, Urea Nitrogen, and Uric Acid.

### SUMMARY AND PRINCIPLE

The use of quality control materials is indicated as an objective assessment of the precision of methods and techniques in use and is an integral part of good laboratory practices. Two levels of control are available to allow performance monitoring within the clinical range.

### REAGENT

This product is prepared from human serum with added constituents of purified biochemicals (tissue extracts of human and animal origin), chemicals, therapeutic drugs, preservatives and stabilizers. The control is provided in lyophilized form for increased stability.

### STORAGE AND STABILITY

This product will be stable until the expiration date when stored unopened at 2 to 8°C. Once the control is reconstituted, all analytes will be stable for 7 days when stored tightly capped at 2 to 8°C with the following exception: Acid Phosphatase will be stable for 3 days, AST (GOT) for 1 day, CK and LDH for 6 days when stored tightly capped at 2 to 8°C.

After reconstituting and freezing the control all analytes will be stable for 20 days when stored tightly capped at -10 to -20°C. Once thawed, do not refreeze the control; discard remaining material.

### RECONSTITUTION

Using a volumetric pipette, reconstitute each vial with 5.0 mL of distilled or deionized water. Replace the stopper and allow the control to stand for 20 minutes, swirling occasionally. Before sampling, gently swirl the vial several times to ensure homogeneity.

### PROCEDURE

This product should be treated the same as patient specimens and run in accordance with the instructions accompanying the instrument, kit or reagent being used. Replace the stopper securely after each use.

Dispose of any discarded materials in accordance with the requirements of your local waste management authorities. In the event of damage to packaging, contact the local Diamond Diagnostics, Inc. Sales Office.

### LIMITATIONS

- This product should not be used past the expiration date.
- If there is evidence of microbial contamination or excessive turbidity in the reconstituted control, discard the vial.
- This product is not intended for use as a standard.

### ASSIGNMENT OF VALUES

The mean values printed in this insert were derived from replicate analyses and are specific for this lot of product. The tests listed were performed by the reagent manufacturer and/or independent laboratories using manufacturer supported reagents and a representative sampling of this lot of control. Individual laboratory means should fall within the corresponding acceptable range; however, laboratory means may vary from the listed values during the life of this control. Variations over time and between laboratories may be caused by differences in laboratory technique, instrumentation and reagents, or by manufacturer test method modifications. It is recommended that each laboratory establish its own means and acceptable ranges and use those provided only as guides.

Refer to [www.diamonddiagnostics.com](http://www.diamonddiagnostics.com) for insert update information.

### SPECIFIC PERFORMANCE CHARACTERISTICS

This product is a freeze-dried product manufactured under rigid quality control standards. To obtain consistent vial-to-vial assay values, the control requires proper storage and handling as described.

DEUTSCH

### VORGEGEHENER VERWENDUNGSZWECK

Die Mission CliniCheck Assayed Chemistry Control ist eine Qualitätskontrolle für klinisch-chemische Analysegeräte, die durch die Vorgabe von zu erreichenden Zielwerten, die Präzision der Abläufe von Labor Tests überwachen soll. Folgende Analyte werden gemessen: Saure Phosphatase (total), Alanine Aminotransferase (ALT/SGPT), Albumin, alkalische Phosphatase (ALP), Amylase, Aspartate Aminotransferase (AST/SGOT), Bicarbonate (CO<sub>2</sub>), Bilirubin (direkt), Bilirubin (total), Kalzium, Chloride, Cholesterin (total), Cholesterin (HDL), Cholesterin (LDL), Cholinesterasen, Creatin-Kinase (CK), Kreatinin, Gamma-Glutamyltransferase (GGT), Glucose, Eisen, Eisen (UIBC), Lactate, Lactatdehydrogenase (LDH), Lipasen, Lithium, Magnesium, Phosphor, Kalium, Proteine-Total, Natrium, Triglyceride, Harnstoff, Harnstoff-Stickstoff und Harnsäure.

### EINLEITUNG UND ZUSAMMENFASSUNG

Die Verwendung entsprechender Kontrollmaterialien dient der objektiven Beurteilung der Qualität von im Labor durchgeführten Untersuchungen und ist ein unerlässlicher Bestandteil der guten Laborpraxis. Die zwei Level dieser Kontrolle ermöglichen eine umfassende Qualitätssicherung im gesamten klinisch relevanten Bereich

### REAGENZ

Dieses Produkt wurde aus Humanserum hergestellt und enthält Zusätze von gereinigten, biochemischen Materialien (Gewebeextrakte menschlichen und tierischen Ursprungs), Chemikalien, Medikamenten, Konservierungsmitteln und Stabilisatoren. Die Kontrolle wurde zur Verbesserung der Stabilität lyophilisiert.

### LAGERUNG UND HALTBARKEIT

Dieses Produkt ist bis zum angegebenen Haltbarkeitsdatum stabil, sofern es ungeöffnet und bei 2 bis 8°C gelagert wird. Nach Rekonstitution der Kontrolle sind alle Analyte 7 Tage lang stabil, sofern die Ampulle fest verschlossen bei 2 bis 8°C gelagert wird. Einzige Ausnahme: Saure Phosphatase, diese ist 3 Tage, bei einer dicht verschlossenen Lagerung von 2 bis 8°C, haltbar.

Wenn die Kontrolle nach der Rekonstitution eingefroren wird, sind alle Analyte 20 Tage lang stabil, sofern die Ampulle dicht verschlossen bei -10 bis -20°C gelagert wird. Das Kontrollmaterial nach dem Auftauen nicht erneut einfrieren, das übrig gebliebene Material ist zu entsorgen.

### REKONSTITUTION

In jedes Fläschchen mit einer Vollpipette genau 5,0 ml destilliertes oder deionisiertes Wasser pipettieren. Mit den Stopfen verschließen, sorgfältig mischen und bis zur vollständigen Rekonstitution 20 Minuten stehen lassen, dabei gelegentlich umschwenken. Um die Homogenität sicherzustellen, vor Entnahme einer Probe nochmals vorsichtig durchmischen.

### HANDHABUNG

Das Produkt ist genau wie eine Patientenprobe zu behandeln und in Übereinstimmung mit den Vorschriften des Geräte-, Kit- oder Reagenzherstellers anzuwenden. Nach jedem Gebrauch wieder fest verschließen.

Die Entsorgung aller Abfälle ist nach den geltenden lokalen Abfallbestimmungen vorzunehmen. Falls die Verpackung beschädigt ist, nehmen Sie bitte Kontakt zur Diamond Diagnostics Niederlassung auf.

### EINSCHRÄNKUNGEN

- Dieses Produkt nach Ablauf des Haltbarkeitsdatums nicht mehr verwenden
- Bei Anzeichen einer mikrobiellen Kontamination oder einer starken Trübung der rekonstituierten Kontrolle, ist das Fläschchen zu verworfen.
- Dieses Produkt ist nicht zur Verwendung als Standard geeignet.

### WERTEERMITTLUNG

Die in dieser Packungsbeilage angegebenen Mittelwerte stammen aus Vielfachbestimmungen und gelten speziell für diese Produktcharge. Die angegebenen Tests wurden vom Reagenzhersteller und/oder von unabhängigen Laboratorien mit vom Hersteller unterstützten Reagenzien durchgeführt; dazu wurde eine repräsentative Stichprobe dieser Produktcharge eingesetzt. Die einzelnen Werte sollten im entsprechenden Akzeptanzbereich liegen. Die tatsächlich erzielten Werte können jedoch während der Lebensdauer dieser Kontrolle von den angegebenen Zielwerten abweichen. Abweichungen im Laufe der Zeit und zwischen verschiedenen Laboratorien sind möglicherweise auf unterschiedliche Labortechniken, Geräte und Reagenzien oder auf Modifikationen der Testmethoden durch den Hersteller zurückzuführen. Jedem Labor wird empfohlen, eigene Mittelwerte und Akzeptanzbereiche zu ermitteln und die hier aufgeführten Werte als Richtwerte zu betrachten.

Aktualisierte Zielwerttabellen finden Sie im Internet unter [www.diamonddiagnostics.com](http://www.diamonddiagnostics.com).

### SPEZIFISCHE EIGENSCHAFTEN

Dieses gefriergetrocknete Produkt wurde nach strengen Qualitätsstandards hergestellt. Richtige und präzise Ergebnisse erfordern sachgerechte Lagerung und Handhabung wie angegeben.

FRAANÇAIS

### UTILISATION

Mission CliniCheck Assayed Contrôle Chimique est destiné à être utilisé comme un sérum de contrôle de qualité de dosage pour surveiller la précision des procédures de tests de laboratoire pour les analyses suivantes Acide Phosphatase (Total), Albumine, Alanine Aminotransférase (ALT/SGPT), Alcaline Phosphatase (ALP), Amylase, Aspartate Aminotransférase (AST/SGOT), Bicarbonate (CO<sub>2</sub>), Bilirubine (Direct), Bilirubine (Total), Calcium, Chlorure, Cholestérol (Total), Cholestérol (HDL), Cholestérol (LDL), Cholinestérase, Créatine Kinase (CK), Créatinine, Gamma Glutamyltransférase (GGT), Glucose, Fer, Fer (UIBC), Lactate (acide Lactique), Lactate Déshydrogénase (LDH), Lipase, Lithium, Magnésium, Phosphore, Potassium, Protéine-Total, Sodium, Triglycérides, Urea, Urea Nitrogène et Acide Uréique.

### INTRODUCTION ET PRINCIPE

L'utilisation de produits de contrôle de la qualité est indiquée pour évaluer de façon objective la précision des méthodes et des techniques utilisées, et fait partie intégrante des bonnes pratiques de laboratoire. Deux concentrations sont disponibles afin de permettre un contrôle de la qualité sur l'ensemble de la plage de valeurs cliniques.

### REACTIF

Ce produit est préparé à partir de sérum humain auquel ont été ajoutés des constituants de produits biochimiques purifiés (extraits de tissus d'origines humaine et animale), des produits chimiques, des médicaments thérapeutiques, des agents conservateurs et des stabilisants. Le contrôle est fourni sous forme lyophilisée pour assurer une meilleure stabilité.

### CONSERVATION ET STABILITE

Ce produit sera stable jusqu'à la date d'expiration lors d'un stockage non ouvert de 2 à 8°C. Une fois le contrôle est reconstitué, toutes les substances seront stables pendant 7 jours en stockant étroitement fermé de 2 à 8°C à l'exception suivante: Acide Phosphatase sera stable pour 3 jours en stockant étroitement fermé de 2 à 8°C.

Après reconstitution et congélation de contrôle, toutes les substances seront stables pendant 20 jours en stockant étroitement fermé de -10 à -20°C. Une fois décongelé, ne pas recongeler le contrôle; se débarrasser du matériel restant.

### RECONSTITUTION

A l'aide d'une pipette volumétrique, reconstituer chaque flacon avec 5,0 ml d'eau distillée ou désionisée. Remplacer le bouchon et laisser le produit reposer pendant 20 minutes, en agitant de temps en temps. Avant utilisation, homogénéiser le produit en agitant plusieurs fois le flacon. Ne pas mélanger par retournement si une analyse de trace métallique doit être effectuée.

### MODE OPERATOIRE

Ce produit doit être traité comme les échantillons de patients, en respectant les instructions accompagnant l'appareil, le kit ou le réactif utilisé. Bien reboucher le flacon après chaque utilisation.

Tout déchet doit être éliminé conformément aux réglementations en vigueur dans le laboratoire pour le traitement des déchets. Si le conditionnement est endommagé, contacter votre service technique Diamond Diagnostics, Inc. local.

### LIMITES

- Ne pas utiliser ce produit après la date de péremption.
- En cas de contamination microbienne ou de trouble excessif du contrôle reconstitué, éliminer le flacon.
- Ce produit n'est pas conçu pour être utilisé comme étalon.

