DIAMOND®
DIAGNOSTICS

PACK INSERT
Fluid Pack
Diamond SMARTLYTE, CARELYTE, GEMLYTE, Roche AVL 91XX Electrolyte Analyzers
AV-BP5186D

Manufacturer and Product Information

Diamond Diagnostics, 333 Fiske Street, Holliston, MA.
For Technical Assistance call:
Diamond Diagnostics Technical Services at 1-508-429-0450

Intended Use: This Fluid Pack is intended for use only on the Diamond SMARTLYTE, CARELYTE, GEMLYTE, and Roche AVL 91XX Electrolyte Analyzers.

Reagents: Each Fluid Pack contains Standard A, Standard B, Standard C and Reference Solution

Containing: Standard A –350 mL - active ingredients: Sodium 150.0 mmol/L, Potassium 5.0 mmol/L, Chloride 115.0 mmol/L, Calcium 0.9 mmol/L, Lithium 0.3 mmol/L

Standard B – 85mL - active ingredients: Sodium 100.0 mmol/L, Potassium 1.8 mmol/L, Chloride 72.0 mmol/L, Calcium 1.5 mmol/L, Lithium 0.3 mmol/L

Standard C – 85mL – active ingredients: Sodium 150.0 mmol/L, Potassium 5.0 mmol/L, Chloride 115.0 mmol/L, Calcium 0.9 mmol/L, Lithium 1.4 mmol/L

Reference Solution 100mL – active ingredients: Potassium Chloride 1.2 mol/L

Also included are other non-reactive ingredients necessary for optimal system operation.

For *in vitro* diagnostic use only

Cautions: Do not freeze. When used, the Fluid Pack contains human body fluids. Handle with appropriate care.

DO NOT turn the instrument power OFF with the Fluid Pack installed, as this can cause contamination of the unused standard solutions remaining in the pack.

Additional Instructions: Complete instructions for the use of this Fluid Pack are contained in the corresponding Operator's manual.

Storage and Stability: The contents of this package are stable when stored at 18-25° C until the expiration date printed on the label.

Installation Instructions

Procedure:

1 - Press **NO** until the prompt, **OPERATION SETTINGS?** is displayed.
Press **YES**, the prompt **VERIFY PACK?** will be displayed.
The analyzer will display the amount of fluid remaining.

2 - **Removal of Used Fluid Pack** - Grasp the pack firmly and pull outward. If removal is difficult, press on the end of the Fluid Pack guide pin (protruding through the connector located to the left of the measuring chamber inside the front door).

***NOTE**: The Fluid Pack must be treated as medical waste and disposed of in accordance with local regulations.*

3 - **Preparation of New Fluid Pack** - Before use, remove the red plastic caps from the connector nipples. Save caps to close the connector nipples of used packs.
Write the date of installation on the label side of the Fluid Pack with a permanent marker.
Press the new Fluid Pack firmly into the cavity on the left side of the instrument while holding the right side securely for stability.

4 - The prompt **PACK CHANGED?** will appear.
Press **YES** to indicate that a new Fluid Pack is installed. The analyzer will prompt **ARE YOU SURE?**
Press **YES**, and the Electrolyte Analyzer will automatically reset the Fluid Pack counter to 100% and commence system calibration.

PACK INSERT
Electrode Conditioning Solution
Diamond, AVL/pH Blood Gas Analyzers
AV-BP0380D

Manufacturer and Product Information

Diamond Diagnostics, 333 Fiske Street, Holliston, MA.
For Technical Assistance call:
Diamond Diagnostics Technical Services at 1-508-429-0450

Intended Use: To condition the electrode.

Summary And Principle: This product is intended to serve as a functional equivalent to pre-existing material distributed by the Original Equipment Manufacturer (OEM). Diamond Diagnostics calibrating standards have defined electrolyte concentrations that provide internal calibration points against which samples are measured by direct Ion Selective Electrode methods.

Contents: Ammonium hydrogen bifluoride

For *in vitro* diagnostic use only

Cautions: Exercise normal laboratory precautions. If contact occurs with skin, rinse affected area with water. If contact with eyes occurs, immediately rinse with copious amount of clean water or eye rinse. In cases of accidental ingestion, contact a physician immediately.