### DETERMINATION DES VALEURS

Les valeurs moyennes indiquées sur cette notice ont été déterminées à partir d'analyses répétées et concernent spécifiquement ce numéro de lot du produit. Les essais indiqués ont été réalisés par le fabricant du réactif et/ou par des laboratoires indépendants à l'aide de réactifs acceptés par le fabricant et sur un échantillonnage représentatif de ce lot de contrôle. Les moyennes obtenues par un laboratoire donné doivent se trouver sur la plage de valeurs acceptables correspondante; cependant, les moyennes obtenues par le laboratoire peuvent varier par rapport aux valeurs indiquées pendant la durée de vie de ce contrôle. Les variations dans le temps et entre laboratoires peuvent être dues à des différences de méthodes, d'appareils et de réactifs employés par chaque laboratoire ou à des modifications de la méthode d'analyse employée par le fabricant. Il est recommandé à chaque laboratoire d'établir ses propres moyennes et plages de valeurs acceptables et de l'utiliser les valeurs fournies qu'à titre indicatif.

Consulter le site [www.diamonddiagnostics.com](http://www.diamonddiagnostics.com) pour obtenir une mise à jour de la notice.

### CARACTERISTIQUES

Ce produit lyophilisé est fabriqué selon des normes rigoureuses de contrôle de la qualité. Pour obtenir des résultats reproductibles d'un flacon à l'autre, le contrôle doit être convenablement conservé et manipulé, tel que décrit dans cette notice.



**Warning**

Biological source material. Treat as potentially infectious.

Each human donor unit used to manufacture this control was tested by FDA accepted methods and found non-reactive for Hepatitis B Surface Antigen (HBsAg), antibody to Hepatitis C (HCV) and antibody to HIV-1/HIV-2. This product may also contain other human source material for which there are no approved tests. In accordance with good laboratory practice, all human source material should be considered potentially infectious and handled with the same precautions used with patient specimens. Material Safety Data Sheet (MSDS) available for professional users on [www.diamonddiagnostics.com](http://www.diamonddiagnostics.com).



**Warnung**

Material biologischer Herkunft. Als potentiell infektiös zu behandeln.

Jede zur Herstellung dieser Kontrolle verwendete menschliche Spenderreinheit wurde mit von der amerikanischen Arzneimittelbehörde FDA (Food and Drug Administration) zugelassenen Methoden getestet und als nicht-reaktiv bezüglich Hepatitis-B-Oberflächen-Antigen (HBsAg), Antikörper gegen Hepatitis C (HCV) und Antikörper gegen HIV-1/HIV-2 befunden. Das Produkt enthält möglicherweise auch andere Bestandteile menschlichen Ursprungs, für die keine zugelassenen Tests existieren. In Übereinstimmung mit der guten Laborpraxis sollen alle Materialien menschlichen Ursprungs als potentiell infektiös betrachtet und mit der gleichen Sorgfalt wie Patientenproben behandelt werden. Sicherheitsdatenblätter (MSDS) stehen Ihnen im Internet unter [www.diamonddiagnostics.com](http://www.diamonddiagnostics.com) zur Verfügung.



**Attention**

Produit d'origine biologique. A considérer comme potentiellement infectieux.

Chaque unité de produit provenant d'un donneur humain et utilisée/employée dans la préparation de ce contrôle a été analysée à l'aide de méthodes approuvées par la FDA et a présenté des résultats négatifs pour l'antigène de surface de l'hépatite B (AgHBs), et les anticorps de l'hépatite C (VHC) et du VIH-1/VIH-2. Il est possible que ce produit contienne d'autres substances d'origine humaine pour lesquelles il n'existe pas de test agréé. Conformément aux bonnes pratiques de laboratoire, toute substance d'origine humaine doit être considérée comme potentiellement infectieuse et manipulée avec les mêmes précautions que les échantillons provenant de patients. Une fiche de sécurité est à disposition des utilisateurs professionnels sur le site [www.diamonddiagnostics.com](http://www.diamonddiagnostics.com).



# Mission CliniCheck Assayed Chemistry Control

## Level 1 and Level 2

### ESPAÑOL

#### USO

Control de Química ensayado Misión CliniCheck está diseñado para ser usado como un suero de control referencial para monitorear la precisión en los métodos de procesamiento de pruebas de laboratorio en los siguientes análisis: Ácido Fosfático (Total), Albumina, Fosfatasa Alcalina (ALP), Amilasa, Aspartato Aminotransferasa (AST/GOT), Bicarbonato (CO2), Bilirrubina (Directa), Bilirrubina (Total), Calcio, Cloro, Colesterol (Total), Colesterol (HDL), Colesterol (LDL), Colesterasa, Creatina Quinasa (CK), Creatinina, Gamma Glutamil Transpeptidasa (GGT), Glucosa, Hierro, Hierro (UIBC), Lactato (Ácido Láctico), Lactato deshidrogenasa (LDH), Lipasa, Litio, Magnesio, Fósforo, Potasio, Proteína Total, Sodio, Triglicéridos, Urea, Nitrógeno Urico y Ácido Urico.

El uso de materiales de control de la calidad está indicado para la evaluación objetiva de la precisión de los métodos y las técnicas en uso, y forma parte integral de las buenas prácticas del laboratorio. Existen dos niveles de control para permitir supervisar el funcionamiento dentro del rango clínico.

#### REACTIVOS

Este producto está preparado a partir de suero humano al que se añaden constituyentes bioquímicos purificados (extractos de tejido de origen humano y animal), sustancias químicas, drogas terapéuticas, conservantes y estabilizadores. El control se suministra liofilizado para aumentar su estabilidad.

#### CONSERVACIÓN Y ESTABILIDAD

Este producto permanecerá estable hasta la fecha de caducidad, siempre que esté almacenado sin abrir a una temperatura entre 2 y 8 °C. Una vez reconstituido el control, si se almacena bien tapado entre 2 y 8 °C, todos los análisis permanecerán estables durante 7 días, excepto Fosfatasa Ácida y Fosfatasa Ácida Proxática, que permanecerán estables durante 3 días siempre que se almacene bien tapado entre 2 y 8 °C.

Una vez reconstituido y congelado el control, siempre que se almacene bien tapado entre -10 y -20 °C, todos los análisis permanecerán estables durante 20 días, excepto Tobramicina, que permanecerá estable durante 20 días siempre que se almacene bien tapado entre -10 y -20 °C. No vuelva a congelar el control una vez descongelado. Deseche el material sobrante.

#### RECONSTITUCIÓN

Utilizando una pipeta volumétrica, reconstituya cada vial con 5,0 ml de agua destilada o desionizada. Vuelva a taponarlo y deje reposar el control durante 20 minutos, girándolo en círculos de vez en cuando. Antes del muestreo, gire el vial en círculos con cuidado para garantizar su homogeneidad. Si está realizando un análisis para la detección de metales traza, no lo invierta para mezclarlo.

#### PROCEDIMIENTO

Este producto permanecerá estable hasta la fecha de su vencimiento, cuando se almacena, sin abrir, entre 2 y 8 °C. Una vez reconstituido el control, todos los análisis permanecerán estables durante 7 días, si se almacena herméticamente cerrado entre 2 y 8 °C. Se exceptúa la Fosfatasa Ácida, que permanecerá estable por 3 días, si se almacena herméticamente cerrado a temperaturas entre 2 y 8 °C. Luego de que el control es reconstituido y congelado, todos los análisis permanecerán estables por 20 días, si se almacena herméticamente cerrado a temperaturas entre -10 y -20 °C. Una vez descongelado, no vuelva a congelar el control; descarte el material remanente.

#### LIMITACIONES

- Este producto no debe utilizarse después de la fecha de caducidad.
- Si hubiese indicios de contaminación microbiana o exceso de turbidez en el producto reconstituido, deseche el vial.
- Este producto no está previsto para ser utilizado como estándar.

#### ASIGNACIÓN DE VALORES

Los valores medicos que figuran en este prospecto se obtuvieron a partir de la replicación de análisis y son específicos de este lote de producto. Las pruebas fueron realizadas por el fabricante del reactivo o por laboratorios independientes que utilizaron reactivos admitidos por el fabricante y una muestra representativa de este lote de control. Las medias de cada laboratorio deben estar comprendidas en el correspondiente rango aceptable, pero pueden apartarse de los valores indicados mientras dure este control. Las variaciones a lo largo de tiempo y entre laboratorios pueden deberse a diferencias en las técnicas del laboratorio, su instrumental y sus reactivos, o a modificaciones introducidas en el método de medida del fabricante. Se recomienda que cada laboratorio establezca sus propias medias y rangos aceptables y utilice los que aquí se proporcionan sólo como orientación.

Puede consultar las actualizaciones de prospectos en la página web [www.diamonddiagnostics.com](http://www.diamonddiagnostics.com).

#### CARACTERÍSTICAS ESPECÍFICAS DEL PREPARADO

Éste es un producto liofilizado que ha sido fabricado según las más estrictas normas de control de la calidad. Para que obtener valores de ensayo coherentes entre viales, será necesario almacenar y manipular el control según se indica.

### PORTUGUÊS

#### UTILIZAÇÃO

Mission CliniCheck é um controle de química clínica que deve ser utilizado como um controle de qualidade de soro ensaiado para monitorar a precisão dos procedimentos de laboratório para os seguintes análises: Fosfatase Ácida (Total), Albumina, Fosfatase Alcalina (ALP), Amilase, Aspartato Aminotransferase (AST / GOT), Bicarbonato (CO2), Bilirrubina (Direta), Bilirrubina (Total), Cálcio, Cloro, Colesterol (Total), Colesterol (HDL), Colesterol (LDL), Colinesterase, Creatina Kinase (CK), Colinesterase, Gama Glutamitransferase (GGT), Glicose, Ferro, Ferro (UIBC), Lactato (Ácido Láctico), Lactato Desidrogenase (LDH), Lipase, Litio, Magnésio, Fósforo, Potássio, Proteína-total, Sódio, Triglicéridos, Ureia, Nitrogênio de Ureia e Ácido Úrico.

#### SUMÁRIO E PRINCÍPIO

A utilização de materiais de controle de qualidade é indicada como uma avaliação objetiva da precisão dos métodos e técnicas aplicadas e constitui uma parte integrante das boas práticas laboratoriais. Encontram-se disponíveis dois níveis de controle para permitir aferir o desempenho dentro dos limites clínicos.

#### REAGENTE

Este produto é preparado a partir de soro humano acrescido de constituintes de bioquímicos purificados (extractos de tecidos de origem humana e animal), químicos, fármacos terapêuticos, conservantes e estabilizadores. O controle é fornecido sob forma liofilizada para maior estabilidade.

#### ARMAZENAMENTO E ESTABILIDADE

Este produto permanecerá estável até ao fim do prazo de validade desde que seja armazenado por abrir a uma temperatura de 2 a 8 °C. Depois de o controlo ter sido reconstituído, todas as substâncias a analisar permanecerão estáveis durante 7 dias desde que o produto seja armazenado com a tampa firmemente apertada a uma temperatura de 2 a 8 °C, com as seguintes excepções: A fosfatase ácida e fosfatase ácida próstática permanecerão estáveis durante um período de 3 dias quando armazenados com a tampa firmemente apertada a uma temperatura de 2 a 8 °C.

Depois de reconstituído e congelado o controlo, todas as substâncias a analisar permanecerão estáveis durante 20 dias desde que sejam armazenadas com a tampa firmemente apertada a uma temperatura de -10 a -20 °C com as seguintes excepções: A tobramicina permanecerá estável durante um período de 20 dias quando o controlo é armazenado com a tampa firmemente apertada a uma temperatura de -10 a -20 °C. Depois de o controlo ter sido descongelado, não deve voltar a ser congelado; elimine qualquer material restante.

#### RECONSTITUIÇÃO

Utilizando uma pipeta volumétrica, reconstitua cada frasco com 5,0 ml de água destilada ou desionizada. Reponha a tampa e deixe o controlo à temperatura ambiente durante 20 minutos, agitando o frasco de vez em quando. Antes de efectuar a recolha da amostra, agite suavemente o frasco várias vezes para assegurar a homogeneidade. Caso esteja a efectuar uma análise aos vestígios de substâncias metálicas, não deve homogeneizar por meio de inversão.

#### PROCEDIMENTO

Este produto será estável até a data de validade quando armazenado fechado a 2 °C a 8 °C. Uma vez que o controlo é reconstituído, todos os análises será estável durante 7 dias quando armazenado com tampa bem fechada a 2 °C a 8 °C, com a seguinte excepção: fosfatase ácida será estável durante 3 dias, quando armazenado com tampa bem fechada a 2 °C a 8 °C.

Após reconstituição e congelamento do controlo todos os análises será estável por 20 dias, quando armazenados com tampa bem fechada a -10 °C a 20 °C. Uma vez descongelado, não congelar o controlo; descartar material restante.

#### LIMITAÇÕES

- Este produto não deve ser utilizado após o fim do prazo de validade.
- Se existir evidência de contaminação microbiana ou se se observar um aspecto turvo excessivo no controlo reconstituído, elimine o frasco.
- Este produto não deve ser utilizado como um calibrador.

#### VALORIZAÇÕES

Os valores médios impressos neste folheto derivam de análises repetidas e são específicos deste lote do produto. As análises enunciadas foram efectuadas pelo fabricante do reagente e/ou laboratórios independentes utilizando reagentes aprovados pelo fabricante e uma amostra representativa deste lote do controlo. As médias laboratoriais individuais devem estar dentro dos limites correspondentes aceitáveis; no entanto, as médias laboratoriais podem variar dos valores enunciados durante o tempo de duração deste controlo. As variações ao longo do tempo e entre laboratórios podem ser provocadas por diferenças nas técnicas laboratoriais, instrumentação e reagentes ou por modificações no método de análise do fabricante. Recomendamos que cada laboratório estabeleça as suas próprias médias e limites aceitáveis e utilize as que são fornecidas apenas como guias.

Consulte o site [www.diamonddiagnostics.com](http://www.diamonddiagnostics.com) para obter informações sobre actualizações de folhetos informativos

#### CARACTERÍSTICAS ESPECÍFICAS DE FUNCIONAMENTO

Este produto é um produto liofilizado, fabricado de acordo com padrões rígidos de controlo da qualidade. Para obter valores de análise consistentes de frasco para frasco, o controlo deve ser manuseado e armazenado de acordo com o descrito.

### CHINESE

#### 用途

Mission CliniCheck 定值化学控制品是一种定值质量控制血清，它适用于监测多种分析物在实验测试中的精确度，这些分析物包括：总胆红素测定、白蛋白、碱性磷酸酶(ALP)、淀粉酶、天冬氨酸转氨酶(AST/GOT)、碳酸氢盐(CO2)、直接胆红素、总胆红素、钙、氯、总胆固醇、高密度脂蛋白胆固醇(HDL)、低密度脂蛋白胆固醇(LDL)、胆碱酯酶、腺苷酸(CK)、肌酸酐、肌酐-谷氨酰转氨酶(GGT)、葡萄糖、血尿素氮和铁结合力、血尿素氮和铁结合力(UIBC)、乳酸乳酸盐、乳酸脱氢酶(LDH)、脂肪酶、糖、蛋白质和尿酸

质量控制品的使用旨在临床检测方法和技术准确性针对性的评价，它是确保实验室管理必需的一部分，2个水平的质量控制应用可以保证测试结果在临床许可的范围之内

#### 试剂

本产品是用血清加以提纯的生物化学成分(人或动物组织提取物)、化学成分、治疗性药物、保护剂和稳定剂配制而成，为了增加稳定性，质量控制是以冻干状态供应。

#### 储存和稳定性

本产品未开封保存可在2-8摄氏度可以稳定至末期。一旦复溶后，除以下列物质外，盖紧后可在2-8摄氏度稳定7天，碱性磷酸酶和前列腺体磷酸酯酶盖紧后可在2-8摄氏度稳定3天。

复溶后，密封在零下10-20度冷冻保存，可稳定20天，一旦再融化后，不要再冷冻物质，丢弃剩下的质控物。

#### 复溶

用准确的移液管，用5毫升去离子水或蒸馏水复溶，盖盖后放置20分钟，偶尔均匀，在当样本应用前，为了确保均匀，轻轻摇晃质控品几次，如果用于金属元素分析，不要摇晃金属元素。

#### 应用程序

产品在未打开情况下于2-8摄氏度保存可以稳定至末期，产品一旦复溶后，在密封状况下2-8摄氏度保存磷酸酯酶项目可稳定7天，碱性磷酸酶可稳定3天。

复溶后，密封在零下10-20度冷冻保存，可稳定20天，一旦再融化后，不要再冷冻物质，丢弃剩下的质控物。

#### 局限性

- 本产品过期后不应当使用。
- 如果有证据显示受到微生物的污染或复溶后格外的混浊，应当丢弃。
- 本产品不可以当作校准品使用。

#### 定值

本产品说明书打印的平均值质量测试的结果仅对本批号的定值，列出的测试试剂制造商和独立实验室用制造商支持的试剂代表性的本批号测试过的结果，单个实验室平均应在质控品的范围内，但是实验室的平均值也可能在质控范围内质量保证的范围，持续的和非同实验室之间误差可能由于实验室之间不同的技术，仪器试剂或试剂生产厂家测试方法的变化而造成，建议每个实验室建立自己的平均值和可接受范围，此值仅供参考。

参见 [www.diamonddiagnostics.com](http://www.diamonddiagnostics.com) 查看产品更新信息

#### 特殊的性能特征

本产品是冻干产品，在严格质量控制下生产，为了保持不同批次之间的稳定性，质量控制按照上述的方法正确的贮藏和处理。

### Русский

#### ПРЕДНАЗНАЧЕНИЕ

предназначен для пользования в качестве испытанной сыворотки для контроля качества с целью мониторинга точности лабораторных исследований следующих анализов: кислоты фосфатазы (Acid Phosphatase) (полный), альбумина, алкального фосфатаза (ALP), амилазы, аспартата аминотрансферазы (AST/GOT), бикарбоната (CO2), билирубина (полного), билирубина (полюного), кальция, хлорида, холестерина (полного), холестерина (HDL), холестерина (LDL), коллинстераза, креатинина (CK), креатинина, гамма глутамилтрансфераза (GGT), глюкозы, железа, железа (UIBC), лактата (лактатической кислоты), лактата дегидрогеназа (LDH), липаза, литиума, магния, фосфора калия, мочевины (полного), натрия, триглицеридов, карбамида, карбамид азота и протейна-липола.

#### ВЫВОДЫ И ПРИНЦИПЫ

Использование контроля качества материалов применяется как объективная оценка методики и технологий, являющихся неотъемлемой частью лабораторной практики. Два уровня контроля могут быть доведены для характеристик в клиническом интервале.

#### РЕАГЕНТ

Данный продукт изготовлен из человеческой сыворотки с добавлением компонентов очищенных биохимикалиев (экстракты тканей человеческого и животного происхождения), химикалий, терапевтических деаэракт, консервантов и стабилизаторов. Анализ проводится в лиофилизированной форме для повышения стабильности.

#### ХРАНЕНИЕ И СТАБИЛЬНОСТЬ

Продукт сохранит свою стабильность до конца срока действия, если он будет храниться в стабильном состоянии при 2-8 °C. Анализ будет повторенные величины будут выполняться в течение 7 дней при хранении плотно закрытыми при 2-8 °C, за исключением следующих: фосфатазы калия и фосфатазы протестической кислоты стабильны в течение 3 дней при хранении плотно закрытыми при 2-8 °C.

После вскрытия упаковки вымораживания все контрольные анализы были стабильны в течение 20 дней при хранении плотно закрытыми от -10 до -20 °C за следующим исключением: тобрамицин был стабильн в течение 20 дней при хранении образцов плотно закрытыми от -10 до -20 °C. После оттаивания образцы нельзя замораживать вновь, они выбрасываются

#### ВОСПРОИЗВЕДЕНИЕ

Используя объемную пипетку каждый пузырек воспроизводился (разбавлялся) 5 мл дистиллированной или безионной воды. После закрытия пробки он оставался на 20 минут при перемешивании время от времени. Перед взятием образца делается несколько круговых движений пузырьком для гомогенизации. При анализе следов металла нижнего не перерывайте пузырек.

#### МЕТОДИКА

Этот продукт будет стабильным в течение срока, если он хранится при температуре с 2 до 8 градусов Цельсия. Когда контрольный материал уже в оригинальном состоянии, все анализы будут стабильными в течение 7 дней, если они хранятся в герметичном состоянии при температуре с 2 до 8 После восстановления состояния и заморозки контрольного материала; все анализы будут стабильными в течение 20 дней, если они крепко закрыты при температуре с -10 до -20 градусов Цельсия. После размораживания нельзя снова замораживать контрольный материал; неиспользованный материал надо ОТГРНИЧИВАТЬ

- Этот продукт не должен быть использован после истечения срока его действия
- Если наблюдается его бактериальная загрязненность или чрезвычайная мутность при контроле воспроизводимости, выбросите пузырек
- Этот продукт не предназначен для использования в качестве стандарта.

#### ЗАДАНИЕ ЗНАЧЕНИЙ

Основные параметры, указанные в данной распечатке, были получены при анализе, проведенном специально для данной серии. Указанные тесты были проведены производителем и/или независимой лабораторией, использующей реагенты и репрезентативные образцы производимой по данной серии. Лабораторные данные должны попадать в предумотренный интервал, однако они могут отличаться в определенных пределах в процессе проведения анализа. Отличия могут объясняться различными лабораторного оборудования, технологии и реагентов или же изменением метода анализа производителем. Рекомендуется определение предумотренного интервала для каждой лаборатории и принятие их при проведении тестов.

Смотрите [www.diamonddiagnostics.com](http://www.diamonddiagnostics.com) для получения актуальной информации.

#### СПЕЦИФИЧЕСКИЕ ПАКАЗЫВАЕМЫЕ ХАРАКТЕРИСТИКИ

Данный продукт - продукт высушенный вымораживанием при строгом контроле стандартов. Для получения постоянной величины консистенции каждого пузырька необходимо контролировать хранение и использование согласно предписаниям.

	<b>Precaución</b>		<b>Aviso</b>		<b>警告</b>		<b>ВНИМАНИЕ</b>
Material de origen biológico. Manipular como potencialmente infeccioso. Todas las unidades de donantes humanos utilizadas en la fabricación de este control se han analizado según métodos de análisis aceptados por la FDA (agencia estadounidense para alimentos y fármacos) y se ha determinado que no reaccionan contra el antígeno superficial de la hepatitis B (HBsAg), el anticuerpo de la hepatitis C (VHC) y el anticuerpo del VIH-1/VIH-2. Este producto puede contener asimismo material de origen humano para el que no existen análisis homologados. De acuerdo con las prácticas de laboratorio correctas, todo material de origen humano se debe considerar potencialmente infeccioso y manipular con las mismas precauciones que las muestras de pacientes. La ficha de datos de seguridad (MSDS) está disponible para los usuarios profesionales en <a href="http://www.diamonddiagnostics.com">www.diamonddiagnostics.com</a> .	Material de origem biológica. Manusear como sendo potencialmente infeccioso. Cada unidade do dado humano utilizada no fabrico deste controlo foi testada pelos métodos aprovados pela FDA (Administração dos Alimentos e Fármacos dos Estados Unidos da América), tendo sido considerada não reactiva em antígenos de superfície da Hepatite B (HBsAg), ao anticorpo da Hepatite C (HCV) e ao anticorpo do VIH-1/VIH-2. Este produto também poderá conter outros materiais de origem humana para os quais não existem testes aprovados. De acordo com as boas práticas laboratoriais, todo o material de origem humana deve ser considerado potencialmente infeccioso pelo que deverá ser manuseado com as mesmas precauções utilizadas com as amostras dos pacientes. Existem fichas de dados de segurança (MSDS) disponíveis para os utilizadores profissionais em <a href="http://www.diamonddiagnostics.com">www.diamonddiagnostics.com</a> .	生物源性原料，按照潜在的感染性物质处理，用于制造质量控制每位人血清捐赠者用FDA接受的方法检测未发现HBsAg、HCV抗体和HIV-1/HIV-2抗体。本产品可能含有没有批准检测的真体人血清物质，根据临床实验室操作规范，所有人血清原料应当被认为具有潜在的感染性，应当按照病人样本一样小心处理，对于专业的用户原料安全性能（MSDS）参见 <a href="http://www.diamonddiagnostics.com">www.diamonddiagnostics.com</a> 。	Биологический источник материала. Обращение как с потенциальной инфекцией. Каждый отдельный использованный донор (человек) при производстве был проверен согласно методам FDA и не имел реакции на Гепатит В (HBsAg), на антитела Гепатита С (HCV) и на антитела СПИДА (HIV). Этот продукт может содержать другие материалы донора, для которых не санкционированы тестирования. В соответствии с лабораторной практикой все материалы донора обозначены как потенциальные источники инфекции и рассматриваются с предосторожностью при использовании для планшетов. Доступна информация для профессиональных пользователей на <a href="http://www.diamonddiagnostics.com">www.diamonddiagnostics.com</a> .				