Stability: Package stability is listed on the product label. The product should not be used beyond this date. Store upright at room temperature, 18-25 °C.

Procedure

Procedure: The product is manufactured in a ready to use form. It is intended to serve as a direct replacement to pre-existing materials distributed by the OEM. For a detailed description of the use of this reagent, refer to the Instrument's Operator Manual.

Quality Control: Diamond Diagnostics suggests the use of commercially available control material with results assayed for the instrument used. Controls should be run at Normal and Abnormal levels. Diamond Diagnostics suggests measuring controls before patient samples are run and following instrument maintenance.

Limitations

Limitations: If the instrument fails calibration or controls do not measure within acceptable range when Diamond Diagnostics products are used, Diamond Diagnostics suggests the following:

Verify that the internal calibrators used to standardize the instrument are correct for the instrument, have adequate expiration, and do not contain visually evident contamination.

Follow the procedures delineated within the Operator's Manual listed under Troubleshooting.

Ensure that all appropriate Maintenance Procedures, as listed in the Operator's Manual, have been performed.

If problems still exist, contact Diamond Diagnostics' Technical Service Department.

CE

PACK INSERT
ISE Cleaning Solution
Diamond, AVL/pH Blood Gas Analyzers
AV-BP1025D

Manufacturer and Product Information

Diamond Diagnostics, 333 Fiske Street, Holliston, MA.
For Technical Assistance call:
Diamond Diagnostics Technical Services at 1-508-429-0450

Intended Use: To clean the sample path.

Summary And Principle: This product is intended to serve as a functional equivalent to pre-existing material distributed by the Original Equipment Manufacturer (OEM). Diamond Diagnostics calibrating standards have defined electrolyte concentrations that provide internal calibration points against which samples are measured by direct Ion Selective Electrode methods.

Contents: An aqueous solution containing Neodisher MA and NaCl.

For *in vitro* diagnostic use only

Cautions: Exercise normal laboratory precautions. If contact occurs with skin, rinse affected area with water. If contact with eyes occurs, immediately rinse with copious amount of clean water or eye rinse. In cases of accidental ingestion, contact a physician immediately.

Stability: Package stability is listed on the product label. The product should not be used beyond this date. Store upright at room temperature, 18-25 °C.

Procedure

Procedure: The product is manufactured in a ready to use form. It is intended to serve as a direct replacement to pre-existing materials distributed by the OEM. For a detailed description of the use of this reagent, refer to the Instrument's Operator Manual.

Quality Control: Diamond Diagnostics suggests the use of commercially available control material with results assayed for the instrument used. Controls should be run at Normal and Abnormal levels. Diamond Diagnostics suggests measuring controls before patient samples are run and following instrument maintenance.

Limitations

Limitations: If the instrument fails calibration or controls do not measure within acceptable range when Diamond Diagnostics products are used, Diamond Diagnostics suggests the following:

Verify that the internal calibrators used to standardize the instrument are correct for the instrument, have adequate expiration, and do not contain visually evident contamination.

Follow the procedures delineated within the Operator's Manual listed under Troubleshooting.

Ensure that all appropriate Maintenance Procedures, as listed in the Operator's Manual, have been performed.

If problems still exist, contact Diamond Diagnostics' Technical Service Department.

CE

DIAMOND®
DIAGNOSTICS

PACK INSERT
Deproteinizer Solution
Diamond AVL pH/Blood Gas Analyzers
AV-BP0521D

Manufacturer and Product Information

Diamond Diagnostics, 333 Fiske Street, Holliston, MA.
For Technical Assistance call:
Diamond Diagnostics Technical Services at 1-508-429-0450

Intended Use: To remove protein build-up from the sample flow path.

Summary And Principle: This product is intended to serve as a functional equivalent to pre-existing material distributed by the Original Equipment Manufacturer (OEM). Diamond Diagnostics calibrators have defined electrolyte concentrations that provide internal calibration points against which samples are measured by direct Ion Selective Electrode Methods.