# Mission CliniCheck Assayed Chemistry Control

## Level 1 and Level 2

### ABBOTT CHEMISTRY ANALYZERS

ANALYTE	METHOD	Units	Level 1 - R0F113-EU				Level 2 - R0G111-EU				SI	Level 1 - R0F113-EU				Level 2 - R0G111-EU			
			Mean	Range	Mean	Range	Mean	Range	Mean	Range		Mean	Range	Mean	Range				
Acid Phosphatase	Alpha-naphthylIPO4, Colorimetric	U/L	35.2	28.2 - 42.3	0.000	0.000	-	0.000	μmol/L.sec	0.589	0.471 - 0.707	0.000	0.000	-	0.000				
ALT (GPT)	IFCC 2002 (UV without P5P)	U/L	39.3	34.7 - 43.8	93.4	82.7	-	104	μmol/L.sec	0.656	0.580 - 0.731	1.56	1.38	-	1.74				
Albumin	(BCG) Bromcresol Green	g/dL	3.29	2.88 - 3.70	2.50	2.19	-	2.81	g/L	32.9	28.8 - 37.0	25.0	21.9	-	28.1				
ALP	PNPP, AMP Buffer, IFCC 2002	U/L	112	97.4 - 126	461	401	-	521	μmol/L.sec	1.86	1.62 - 2.10	7.66	6.66	-	8.66				
Amylase	CNPG3	U/L	86.5	69.1 - 104	527	421	-	632	μmol/L.sec	1.45	1.16 - 1.74	8.80	7.03	-	10.6				
AST (GOT)	IFCC 2002 (UV without P5P)	U/L	17.8	15.7 - 19.8	234	207	-	260	μmol/L.sec	0.297	0.262 - 0.331	3.90	3.45	-	4.35				
Bilirubin-Direct	Diazotization, DPD	mg/dL	0.433	0.148 - 0.718	1.08	0.921	-	1.25	μmol/L	7.41	2.53 - 12.29	18.5	15.7	-	21.3				
Bilirubin-Total	Diazotization, DPD	mg/dL	1.00	0.78 - 1.22	5.00	4.35	-	5.65	μmol/L	17.1	13.4 - 20.9	85.7	74.6	-	97				
Calcium-Total	Arsenazo III	mg/dL	8.97	8.43 - 9.50	13.2	12.4	-	14.0	mmol/L	2.25	2.11 - 2.38	3.30	3.11	-	3.50				
Carbon Dioxide	PEP Carboxylase	mEq/L	22.4	17.9 - 26.9	14.0	11.2	-	16.8	mmol/L	22.4	17.9 - 26.9	14.0	11.2	-	16.8				
Chloride	ISE Indirect	mEq/L	95.8	91.4 - 100	82.1	78.4	-	85.8	mmol/L	95.8	91.4 - 100	82.1	78.4	-	85.8				
Cholesterol-HDL	Accelerator Selective Detergent	mg/dL	57.3	51.6 - 62.9	23.6	19.8	-	27.4	mmol/L	1.48	1.34 - 1.63	0.612	0.512	-	0.711				
Cholesterol-LDL	Colorimetric/Direct/Enzymatic	mg/dL	60.6	48.5 - 72.7	22.3	17.8	-	26.7	mmol/L	1.57	1.26 - 1.88	0.576	0.461	-	0.692				
Cholesterol-Total	Cholesterol, esterase, oxidase, peroxidase	mg/dL	220	205 - 236	102	95.1	-	109	mmol/L	5.70	5.31 - 6.10	2.65	2.46	-	2.83				
Cholinesterase	Butyrylthiocholin	U/L	4101	3281 - 4922	827	661	-	992	μmol/L.sec	68.5	54.8 - 82.2	13.8	11.0	-	16.6				
CK (ATP)	NAC activated	U/L	114	101.6 - 127	432	384	-	479	μmol/L.sec	1.91	1.70 - 2.11	7.21	6.42	-	8.00				
Creatinine	Enzymatic	mg/dL	0.983	0.870 - 1.10	4.90	4.34	-	5.46	μmol/L	86.7	76.7 - 97	432	382	-	482				
Glucose	Hexokinase	mg/dL	105	93.6 - 117	281	250	-	312	mmol/L	5.84	5.20 - 6.48	15.6	13.9	-	17.3				
GGT	P-Nitrophenol	U/L	36.8	32.5 - 41.0	161	143	-	180	μmol/L.sec	0.614	0.543 - 0.684	2.69	2.38	-	3.00				
Iron	Ferene, FerroZine	μg/dL	185	148 - 221	54.4	43.5	-	65.3	μmol/L	33.0	26.4 - 39.6	9.74	7.79	-	11.7				
Iron - UIBC	Ferene, FerroZine	μg/dL	67.5	54.0 - 81.0	194	155	-	233	μmol/L	12.1	9.7 - 14.5	34.7	27.7	-	41.6				
Lactate	Colorimetric, Enzymatic	mg/dL	39.3	35.0 - 43.6	12.7	11.3	-	14.1	mmol/L	4.37	3.89 - 4.85	1.41	1.25	-	1.56				
LDH	LDH-L (IFCC 2002)	U/L	123	111.7 - 134	328	299	-	358	mmol/L.sec	2.05	1.87 - 2.24	5.48	4.99	-	5.97				
Lipase	Colorimetric	U/L	40.5	35.6 - 45.4	101	88.9	-	113	μmol/L.sec	0.676	0.595 - 0.758	1.69	1.48	-	1.89				
Lithium	ISE Direct	mEq/L	0.460	0.432 - 0.488	1.78	1.67	-	1.89	mmol/L	0.460	0.432 - 0.488	1.78	1.67	-	1.89				
Magnesium	Xylidyl Blue	mg/dL	2.01	1.86 - 2.16	4.28	3.96	-	4.60	mmol/L	0.826	0.764 - 0.888	1.76	1.63	-	1.89				
Phosphorus	Ammonium/Phospho Molybdate	mg/dL	2.85	2.59 - 3.11	6.30	5.73	-	6.87	mmol/L	0.920	0.837 - 1.00	2.03	1.85	-	2.22				
Potassium	ISE Indirect	mEq/L	3.57	3.41 - 3.73	5.86	5.60	-	6.13	mmol/L	3.57	3.41 - 3.73	5.86	5.60	-	6.13				
Protein-Total	Biuret	g/dL	4.80	4.51 - 5.09	3.83	3.60	-	4.05	g/L	48.0	45.1 - 50.9	38.3	36.0	-	40.5				
Salicylate	Enzymatic	mg/dL	3.36	2.69 - 4.04	12.4	9.93	-	14.9	mmol/L	0.244	0.195 - 0.293	0.900	0.720	-	1.08				
Sodium	ISE indirect	mEq/L	136	132 - 140	121	118	-	125	mmol/L	136	132 - 140	121	118	-	125				
Transferrin	Immuno-turbidimetric	mg/dL	206	186 - 225	146	132	-	160	g/L	2.06	1.86 - 2.25	1.46	1.32	-	1.60				
Triglyceride	Enzymatic, GPO	mg/dL	214	195 - 233	61.0	55.5	-	66.5	mmol/L	2.42	2.20 - 2.64	0.689	0.627	-	0.751				
Urea	Urease, UV / GLDH	mg/dL	32.5	29.1 - 35.9	93.9	75.1	-	113	mmol/L	5.41	4.33 - 6.50	15.7	12.5	-	18.8				
Urea Nitrogen	Urease, UV / GLDH	mg/dL	15.2	12.1 - 18.2	43.9	35.1	-	52.7	mmol/L	5.41	4.33 - 6.50	15.7	12.5	-	18.8				
Uric Acid	Uricase, colorimetric	mg/dL	7.37	6.85 - 7.88	9.36	8.70	-	10.0	μmol/L	438	407 - 468	556	517	-	595				

\* Instruments Include: Abbott Aeroset, Abbott Architect, Abbott c8000

 <p><b>IVD</b> For In Vitro Diagnostic Use In Vitro Diagnostic Usage In Vitro Para Uso Diagnostico In Vitro Utilizar Apenas Em Diagnostico In Vitro Ti In Vitro diagnosticering 仅供体外诊断使用 Для использования в диагностике In Vitro</p>	 <p><b>CE</b> European Conformity CE-Konformitätskennzeichnung Conformité aux normes européennes Conformidade europeia Conformidade com as normas europeias Europaisk overensstemmelse 符合欧 Европейская Адекватность</p>	 <p><b>Temperature Limit</b> Temperaturlimit Limite de température Limite de temperatura Temperaturgrenze 温度范围限制 Температурные ограничения</p>	 <p><b>Consult Instructions for Use</b> Gebrauchsanweisung beachten Consulter la notice d'emploi Consulte las instrucciones de uso Consulte as instruções de utilização Benyt bruksanvisningen 参考说明书使用 Ремесциация по применению</p>	 <p><b>LOT</b> Lot Number Chargen-Nr. Número de lote Número de lote Número de lote Batchnummer 批号 Номер серии</p>	 <p><b>Use by (YY-MM-DD)</b> Verwendbar bis (JJJJ-MM-TT) Date de péremption (AAAA-MM-JJ) Usar hasta el (AAAA-MM-DD) Utilizar até (AAAA-MM-DD) Avend for (AAAA-MM-DD) 有效期至 (YYYY-MM-DD) Используется до (год-месяц-день рождения)</p>	 <p><b>Caution</b> Vorsicht Attention Precaución Cuidado Forsiglig 注意 Меры предосторожности</p>	 <p><b>Manufactured by</b> Hergestellt von Fabriqué par Fabricado por Representante autorizado Fabricado por Fremstillet af *** 制造</p>	 <p><b>EC REP</b> Authorized Representative Bevollmächtigter Représentant agréé Representante autorizado Representante autorizado Autoriseret representant 授权的代表 Санкционированный представитель</p>	<p><b>+ 5.0 mL H2O</b> Reconstitute With Rekonstituieren mit À reconstituer avec Reconstituir con Rekonstituier med 用***复溶 Воспроизводить</p>	 <p><b>REF</b> Catalog Number Katalognummer Número de catálogo Número de catálogo Número de catálogo Каталог 产品编号 Номер каталога</p>
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

# Mission CliniCheck Assayed Chemistry Control

## Level 1 and Level 2

### ROCHE HITACHI CHEMISTRY ANALYZERS

ANALYTE	METHOD	Units	Level 1 - R0F113-EU			Level 2 - R0G111-EU			SI	Level 1 - R0F113-EU			Level 2 - R0G111-EU		
			Mean	Range		Mean	Range			Mean	Range		Mean	Range	
Acid Phosphatase	Alpha-naphthylIPO4, Colorimetric	U/L	35.2	28.2 - 42.3	0.000	0.000	-	0.000	µmol/L.sec	0.589	0.471 - 0.707	0.000	0.000	-	0.000
ALT (GPT)	IFCC 2002 (UV without P5P)	U/L	26.0	23.0 - 29.0	109	96.8	-	122	µmol/L.sec	0.434	0.384 - 0.484	1.83	1.62	-	2.04
Albumin	(BCG) Bromcresol Green	g/dL	3.88	3.39 - 4.36	3.00	2.63	-	3.38	g/L	38.8	33.9 - 43.6	30.0	26.3	-	33.8
ALP	PNPP, AMP Buffer, IFCC 2002	U/L	116	100.6 - 131	496	432	-	561	µmol/L.sec	1.92	1.67 - 2.17	8.24	7.17	-	9.31
Amylase	CNPG3	U/L	86.9	69.5 - 104	428	342	-	514	µmol/L.sec	1.45	1.16 - 1.74	7.15	5.71	-	8.59
AST (GOT)	IFCC 2002 (UV without P5P)	U/L	16.1	14.3 - 18.0	229	203	-	255	µmol/L.sec	0.269	0.238 - 0.300	3.83	3.39	-	4.27
Bilirubin-Direct	Diazotization, DPD	mg/dL	0.396	0.135 - 0.656	1.32	1.12	-	1.52	µmol/L	6.77	2.32 - 11.22	22.6	19.2	-	26.0
Bilirubin-Total	Diazotization, DPD	mg/dL	1.03	0.80 - 1.26	4.39	3.82	-	4.96	µmol/L	17.6	13.8 - 21.5	75.2	65.4	-	85.0
Calcium-Total	Arsenazo III	mg/dL	8.97	8.43 - 9.50	13.2	12.4	-	14.0	mmol/L	2.25	2.11 - 2.38	3.30	3.11	-	3.50
Carbon Dioxide	PEP Carboxylase	mEq/L	22.1	17.7 - 26.6	16.6	13.3	-	19.9	mmol/L	22.1	17.7 - 26.6	16.6	13.3	-	19.9
Chloride	ISE Indirect	mEq/L	95.4	91.1 - 100	85.1	81.3	-	88.9	mmol/L	95.4	91.1 - 100	85.1	81.3	-	88.9
Cholesterol-HDL	Accelerator Selective Detergent	mg/dL	58.0	52.3 - 63.7	23.1	19.4	-	26.9	mmol/L	1.50	1.36 - 1.65	0.600	0.503	-	0.697
Cholesterol-LDL	Colorimetric/Direct/Enzymatic	mg/dL	83.9	67.1 - 101	29.8	23.9	-	35.8	mmol/L	2.17	1.74 - 2.61	0.772	0.618	-	0.927
Cholesterol-Total	Cholesterol, esterase, oxidase, peroxidase	mg/dL	250	233 - 268	119	111	-	127	mmol/L	6.48	6.02 - 6.93	3.08	2.87	-	3.30
Cholinesterase	Butyrylthiocholin	U/L	4536	3629 - 5443	973	778	-	1167	µmol/L.sec	75.8	60.6 - 90.9	16.2	13.0	-	19.5
CK (ATP)	NAC activated	U/L	110	98.0 - 122	405	360	-	449	µmol/L.sec	1.84	1.64 - 2.04	6.75	6.01	-	7.50
Creatinine	Alkaline picrate	mg/dL	1.02	0.902 - 1.14	5.49	4.86	-	6.13	µmol/L	89.8	79.5 - 100	484	429	-	540
Glucose	Hexokinase	mg/dL	111	98.7 - 123	295	263	-	328	mmol/L	6.16	5.48 - 6.84	16.4	14.6	-	18.2
GGT	P-Nitrophenol	U/L	42.4	37.6 - 47.3	164	145	-	183	µmol/L.sec	0.709	0.627 - 0.790	2.74	2.42	-	3.05
Iron	Ferene, FerroZine	µg/dL	206	165 - 247	66.1	52.9	-	79.4	µmol/L	36.8	29.5 - 44.2	11.8	9.47	-	14.2
Iron - UIBC	Ferene, FerroZine	µg/dL	78.3	66.7 - 100	197	157	-	236	µmol/L	14.0	11.2 - 16.8	35.2	28.1	-	42.2
Lactate	Colorimetric, Enzymatic	mg/dL	38.9	34.6 - 43.2	11.3	10.1	-	12.5	mmol/L	4.33	3.85 - 4.80	1.26	1.12	-	1.39
LDH	LDH-L ( IFCC 2002)	U/L	137	124 - 149	355	323	-	386	µmol/L.sec	2.28	2.08 - 2.49	5.92	5.39	-	6.46
Lipase	Colorimetric	U/L	41.6	36.6 - 46.6	89.7	78.9	-	100	µmol/L.sec	0.694	0.611 - 0.778	1.50	1.32	-	1.68
Lithium	Enzymatic	mEq/L	0.763	0.717 - 0.809	1.63	1.54	-	1.73	mmol/L	0.763	0.717 - 0.809	1.63	1.54	-	1.73
Magnesium	Xylydil Blue	mg/dL	2.03	1.88 - 2.18	3.73	3.45	-	4.01	mmol/L	0.835	0.772 - 0.90	1.54	1.42	-	1.65
Phosphorus	Ammonium/Phospho Molybdate	mg/dL	3.43	3.12 - 3.73	7.87	7.16	-	8.58	mmol/L	1.11	1.01 - 1.21	2.54	2.31	-	2.77
Potassium	ISE Indirect	mEq/L	3.60	3.44 - 3.76	6.08	5.81	-	6.36	mmol/L	3.60	3.44 - 3.76	6.08	5.81	-	6.36
Protein-Total	Biuret	g/dL	5.54	5.20 - 5.87	5.18	4.87	-	5.49	g/L	55.4	52.0 - 58.7	51.8	48.7	-	54.9
Salicylate	Enzymatic	mg/dL	4.61	3.69 - 5.53	14.0	11.2	-	16.9	mmol/L	0.334	0.267 - 0.401	1.02	0.814	-	1.22
Sodium	ISE indirect	mEq/L	139	134 - 143	122	118	-	125	mmol/L	139	134 - 143	122	118	-	125
Transferrin	Immunoturbidimetric	mg/dL	226	205 - 248	159	144	-	174	g/L	2.26	2.05 - 2.48	1.59	1.44	-	1.74
Triglyceride	Enzymatic, GPO	mg/dL	215	196 - 234	71.0	64.6	-	77.4	mmol/L	2.43	2.21 - 2.65	0.801	0.729	-	0.874
Urea	Urease, UV / GLDH	mg/dL	37.6	33.8 - 41.4	107	96.3	-	118	mmol/L	6.27	5.02 - 7.52	17.8	14.3	-	21.4
Urea Nitrogen	Urease, UV / GLDH	mg/dL	17.6	14.1 - 21.1	49.9	40.0	-	59.9	mmol/L	6.27	5.02 - 7.52	17.8	14.3	-	21.4
Uric Acid	Uricase, colorimetric	mg/dL	7.59	7.06 - 8.12	11.3	10.5	-	12.1	µmol/L	451	419 - 483	670	623	-	717

\* Instruments Include: Roche Hitachi 704, 717, 902, 904, 911, 912, 917, Modular

 <p>For In Vitro Diagnostic Use In Vitro Diagnostikum Usage In Vitro Para Use Diagnostico In Vitro Utilizar Aparato En Diagnostico In Vitro Ti In Vitro diagnosticering 体外诊断前使用 Для использования в диагностике In Vitro</p>	 <p>European Conformity CE-Konformitätskennzeichnung Conformité aux normes européennes Conformidad europea Conformidade com as normas europeias Europeisk overensstemmelse 符合性 Европейская Адекватность</p>	 <p>Temperature Limit Temperaturlimit Limite de température Limite de temperatura Temperaturgrenze 温度限度限制 Температурные ограничения</p>	 <p>Consult Instructions for Use Gebrauchsanweisung beachten Consulter la notice d'emploi Consulte las instrucciones de uso Consulte as instruções de utilização Benyt brugsanvisningen 参考说明书使用 Рекомендации по применению</p>	 <p>Lot Number Chargen-Nr. Número de lote Número de lote Número de lote Batchnummer 批号 Номер серии</p>	 <p>Use by (YY-MM-DD) Verwendbar bis (JJJJ-MM-TT) Date de péremption (AAAA-MM-JJ) User hasta el (AAAA-MM-DD) Utilize até (AAAA-MM-DD) Avanced for (YYYY-MM-DD) 有效期至 (YYYY-MM-DD) Используется для (год-месяц-день рождения)</p>	 <p>Caution Vorsicht Attention Precaución Cuidado Forsigtig 注意 Меры предосторожности</p>	 <p>Manufactured by Hergestellt von Fabricado por Fabricado por Fabricado por Fremstillet af 製造 изготовитель</p>	 <p>Authorized Representative Bevollmächtigter Représentant agréé Representante autorizado Representante autorizado Autoriseret repræsentant 授权的代表 Санкционированный представитель</p>	 <p>+ 5.0 mL H2O Reconstitute With Rekonstituieren mit À reconstituer avec Reconstituir con Rekonstruieren mit Rekonstruieren med 用***复溶 Воспроизводитель</p>	 <p>Catalog Number Katalognummer Número de catálogo Número de catálogo Número de catálogo Katalognr. 产品编号 Номер каталога</p>
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