Contents: Sodium Hypochlorite

For *in vitro* diagnostic use only

Cautions: Exercise normal laboratory precautions. If contact occurs with skin, rinse affected area with water. If contact with eyes occurs, immediately rinse with copious amount of clean water or eye rinse. In cases of accidental ingestion, contact a physician immediately.

Stability: Package stability (expiration date) is listed on the product label. Do not use open or closed reagent beyond this date. Store upright at room temperature, 18°-25 °C.

Procedure

Procedure: The product is manufactured in a ready to use form. It is intended to serve as a direct replacement to pre existing materials distributed by the OEM. For a detailed description of the use of this material, refer to the Instrument Operator's Manual.

Quality Control: Diamond Diagnostics suggests the use of commercially available control material with results assayed for the instrument used. Controls should be run at Normal and Abnormal levels. Diamond Diagnostics suggests measuring controls before patient samples are run and following instrument maintenance.

Limitations

Limitations: If the instrument fails calibration or controls do not measure within acceptable range when Diamond Diagnostics products are used, Diamond Diagnostics suggests the following:

Verify that the internal calibrators used to standardize the instrument are correct for the instrument, have adequate expiration, and do not contain visually evident contamination.

Follow the procedures delineated within the Operator's Manual listed under Troubleshooting.

Ensure that all appropriate Maintenance Procedures, as listed in the Operator's Manual, have been performed.

CE

If problems still exist, contact Diamond Diagnostics' Technical Service Department.

DIAMOND®
DIAGNOSTICS

PACK INSERT
Mission Control Level 1

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English

Intended Use:
MISSION CONTROL ™ Blood Gas and Electrolyte Control is an assayed quality control material intended for monitoring the measurements of pH pCO_2, pO_2 in blood gas analyzers and sodium, potassium, chloride, lithium, ionized calcium and total carbon dioxide in ISE electrolyte analyzers.

Product Description:
This control material is provided for monitoring analyzer performance. It is packaged in sealed glass ampules, each containing approximately 1.8 ml of solution. Ampules are packaged 10 per tray with each box containing 3 trays, for a total of 30 ampules per box.

Active Ingredients:
MISSION CONTROL ™ is a buffered solution of electrolytes (Na+, K+, Cl-, Ca++, Li+, $HCO_3/CO_{3,2}$). It has been equilibrated with specific levels of CO_2, O_2, and N_2. This control contains no human-based materials.

Directions for Use
Immediately introduce the liquid from the ampule to the analyzer, following the instrument manufacturer's instructions for sampling a control material. Use direct aspiration, syringe transfer, or capillary mode techniques.

Limitation:
1. This control is sensitive to many instrument related factors that affect analytical results. Because it is not a blood-based material, it may not detect certain malfunctions, which would affect the testing of blood.

2. This product is intended for use as a quality control material and can assist in evaluating the performance of laboratory instruments. It is not for use as a calibration standard and its use should not replace other aspects of a complete quality control program.

Storage:
Store at 18-25°C. Avoid freezing and exposure to temperatures greater than 30°C. You may also store at 4-25°C without adverse effect.

Expected Ranges:
The values for each control analyte on the enclosed Expected Ranges Chart are based on multiple determinations performed on randomly selected samples from each lot. The listing for each instrument represents the expected range for these ampules when tested at 23°C. (Note: pO_2 values will vary inversely by about one percent (1%) per degree C that the temperature of the ampules varies from 23°C).

The Expected Ranges are provided as a guide in evaluating analyzer performance. Since instrument design and operating conditions may vary, each laboratory should establish its own expected values and control limits. The mean value established should fall within the Expected Ranges shown on the chart.

DEUTSCH

Vorgesehener Gebrauch:
MISSION CONTROL ™ Blutgas-und Elektrolyt-Kontrolle ist eine Qualitätskontrollprüfung, die zur Überwachung der Messungen des pH-Wertes pCO_2, pO_2 in Blutgasanalysatoren und Natrium, Kalium, Chlorid, Lithium, ionisiertes Calcium und Total-Kohlendioxid in ISE-Elektrolyt-Analysatoren dient.