# Mission CliniCheck Assayed Chemistry Control

## Level 1 and Level 2

### BECKMAN CHEMISTRY ANALYZERS

ANALYTE	METHOD	Units	Level 1 - R0F113-EU			Level 2 - R0G111-EU			SI	Level 1 - R0F113-EU			Level 2 - R0G111-EU						
			Mean	Range		Mean	Range			Mean	Range		Mean	Range					
ALT (GPT)	IFCC 2002 (UV without P5P)	U/L	11.2	9.90	-	12.5	88.9	78.7	-	99.1	µmol/L.sec	0.187	0.165	-	0.208	1.48	1.31	-	1.66
Albumin	(BCG) Bromcresol Green	g/dL	3.39	2.96	-	3.81	2.74	2.40	-	3.08	g/L	33.9	29.6	-	38.1	27.4	24.0	-	30.8
ALP	PNPP, AMP Buffer, IFCC 2002	U/L	109	95.0	-	123	463	403	-	523	µmol/L.sec	1.81	1.58	-	2.05	7.68	6.68	-	8.68
Amylase	CNPG3	U/L	108	86.0	-	129	703	560	-	846	µmol/L.sec	1.80	1.44	-	2.16	11.9	9.52	-	14.3
AST (GOT)	Henry	U/L	9.83	8.70	-	11.0	209	185	-	233	µmol/L.sec	0.164	0.145	-	0.183	3.49	3.09	-	3.89
Bilirubin-Direct	Diazotization, DPD	mg/dL	0.200	0.068	-	0.332	0.713	0.606	-	0.819	µmol/L	3.42	1.17	-	5.67	12.2	10.36	-	14.0
Bilirubin-Total	Diazotization, DPD	mg/dL	1.14	0.889	-	1.39	4.69	4.08	-	5.30	µmol/L	19.5	15.2	-	23.8	80.5	70.0	-	90.9
Calcium-Total	Arsenazo III	mg/dL	9.08	8.53	-	9.62	12.0	11.3	-	12.7	mmol/L	2.27	2.14	-	2.41	3.01	2.83	-	3.19
Carbon Dioxide	PEP Carboxylase	mEq/L	24.9	19.9	-	29.9	19.7	15.8	-	23.6	mmol/L	2.29	19.9	-	29.9	19.7	15.8	-	23.6
Chloride	ISE Indirect	mEq/L	101	96.8	-	106	89.4	85.4	-	93.4	mmol/L	101	96.8	-	106	89.4	85.4	-	93.4
Cholesterol	HDL - ISE Direct	mg/dL	86.5	78.0	-	95	37.3	31.3	-	43.4	mmol/L	2.24	2.02	-	2.46	0.968	0.811	-	1.12
Cholesterol-LDL	Colorimetric/Direct/Enzymatic	mg/dL	93.2	74.6	-	112	49.8	39.8	-	59.8	mmol/L	2.41	1.93	-	2.90	1.29	1.03	-	1.55
Cholesterol-Total	Cholesterol, esterase, oxidase, peroxidase	mg/dL	267	248	-	285	124	115.2	-	133	mmol/L	6.91	6.42	-	7.39	3.21	2.98	-	3.43
Cholinesterase	Butyrylthiocholin	U/L	4125	3300	-	4950	901	721	-	1081	µmol/L.sec	68.9	55.1	-	82.7	15.0	12.0	-	18.1
CK (ATP)	NAC activated	U/L	93.5	83.2	-	104	334	297	-	370	µmol/L.sec	1.56	1.39	-	1.73	5.57	4.96	-	6.18
Creatinine	Enzymatic	mg/dL	0.944	0.835	-	1.05	5.43	4.80	-	6.05	µmol/L	83.2	73.6	-	92.7	478	423	-	533
Glucose	Hexokinase	mg/dL	104	92.7	-	116	319	284	-	354	mmol/L	5.78	5.14	-	6.42	17.7	15.8	-	19.7
GGT	P-Nitrophenol	U/L	36.2	32.0	-	40.3	119	105.0	-	132	µmol/L.sec	0.604	0.535	-	0.673	1.98	1.75	-	2.21
Iron	Ferene, FerroZine	µg/dL	273	218	-	328	54.0	43.2	-	64.8	µmol/L	48.9	39.1	-	58.6	9.66	7.73	-	11.6
Iron - UIBC	Ferene, FerroZine	µg/dL	96.7	77.4	-	116	254	203	-	305	µmol/L	17.3	13.8	-	20.8	45.4	36.3	-	54.5
Lactate	Colorimetric, Enzymatic	mg/dL	36.4	32.4	-	40.5	9.90	8.81	-	11.0	mmol/L	4.05	3.60	-	4.50	1.10	0.979	-	1.22
LDH	LDH-L (IFCC 2002)	U/L	131	119	-	143	258	235	-	282	mmol/L.sec	2.19	1.99	-	2.38	4.32	3.93	-	4.70
Lipase	Colorimetric	U/L	29.4	25.9	-	32.9	82.2	72.3	-	92	µmol/L.sec	0.491	0.432	-	0.550	1.37	1.21	-	1.54
Lithium	Enzymatic	mEq/L	1.02	0.954	-	1.08	1.69	1.59	-	1.79	mmol/L	1.02	0.954	-	1.08	1.69	1.59	-	1.79
Magnesium	Xylidyl Blue	mg/dL	2.33	2.15	-	2.50	3.63	3.36	-	3.90	mmol/L	0.957	0.885	-	1.03	1.49	1.38	-	1.61
Phosphorus	Ammonium/Phospho Molybdate	mg/dL	3.64	3.32	-	3.97	7.29	6.63	-	7.94	mmol/L	1.18	1.07	-	1.28	2.35	2.14	-	2.56
Potassium	ISE Indirect	mEq/L	3.83	3.66	-	4.00	6.18	5.90	-	6.46	mmol/L	3.83	3.66	-	4.00	6.18	5.90	-	6.46
Protein-Total	Biuret	g/dL	5.42	5.09	-	5.74	4.36	4.10	-	4.62	g/L	54.2	50.9	-	57.4	43.6	41.0	-	46.2
Salicylate	Enzymatic, Enzymatic	mg/dL	7.43	5.94	-	8.91	18.2	14.6	-	21.8	mmol/L	0.538	0.431	-	0.646	1.32	1.06	-	1.58
Sodium	ISE indirect	mEq/L	139	135	-	143	128	124	-	132	mmol/L	139	135	-	143	128	124	-	132
Transferrin	Immunoturbidimetric	mg/dL	231	209	-	252	196	177	-	215	g/L	2.31	2.09	-	2.52	1.96	1.77	-	2.15
Triglyceride	Enzymatic, GPO	mg/dL	234	213	-	255	80.4	73.2	-	87.7	mmol/L	2.64	2.41	-	2.88	0.908	0.826	-	0.99
Urea	Urease, UV / GLDH	mg/dL	33.4	30.1	-	36.7	107	95.4	-	118	mmol/L	5.58	4.46	-	6.69	17.9	14.3	-	21.4
Urea Nitrogen	Urease, UV / GLDH	mg/dL	15.6	12.5	-	18.8	50.1	40.1	-	60.1	mmol/L	5.58	4.46	-	6.69	17.9	14.3	-	21.4
Uric Acid	Uricase, colorimetric	mg/dL	7.33	6.81	-	7.84	9.98	9.28	-	10.7	µmol/L	435	405	-	466	593	552	-	635

\* Instruments Include: Beckman CX3, CX4, CX5, CX7  
 Beckman CX3 Delta, CX4 Delta, CX5 Delta, CX7 Delta, CX9 ALX  
 Beckman CX3 PRO, CX4 PRO, CX5 PRO, CX7 PRO, CX9 PRO

 <p><b>IVD</b> For In Vitro Diagnostic Use In Vitro Diagnosticum Usage In Vitro Para Uso Diagnóstico In Vitro Utilizar Aparatos Em Diagnóstico In Vitro In Vitro Diagnosticum 仅供体外诊断使用 Для использования в диагностике In Vitro</p>	 <p><b>CE</b> European Conformity CE-Konformitätskennzeichnung Conformité aux normes européennes Conformidade europea Conformidade com as normas europeias Европейская Адекватность</p>	 <p><b>Temperature Limit</b> Temperaturlimit Limite de température Limite de temperatura Temperaturgrenze 温度限制 Температурные ограничения</p>	 <p><b>Consult Instructions for Use</b> Gebrauchsanweisung beachten Consulter la notice d'emploi Consulte las instrucciones de uso Consulte as instruções de utilização Benyt brugsanvisningen 參考說明書使用 Рекомендации по применению</p>	 <p><b>LOT</b> Lot Number Chargen-Nr. Número de lote Número de lote Batchnummer 批号 Новый серий</p>	 <p><b>Use by (YYYY-MM-DD)</b> Verwendbar bis (JJJJ-MM-TT) Date de péremption (AAAA-MM-JJ) Usar hasta el (AAAA-MM-DD) Utilizar até (AAAA-MM-DD) Amend (or (AAAA-MM-DD)) 有效期至(YYYY-MM-DD)</p>	 <p><b>Caution</b> Vorsicht Attention Precaución Cuidado Forislag 注意 Меры предосторожности</p>	 <p><b>Manufactured by</b> Hergestellt von Fabriqué par Fabricado por Fabricado por Fremstillet af 製造 оказатель</p>	 <p><b>EC REP</b> Authorized Representative Bevollmächtigter Représentant agréé Representante autorizado Representante autorizado Autoriseret repræsentant 授权的代表 Санкционированный представитель</p>	<p><b>+ 5.0 mL H2O</b> Reconstitute With Rekonstituieren mit À reconstituer avec Reconstituieren con Rekonstituieren med 用 ** 毫升 Воспроизводить</p>	 <p><b>REF</b> Catalog Number Katalognummer Número de catalogue Número de catálogo Каталог 产品编号 Новый каталог</p>
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







# Mission CliniCheck Assayed Chemistry Control

## Level 1 and Level 2

### OLYMPUS CHEMISTRY ANALYZERS

ANALYTE	METHOD	Units	Level 1 - R0F113-EU				Level 2 - R0G111-EU				SI	Level 1 - R0F113-EU				Level 2 - R0G111-EU			
			Mean	Range			Mean	Range				Mean	Range			Mean	Range		
ALT (GPT)	IFCC 2002 (UV without P5P)	U/L	30.5	27.0	-	34.0	84.2	74.5	-	93.8	µmol/L.sec	0.510	0.451	-	0.569	1.41	1.24	-	1.57
Albumin	(BCG) Bromcresol Green	g/dL	3.20	2.80	-	3.60	2.49	2.18	-	2.80	g/L	32.0	28.0	-	36.0	24.9	21.8	-	28.0
ALP	PNPP, AMP Buffer, IFCC 2002	U/L	111	96.6	-	125	469	408	-	530	µmol/L.sec	1.75	1.52	-	1.97	7.80	6.78	-	8.81
Amylase	CNPG3	U/L	69.7	55.7	-	83.7	422	337	-	507	µmol/L.sec	1.16	0.930	-	1.40	7.05	5.63	-	8.47
AST (GOT)	IFCC 2002 (UV without P5P)	U/L	14.2	12.6	-	15.8	187	165	-	208	µmol/L.sec	0.237	0.210	-	0.265	3.12	2.76	-	3.48
Bilirubin-Direct	Diazotization, DPD	mg/dL	0.384	0.131	-	0.636	1.00	0.851	-	1.15	µmol/L	6.56	2.24	-	10.9	17.1	14.6	-	19.7
Bilirubin-Total	Diazotization, DPD	mg/dL	1.05	0.816	-	1.28	4.51	3.92	-	5.10	µmol/L	17.9	14.0	-	21.9	77.3	67.3	-	87.4
Calcium-Total	Arsenazo III	mg/dL	8.19	7.70	-	8.68	12.5	11.7	-	13.2	mmol/L	2.05	1.93	-	2.18	3.13	2.94	-	3.32
Carbon Dioxide	PEP Carboxylase	mEq/L	21.2	16.9	-	25.4	15.8	12.7	-	19.0	mmol/L	21.2	16.9	-	25.4	15.8	12.7	-	19.0
Chloride	ISE Indirect	mEq/L	99.0	94.5	-	103	85.3	81.5	-	89.1	mmol/L	99.0	94.5	-	103	85.3	81.5	-	89.1
Cholesterol-HDL	Accelerator Selective Detergent	mg/dL	50.6	45.6	-	55.5	17.2	14.5	-	20.0	mmol/L	1.31	1.18	-	1.44	0.447	0.375	-	0.520
Cholesterol-LDL	Colorimetric/Direct/Enzymatic	mg/dL	116.8	93.4	-	140.1	54.1	43.3	-	64.9	mmol/L	3.02	2.42	-	3.63	1.40	1.12	-	1.68
Cholesterol-Total	Cholesterol, esterase, oxidase, peroxidase	mg/dL	245	228	-	262	121	112.6	-	130	mmol/L	6.33	5.89	-	6.78	3.13	2.92	-	3.35
Cholinesterase	DGKC '72	U/L	3897	3117	-	4676	857	685	-	1028	µmol/L.sec	65.1	52.1	-	78.1	14.3	11.4	-	17.2
CK (ATP)	NAC activated	U/L	97.2	86.5	-	108	394	350	-	437	µmol/L.sec	1.62	1.44	-	1.80	6.57	5.85	-	7.29
Creatinine	Enzymatic	mg/dL	0.959	0.849	-	1.07	5.36	4.74	-	5.97	µmol/L	84.6	74.8	-	94	472	418	-	526
Glucose	Hexokinase	mg/dL	103	91.9	-	115	281	250	-	312	mmol/L	5.73	5.10	-	6.36	15.6	13.9	-	17.3
GGT	P-Nitrophenol	U/L	29.9	26.4	-	33.3	136	120	-	152	µmol/L.sec	0.498	0.441	-	0.556	2.27	2.01	-	2.53
Iron	TPTZ, Ferene	µg/dL	225	180	-	271	56.2	45.0	-	67.4	µmol/L	40.4	32.3	-	48.4	10.1	8.05	-	12.1
Iron - UIBC	Ferene, FerroZine	µg/dL	83.4	66.7	-	100	188	151	-	226	µmol/L	14.9	11.9	-	17.9	33.7	27.0	-	40.4
Lactate	Colorimetric, Enzymatic	mg/dL	35.6	31.7	-	39.5	9.68	8.61	-	10.7	mmol/L	3.96	3.52	-	4.39	1.08	0.957	-	1.19
LDH	LDH-L ( IFCC 2002)	U/L	140	128	-	153	376	342	-	410	µmol/L.sec	2.34	2.13	-	2.55	6.28	5.72	-	6.85
Lipase	Colorimetric	U/L	32.5	28.6	-	36.4	95.8	84.3	-	107	µmol/L.sec	0.543	0.478	-	0.608	1.60	1.41	-	1.79
Lithium	Enzymatic	mEq/L	0.648	0.609	-	0.687	1.68	1.58	-	1.78	mmol/L	0.648	0.609	-	0.687	1.68	1.58	-	1.78
Magnesium	Xylidyl Blue	mg/dL	2.18	2.02	-	2.35	3.98	3.68	-	4.28	mmol/L	0.898	0.831	-	0.97	1.64	1.52	-	1.76
Phosphorus	Ammonium/Phospho Molybdate	mg/dL	3.18	2.89	-	3.46	7.82	7.12	-	8.53	mmol/L	1.03	0.933	-	1.12	2.53	2.30	-	2.75
Potassium	ISE Indirect	mEq/L	3.68	3.51	-	3.84	5.90	5.64	-	6.17	mmol/L	3.68	3.51	-	3.84	5.90	5.64	-	6.17
Protein-Total	Biuret	g/dL	4.97	4.67	-	5.27	4.03	3.79	-	4.27	g/L	49.7	46.7	-	52.7	40.3	37.9	-	42.7
Salicylate	Enzymatic	mg/dL	8.09	6.47	-	9.70	16.8	13.4	-	20.1	µmol/L	586	469	-	703	1215	972	-	1458
Sodium	ISE indirect	mEq/L	136	132	-	140	124	121	-	128	mmol/L	136	132	-	140	124	121	-	128
Transferrin	Immunoturbidimetric	mg/dL	255	231	-	279	192	174	-	210	g/L	2.55	2.31	-	2.79	1.92	1.74	-	2.10
Triglyceride	Enzymatic, GPO	mg/dL	218	198	-	237	75.9	69.1	-	82.7	mmol/L	2.46	2.24	-	2.68	0.857	0.780	-	0.934
Urea	Urease, UV / GLDH	mg/dL	29.4	26.5	-	32.3	95.2	85.7	-	105	mmol/L	4.91	3.93	-	5.89	15.9	12.7	-	19.1
Urea Nitrogen	Urease, UV / GLDH	mg/dL	13.8	11.0	-	16.5	44.5	35.6	-	53.4	mmol/L	4.91	3.93	-	5.89	15.9	12.7	-	19.1
Uric Acid	Uricase, colorimetric	mg/dL	7.16	6.66	-	7.66	11.1	10.3	-	11.9	µmol/L	426	396	-	455	660	614	-	706

\* Instruments Include: Olympus AU400, AU600, AU640, AU680, AU2700, AU5400

 <p>For In Vitro Diagnostic Use In Vitro Diagnostikum Usage In Vitro Para Uso Diagnóstico In Vitro Utilizar Apenas Em Diagnóstico In Vitro Ti In Vitro diagnosticeering 仅供体外诊断使用 Для использования в диагностике In Vitro</p>	 <p>European Conformity CE-Konformitätskennzeichnung Conformité aux normes européennes Conformidad europea Conformidade com as normas europeias Europäische Übereinstimmung 符合欧 Европейская Адекватность</p>	 <p>Temperature Limit Temperaturlimit Limite de température Limite de temperatura Limite de temperatura Temperaturgrenze 温度限制材料 Температурные ограничения</p>	 <p>Consult Instructions for Use Gebrauchsanweisung beachten Consulter la notice d'emploi Consulte las instrucciones de uso Consulte as instruções de utilização Beijf Instruktionering 参考说明书使用 Рекомендации по применению</p>	 <p>Lot Number Chargen-Nr. Número de lote Número de lote Batchnummer 批号 Номер серии</p>	 <p>Use by (YY-MM-DD) Verwendbar bis (JJJJ-MM-TT) Date de péremption (AAAA-MM-JJ) Usar hasta el (AAAA-MM-DD) Utilizar até (AAAA-MM-DD) Awend for (AAAA-MM-DD) 有效期至 (YYYY-MM-DD) Используется для (год-месяц-день рождения)</p>	 <p>Caution Vorsicht Attention Precaución Cuidado Forsig 注意 Меры предосторожности</p>	 <p>Manufactured by Hergestellt von Fabriqué par Fabricado por Fabricado por Fremstillet af *** 制造 изготовитель</p>	 <p>Authorized Representative Bevollmächtigter Représentant agréé Representante autorizado Representante autorizado Autoriseret representant 授权的代理 Санкционированный представитель</p>	<p>+ 5.0 mL H2O</p> <p>Reconstitute With Rekonstituieren mit À reconstituer avec Reconstituir con Reconstituír com Rekonstruere med 用***复溶 Воспроизводить</p>	 <p>Catalog Number Katalognummer Número de catálogo Número de catálogo Katalognr. 产品编号 Номер каталога</p>
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







# Mission CliniCheck Assayed Chemistry Control

## Level 1 and Level 2

### ROCHE DIAGNOSTICS COBAS MIRA ANALYZERS

ANALYTE	METHOD	Units	Level 1 - R0F113-EU			Level 2 - R0G111-EU			SI	Level 1 - R0F113-EU			Level 2 - R0G111-EU		
			Mean	Range		Mean	Range			Mean	Range		Mean	Range	
Acid Phosphatase	Alpha-naphthylIPO4, Colorimetric	U/L	22.4	17.9 - 26.9	0.000	0.000	- 0.000	µmol/L.sec	0.375	0.300 - 0.450	0.000	0.000	- 0.000		
ALT (GPT)	IFCC 2002 (UV without P5P)	U/L	23.1	20.5 - 25.8	82.1	72.7	- 91.6	µmol/L.sec	0.386	0.342 - 0.431	1.37	1.21	- 1.53		
Albumin	(BCG) Bromcresol Green	g/dL	3.07	2.68 - 3.45	2.46	2.15	- 2.77	g/L	30.7	26.8 - 34.5	24.6	21.5	- 27.7		
ALP	PNPP, AMP Buffer, IFCC 2002	U/L	101	88.1 - 114	430	374	- 486	µmol/L.sec	1.68	1.46 - 1.90	7.14	6.21	- 8.06		
Amylase	CNPG3	U/L	73.2	58.5 - 87.9	454	362	- 545	µmol/L.sec	1.22	0.977 - 1.47	7.58	6.06	- 9.11		
AST (GOT)	IFCC 2002 (UV without P5P)	U/L	16.1	14.0 - 18.19	191	169	- 213	µmol/L.sec	0.451	0.399 - 0.503	3.19	2.83	- 3.56		
Bilirubin-Direct	Diazotization, DPD	mg/dL	0.41	0.14 - 0.686	1.62	1.38	- 1.86	µmol/L	7.07	2.42 - 11.7	27.7	23.5	- 31.8		
Bilirubin-Total	Diazotization, DPD	mg/dL	0.95	0.74 - 1.16	4.43	3.85	- 5.00	µmol/L	16.4	12.8 - 20.0	75.9	66.1	- 85.8		
Calcium-Total	Arsenazo III	mg/dL	8.89	8.35 - 9.42	11.7	11.0	- 12.4	mmol/L	2.23	2.09 - 2.36	2.94	2.76	- 3.11		
Carbon Dioxide	PEP Carboxylase	mEq/L	22.2	17.8 - 26.6	15.8	12.6	- 18.9	mmol/L	22.2	17.8 - 26.6	15.8	12.6	- 18.9		
Chloride	ISE Direct	mEq/L	105	100 - 109	95.0	90.7	- 99	mmol/L	105	100.0 - 109	95.0	90.7	- 99.3		
Cholesterol-HDL	Accelerator Selective Detergent	mg/dL	59.2	53.4 - 65.0	20.1	16.8	- 23.4	mmol/L	1.53	1.38 - 1.68	0.521	0.437	- 0.606		
Cholesterol-LDL	Colorimetric/Direct/Enzymatic	mg/dL	91.9	73.5 - 110	34.4	27.5	- 41.3	mmol/L	2.38	1.90 - 2.86	0.891	0.713	- 1.069		
Cholesterol-Total	Cholesterol, esterase, oxidase, peroxidase	mg/dL	254	236 - 271	130	121	- 139	mmol/L	6.57	6.11 - 7.03	3.36	3.13	- 3.60		
Cholinesterase	Butyrylthiocholin	U/L	6113	4890 - 7335	827	661	- 992	µmol/L.sec	102	81.7 - 123	13.8	11.0	- 16.6		
CK (ATP)	NAC activated	U/L	97.3	86.6 - 108	348	310	- 387	µmol/L.sec	1.62	1.44 - 1.80	5.81	5.18	- 6.45		
Creatinine	Enzymatic	mg/dL	1.06	0.936 - 1.18	5.82	5.15	- 6.48	µmol/L	93.2	82.5 - 104	513	454	- 571		
Glucose	Hexokinase	mg/dL	119	105 - 132	302	269	- 336	mmol/L	6.58	5.85 - 7.30	16.8	14.9	- 18.6		
GGT	P-Nitrophenol	U/L	45.5	40.2 - 50.7	164	145	- 183	µmol/L.sec	0.759	0.672 - 0.846	2.74	2.43	- 3.06		
Iron	Ferene, FerroZine	µg/dL	233	187 - 280	56.2	45.0	- 67.4	µmol/L	41.7	33.4 - 50.1	10.1	8.05	- 12.1		
Iron - UIBC	Ferene, FerroZine	µg/dL	91.4	73.1 - 110	226	181	- 271	µmol/L	16.4	13.1 - 19.6	40.4	32.4	- 48.5		
Lactate	Colorimetric, Enzymatic	mg/dL	35.7	31.8 - 39.6	8.89	7.91	- 9.9	mmol/L	3.97	3.53 - 4.40	0.988	0.880	- 1.10		
LDH	LDH-L IFCC 2002	U/L	133	121 - 145	307	280	- 335	µmol/L.sec	2.22	2.02 - 2.42	5.13	4.67	- 5.60		
Lipase	Colorimetric	U/L	31.0	27.3 - 34.7	78.5	69.1	- 87.9	µmol/L.sec	0.518	0.456 - 0.580	1.31	1.15	- 1.47		
Lithium	ISE Direct	mEq/L	0.460	0.432 - 0.488	1.78	1.67	- 1.89	mmol/L	0.460	0.432 - 0.488	1.78	1.67	- 1.89		
Magnesium	Xylidyl Blue	mg/dL	2.10	1.94 - 2.25	4.22	3.90	- 4.54	mmol/L	0.863	0.798 - 0.93	1.74	1.61	- 1.87		
Phosphorus	Ammonium/Phospho Molybdate	mg/dL	3.29	2.99 - 3.58	7.52	6.84	- 8.20	mmol/L	1.06	0.965 - 1.16	2.43	2.21	- 2.65		
Potassium	ISE Direct	mEq/L	3.80	3.63 - 3.97	5.88	5.61	- 6.14	mmol/L	3.80	3.63 - 3.97	5.88	5.61	- 6.14		
Protein-Total	Biuret	g/dL	5.75	5.40 - 6.09	4.69	4.41	- 4.97	g/L	57.5	54.0 - 60.9	46.9	44.1	- 49.7		
Salicylate	Enzymatic	mg/dL	4.40	3.52 - 5.28	14.8	11.8	- 17.8	mmol/L	0.319	0.255 - 0.382	1.07	0.858	- 1.29		
Sodium	ISE Direct	mEq/L	137	133 - 141	121	117	- 124	mmol/L	137	133 - 141	121	117	- 124		
Transferrin	Immunoturbidimetric	mg/dL	222	201 - 243	159	144	- 174	g/L	2.22	2.01 - 2.43	1.59	1.44	- 1.74		
Triglyceride	Enzymatic, GPO	mg/dL	244	222 - 266	62.5	56.9	- 68.1	mmol/L	2.75	2.51 - 3.00	0.706	0.642	- 0.769		
Urea	Urease, UV / GLDH	mg/dL	29.5	26.4 - 32.6	111.1	88.9	- 133.4	mmol/L	4.91	3.93 - 5.90	18.5	14.8	- 22.2		
Urea Nitrogen	Urease, UV / GLDH	mg/dL	13.8	11.0 - 16.5	51.9	41.5	- 62.3	mmol/L	4.91	3.93 - 5.90	18.5	14.8	- 22.2		
Uric Acid	Uricase, colorimetric	mg/dL	7.81	7.26 - 8.35	9.43	8.77	- 10.1	µmol/L	464	431 - 496	561	521	- 600		