Produktbeschreibung:
Diese Kontrolle dient für die Überwachung der Analysatorleistung. Es ist in verschlossenen Glasampullen verpackt mit jeweils etwa 1.8 ml Lösung. Ein Karton beinhaltet 3 Fächer mit jeweils 10 Ampullen. Es sind insgesamt 30 Ampullen pro Karton.

Aktive Inhaltsstoffe:
MISSION CONTROL ™ ist eine gepufferte Lösung von Elektrolyten (Na+, K+, Cl-, Ca++, Li+, $HCO_3/CO_{3,2}$). Diese wurde mit bestimmten Ebenen von CO_2, O_2 und N_2 äquilibriert. Diese Kontrolle enthält keine menschlichen Grundmaterialien.

Gebrauchsanweisung:
Nach dem Öffnen, führen Sie sofort die Flüssigkeit aus der Ampulle in den Analysator ein und folgen Sie den Hersteller-Anweisungen für die Probenahme des Kontrollmaterials. Verfahren Sie mit Direkteinführung, Spritzentransfer oder Kapillar-Modus-Techniken

Begrenzung:
1. Diese Kontrolle ist auf viele instrument-bezogenen Faktoren empfindlich, die das analytische Ergebniss verfälschen kann. Da es kein echtes Blutmaterial ist, kann es daher keine Störungen, die sich in der Untersuchung von richtigem Blut zeigt, erkennen.

2. Dieses Produkt dient als Qualitätskontrolle und soll als Bewerter fuer die Leistung von Laborgeräten eingesetzt werden. Es ist kein Kalibrierstandard und dessen Verwendung sollte nicht an Stelle von anderen kompletten Qualitätskontroll-Programmen Ersatz leisten.

Lagerung:
Bei 18-25 ° C aufbewahren. Vermeiden Sie Einfrierung und Aussetzung bei Temperaturen von mehr als 30 ° C. Die Lagerung bei 4-25 ° C ist ohne negative Auswirkung.

Wertbereiche:
Die Werte für jeden Kontrollanalyt auf der beiliegenden Werbereichtabelle basieren auf mehreren Ermittlungen, die von zufällig ausgewählten Proben von jeder Partie stammen. Die Liste für jedes Instrument beschreibt das erwartete Resultat für die jeweilige Ampulle bei der Prüfung bei 23°C. (Hinweis: pO_2 Werte variieren umgekehrt um rund ein Prozent (1%) pro Grad C, die Temperatur der Ampulle variiert um 23°C).

Die erwarteten Wertbereiche sollen als Leitfaden bei der Bewertung der Leistung von Analysiergeräten dienen. Da die Instrumentausführung und Betriebsbedingungen varieren können, sollte jedes Labor seine eigenen Werterwartungen und Kontrollbeschränkungen erstellen. Der selbst-erstellte Mittlwert sollte dem auf der vorgegebenen Wertbereichtabelle entsprechen.

FRANÇAIS

Utilisation prévue :
MISSION CONTROL ™ Contrôle de gaz et d'électrolyte de sang est un matériel pour analyse de contrôle de qualité destiné à surveiller les mesures de pH pCO_2, pO_2 en analyseurs et sodium de gaz de sang, potassium, chlorure, lithium, calcium ionisé et anhydride carbonique total dans des analyseurs d'électrolyte d'ISE.

Description de produit :
Ce matériel de contrôle est donné pour surveiller l'exécution d'analyseur. Il est empaqueté dans les ampules de verre scellés, chaque contient approximativement 1.8 ml de solution. Les ampules sont empaquetés par 10 par plateau avec chaque boîte contenant 3 plates.

Substances actives :
MISSION CONTROL ™ est une solution tampon des électrolytes (Na+, K+, Cl-, Ca++, Li+, $HCO_3/CO_{3,2}$). Elle a été équilibrée avec les niveaux spécifiques du CO_2, de l'O_2, et du N_2. Ce contrôle ne contient aucun matériaux humain-basé.