\* Instruments Include: Cobas Mira Classic, Cobas Mira L, Cobas Mira Plus, Cobas Integra 400,700,800











 <p>For In Vitro Diagnostic Use In Vitro Diagnosticum Usage In Vitro Para Use Diagnostico In Vitro Utilizar Aparato En Diagnostico In Vitro Ti In Vitro diagnosticing 仅供体外诊断使用</p>	 <p>European Conformity CE-Konformitätskennzeichnung Conformité aux normes européennes Conformidad europea Conformidade com as normas europeias Europaisk overensstemmelse 符合欧</p>	 <p>Temperature Limit Temperaturlimit Limite de température Limite de temperatura Limite de temperatura Temperaturgrænse 澳標-溫度限制 温度限制</p>	 <p>Consult Instructions for Use Gebrauchsanweisung beachten Consulter la notice d'emploi Consulte las instrucciones de uso Consulte as instruções de utilização Beviljugsveislingar 参考说明书使用</p>	 <p>Lot Number Chargen-Nr. Número de lote Número de lote Batchnummer 批号</p>	 <p>Use by (YYYY-MM-DD) Verwendbar bis (JJJJ-MM-TT) Date de péremption (AAAA-MM-JJ) User hasta el (AAAA-MM-DD) Utilize até (AAAA-MM-DD) Anvend for (AAAA-MM-DD) 有效期至 (YYYY-MM-DD)</p>	 <p>Caution Vorsicht Attention Precaución Cuidado Fornglig 注意</p>	 <p>Manufactured by Hergestellt von Fabriqué par Fabricado por Fabricado por Fabricado por Fabricado por Fabricado por</p>	 <p>Authorized Representative Bevollmächtigter Représentant agréé Representante autorizado Representante autorizado Autoriseret representant 授权机构的代表</p>	<p>+ 5.0 mL H2O</p> <p>Reconstitute With Rekonstituieren mit À reconstituer avec Reconstituir con Reconstituir com Rekonstituere med 用***复溶</p>	 <p>Catalog Number Katalognummer Número de catálogo Número de catálogo Número de catálogo Katalognr 产品编号 产品编号</p>
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# Mission CliniCheck Assayed Chemistry Control

## Level 1 and Level 2

### SIEMENS DIMENSION SERIES

ANALYTE	METHOD	Units	Level 1 - R0F113-EU			Level 2 - R0G111-EU			SI	Level 1 - R0F113-EU			Level 2 - R0G111-EU		
			Mean	Range		Mean	Range			Mean	Range		Mean	Range	
ALT (GPT)	IFCC 2002 (UV with P5P)	U/L	6.75	5.97 - 7.53		82.1	72.7 - 91.6		µmol/L.sec	0.113	0.100 - 0.126		1.37	1.21 - 1.53	
Albumin	(BCP) Bromocresol Purple	g/dL	2.88	2.52 - 3.24		2.53	2.22 - 2.85		g/L	28.8	25.2 - 32.4		25.3	22.2 - 28.5	
ALP	PNPP, AMP Buffer, IFCC 2002	U/L	106	92.5 - 120		393	342 - 444		µmol/L.sec	1.77	1.54 - 2.00		6.52	5.67 - 7.37	
Amylase	CNPG3	U/L	93.9	75.1 - 113		546	437 - 656		µmol/L.sec	1.57	1.25 - 1.89		9.13	7.30 - 11.0	
AST (GOT)	IFCC 2002 (UV with P5P)	U/L	16.9	15.0 - 18.9		247	219 - 275		µmol/L.sec	0.283	0.250 - 0.315		4.13	3.65 - 4.60	
Bilirubin-Direct	Modified Jendrassik	mg/dL	0.300	0.103 - 0.497		0.987	0.839 - 1.13		µmol/L	5.13	1.75 - 8.51		16.9	14.3 - 19.4	
Bilirubin-Total	Modified Jendrassik	mg/dL	1.09	0.853 - 1.33		4.39	3.82 - 4.96		µmol/L	18.7	14.6 - 22.9		75.3	65.5 - 85.1	
Calcium-Total	CPC/AMP	mg/dL	8.56	8.05 - 9.08		10.7	10.06 - 11.3		mmol/L	2.15	2.02 - 2.27		2.68	2.52 - 2.84	
Carbon Dioxide	PEP Carboxylase	mEq/L	22.6	18.1 - 27.2		16.5	13.2 - 19.8		mmol/L	22.6	18.1 - 27.2		16.5	13.2 - 19.8	
Chloride	ISE Indirect	mEq/L	89.3	85.2 - 93.3		79.1	75.6 - 82.7		mmol/L	89.3	85.2 - 93.3		79.1	75.6 - 82.7	
Cholesterol-HDL	Direct measure	mg/dL	59.3	53.4 - 65.1		22.7	19.0 - 26.4		mmol/L	1.54	1.39 - 1.69		0.588	0.493 - 0.684	
Cholesterol-LDL	Direct measure	mg/dL	91.4	73.1 - 110		32.2	25.8 - 38.6		mmol/L	2.37	1.89 - 2.84		0.834	0.667 - 1.001	
Cholesterol-Total	Cholesterol, esterase, oxidase, peroxidase	mg/dL	232	216 - 248		112	104.1 - 120		mmol/L	6.01	5.59 - 6.43		2.90	2.69 - 3.10	
CK (ATP)	NAC activated	U/L	86.4	76.9 - 96		347	309 - 385		µmol/L.sec	1.44	1.28 - 1.60		5.79	5.15 - 6.42	
Creatinine	Jaffee	mg/dL	0.756	0.669 - 0.843		5.30	4.69 - 5.91		µmol/L	66.7	59.0 - 74.3		467	413 - 521	
Glucose	Hexokinase	mg/dL	105	93.7 - 117		287	256 - 319		mmol/L	5.85	5.20 - 6.49		16.0	14.2 - 17.7	
GGT	P-Nitrophenol	U/L	36.5	32.3 - 40.7		153	135 - 170		µmol/L.sec	0.609	0.539 - 0.680		2.55	2.25 - 2.84	
Iron	Ferene	µg/dL	274	219 - 328		71.5	57.2 - 85.8		µmol/L	49.0	39.2 - 58.8		12.8	10.2 - 15.4	
Lactate	Colorimetric, Enzymatic	mg/dL	39.3	35.0 - 43.6		12.6	11.2 - 14.0		mmol/L	4.37	3.89 - 4.85		1.40	1.25 - 1.55	
LDH	LDH-L IFCC 2002	U/L	115	104.9 - 126		283	258 - 309		µmol/L.sec	1.93	1.75 - 2.10		4.73	4.31 - 5.16	
Lithium	Enzymatic	mEq/L	0.692	0.651 - 0.734		1.68	1.58 - 1.79		mmol/L	0.692	0.651 - 0.734		1.68	1.58 - 1.79	
Magnesium	Methylthymol Blue	mg/dL	1.68	1.55 - 1.80		4.45	4.12 - 4.78		mmol/L	0.690	0.638 - 0.741		1.83	1.69 - 1.97	
Phosphorus	Ammonium/Phospho Molybdate	mg/dL	3.45	3.14 - 3.76		7.70	7.01 - 8.39		mmol/L	1.11	1.01 - 1.21		2.49	2.26 - 2.71	
Potassium	ISE Indirect	mEq/L	3.57	3.41 - 3.73		5.70	5.44 - 5.96		mmol/L	3.57	3.41 - 3.73		5.70	5.44 - 5.96	
Protein-Total	Biuret	g/dL	5.43	5.10 - 5.75		4.33	4.07 - 4.59		g/L	54.3	51.0 - 57.5		43.3	40.7 - 45.9	
Salicylate	Enzymatic	mg/dL	10.8	8.63 - 12.9		17.0	13.6 - 20.4		mmol/L	0.782	0.625 - 0.938		1.23	0.987 - 1.48	
Sodium	ISE Indirect	mEq/L	137	132 - 141		123	119 - 127		mmol/L	137	132 - 141		123	119 - 127	
Transferrin	Immunoturbidimetric	mg/dL	206	186 - 225		146	132 - 160		g/L	2.06	1.86 - 2.25		1.46	1.32 - 1.60	
Triglyceride	Enzymatic, GPO	mg/dL	214	195 - 233		59.8	54.4 - 65.2		mmol/L	2.42	2.20 - 2.64		0.675	0.614 - 0.736	
Urea	Urease, UV / GLDH	mg/dL	31.6	28.3 - 34.9		98.6	88.2 - 108.9		mmol/L	5.26	10.08 - 12.45		16.4	13.2 - 19.7	
Urea Nitrogen	Urease, UV / GLDH	mg/dL	14.8	11.8 - 17.7		46.1	36.9 - 55.3		mmol/L	5.26	4.21 - 6.32		16.4	13.2 - 19.7	
Uric Acid	Uricase, colorimetric	mg/dL	6.86	6.38 - 7.34		10.5	9.73 - 11.2		µmol/L	407	379 - 436		622	578 - 665	

 <p>For In Vitro Diagnostic Use In Vitro Diagnostic Usage In Vitro Para Uso Diagnóstico In Vitro Utilizar Apenas Em Diagnóstico In Vitro Til In Vitro diagnostisering 仅供体外诊断使用 Для использования в диагностике In Vitro</p>	 <p>European Conformity CE-Konformitätskennzeichnung Conformité aux normes européennes Conformidade com as normas europeias Europeisk overensstemmelse 符合欧 Европейская Адекватность</p>	 <p>Temperature Limit Temperaturlimit Limite de température Limite de temperatura Limite de temperatura Temperaturgrenze 温度限制 Температурные ограничения</p>	 <p>Consult Instructions for Use Gebrauchsanweisung beachten Consulter la notice d'emploi Consulte las instrucciones de uso Consulte as instruções de utilização Benyt brugsanvisningen 请参考说明书使用 Рекомендации по применению</p>	 <p>Lot Number Chargen-Nr. Número de lote Número de lote Número de lote Batchnummer 批号 Номер серии</p>	 <p>Use by (YYMM-DD) Verwendbar bis (JJJJ-MM-TT) Date de péremption (AAAA-MM-JJ) Use hasta el (AAAA-MM-DD) Utilizar até (AAAA-MM-DD) Amvend for (YYYY-MM-DD) 有效期至 (YYYY-MM-DD)</p>	 <p>Caution Vorsicht Attention Precaución Cuidado Forsigtig 注意 Меры предосторожности</p>	 <p>Manufactured by Hergestellt von Fabriqué par Fabricado por Fabricado por Fremstillet af *** 制造</p>	 <p>Authorized Representative Bevollmächtigter Représentant agréé Representante autorizado Representante autorizado Autoriseret repræsentant 授权的代理 Санкционированный представитель</p>	<p>+ 5.0 mL H2O Reconstitute With Rekonstituieren mit À reconstituer avec Reconstituir com Rekonstituier med 用***复溶 Воспроизводитель</p>	 <p>Catalog Number Katalognummer Número de catálogo Número de catálogo Número de catálogo Katalognr. 产品编号 Номер каталога</p>
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