Notices d'emploi
Introduire immédiatement le liquide de l'ampule à l'analyseur, suivez les instructions du fabricant d'instrument pour prélever un matériel de contrôle. Utilisez l'aspiration directe, le transfert de seringue, ou les techniques de mode capillaire.

Limitation :
1. Ce contrôle est sensible à beaucoup de facteurs reliés par instrument qui affectent des résultats analytiques. Puisque ce n'est pas un matériel sang-basé, il peut ne pas détecter certains défauts de fonctionnement, qui affecteraient l'essai du sang.

2. Ce produit est prévu pour l'usage comme matériel de contrôle de qualité et peut aider à évaluer l'exécution des instruments de laboratoire. Il ne sert pas car un calibrage standard et son utilisation ne devraient pas remplacer d'autres aspects d'un pr

Stockage :
Stock à la température 18-25°C. Évitez de geler et exposer aux temperatures plus hautes que 30°C. Vous pouvez également stocker 4-25°C sans effet adverse.

Gammes prévues :
Les valeurs pour chaque analyte de contrôle sur le diagramme de gammes inclus sont basées sur des déterminations multiples effectuées sur les échantillons aléatoirement choisis provenant de chaque sort. La liste pour chaque instrument représente la gamme prévue pour ces ampules une fois examinée à 23°C. (Note : les valeurs pO_2 changeront inversement par environ un pour cent (1%) par degré C que la température des ampules change de 23°C).

Les gammes prévues sont fournies comme guide dans l'évaluation de performance d'analyseur. Comme la conception d'instrument et les conditions de fonctionnement peut changer, chaque laboratoire devrait établir ses propres valeurs et limites de commande. La valeur moyenne établie devrait faire partie des marges prévues montrées sur le diagramme.

ESPAÑOL

Uso:
MISSION CONTROL ™ para Gases Arteriales y Electrólitos es un material aprobado para el control de calidad en el monitoreo de mediciones de pH, pCO2, PO2 en analizadores de gases arteriales y de sodio, potasio, cloro, litio, calcio ionizado y dióxido de carbono en analizadores de electrólitos.

Descripción del Producto:
Este material de control es suministrado para monitorear el funcionamiento del analizador. El paquete sellado contiene ampolletas de vidrio, cada una con aproximadamente 1.8 ml de solución. Las ampolletas estan empacadas de a 10 unidades por bandeja y cada caja contiene 3 bandejas, para un total de 30 ampolletas por caja.

Ingredientes Activos:
MISSION CONTROL ™ es una solución buffer de electrólitos (Na+, K+, Cl-, Ca++, Li+, HCO3-/CO3-2). Esta ha sido calibrada con niveles específicos de CO2, O2 y N2. Esta solución de control no contiene ingredientes de base humana.

Instrucción para su uso:
Introduzca el líquido directamente al analizador, a través de la ampolleta, siguiendo las instrucciones del fabricante para el muestreo de material de control. Utilizelo con aspiración directa, transferencia por jeringa o técnicas capilares.

Limitaciones:
1. Este control es sensible a muchos factores relativos al instrumento que pueden afectar los resultados analíticos. Debido a que este material no tiene base sanguínea, no podrá detectar algunas anomalías que podrian afectar los resultados de pruebas de sangre.

2. La intención de este producto es que sea usado como material de control de calidad y pueda asistir en la evaluación del funcionamiento de intrumentos de laboratorio. Esta solución no es para ser usada como un estandar de calibración y no puede ser remplazado en otros aspectos del programa de control de calidad.

Almacenamiento:
Almacenar entre 18-25°C. Evite su congelamiento y la exposición a altas temperaturas, mayores a 30°C. Usted puede tambien almacenarlo entre 4-25°C sin presentar efectos adversos.

Rangos Esperados:
El inserto con los valores esperados para cada parámetro se ha basado en múltiples determinaciones hechas con muestras seleccionadas aleatoriamente por cada lote. El listado para cada instrumento representa el rango esperado por prueba usando ampolletas a temperatura de 25°C. (Nota: Los valores de pO2 pueden variar inversamente en un uno porciento (1%) por cada grado Celsius en proporción a la variación de la temperatura desde los 23°C).

Los rangos esperados se suministran como una guía en la evaluación del funcionamiento de los analizadores. Las condiciones pueden haber variado desde que los instrumentos fueron diseñados y cada laboratorio debera de establecer su propio criterio de aceptación de valores.

PORTUGUÊS

Uso pretendido:
MISSION CONTROL ™ Gás de sangue e Controle do eletrólito é um material analisado do controle da qualidade pretendido para monitorar as medidas de pH, pCO^2, pO^2 em analisadores de gás do sangue e o sódio, potássio, cloreto, lítio, ionizou o cálcio e dióxido de carbono total em analisadores do eletrólito de ISE.

Descrição de produto:
Este material do controle é fornecido para o desempenho do analisador da monitoração. É empacotado em ampola do vidro selado, cada contenção de aproximadamente 1.8 ml da solução. As ampola são empacotadas 10 por a bandeja com cada caixa que contem 3 bandejas, para um total de 30 ampola por a caixa.

Ingredientes ativos:
MISSION CONTROL ™ é uma solução protegida de eletrólitos (Na+, K+, Cl-, Ca++, Li+, $HCO_3/CO_{3,2}$). Foi equilibrado com níveis específicos de CO_2, O_2, and N_2. Este controle não contem nenhum material humano-baseado.

Sentidos para o uso
Introduza imediatamente o líquido da ampola ao analisador, depois do instrumento manufacturer' instruções para provar um material do controle. Aspiração direta do uso, transferência da seringa, ou técnicas capilares da modalidade.

Limitação:
1. Este controle é sensível a muitos proveja os fatores relacionados que afetam resultados analíticos. Porque não é um material sangue-baseado, não pode detectar determinados maus funcionamentos, qual afetaria o teste do sangue.

2. Este produto é pretendido para o uso como um material do controle da qualidade e pode ajudar em avaliar o desempenho de instrumentos do laboratório. Não é para o uso como um padrão da calibração e seu uso não deve substituir outros aspectos de um programa de controle completo da qualidade.

Armazenamento:
Lugar em 18-25°C. Evite congelar-se e exposição às temperaturas maiores do que 30°C. Você pode igualmente lugar em 4-25°C sem efeito adverso.

Escalas previstas:
Os valores para cada analyte do controle na carta de escalas prevista incluida são baseados em determinações múltiplas executado em amostras aleatória selecionadas de cada lote. A lista para cada instrumento representa a escala prevista para estas ampola quando testado em 23°C. (Nota: os valores pO_2 variarão inversa por aproximadamente um por cento (1%) por o grau C que a temperatura das ampola varia de 23°C).

As escalas previstas são fornecidas como um guia no desempenho de avaliação do analisador. Desde o instrumento as condições do projeto e de funcionamento podem variar cada laboratório deve estabeleça seus próprios valores previstos e limites de controle. O valor médio estabeleceu deve cair dentro das escalas previstas mostradas na carta.

CHINESE

用途
MISSION CONTROL
™血气和电解质质控是用于监测血气分析仪测量的pH, pCO_2, pO_2以及电解质分析仪测量的钠，钾，氯，锂，离子钙和总二氧化碳综合力分析质控物质，

产品介绍
本质控物质用于监测仪器的性能表现，它是密封在玻璃安瓿瓶里，每瓶约含有1.8毫升的溶液，每板由10个安瓿瓶，每盒3板共30个安瓿瓶。

活性成份
MISSION CONTROL ™是电解质离子(Na+, K+, Cl-, Ca++, Li+, $HCO_3/CO_{3,2}$)缓冲液，并由特殊水平的CO_2, O_2和N_2平衡而成的，本质控不含有人血清成份，

使用方法
打开后应立即应用于分析仪，按照仪器生产商要求测试质控物质，可以用直接加样吸取，或用注射器转移，应用毛细管方法，

局限性
本质控对能影响分析结果很多仪器相关因素敏感，
因为不是血清基质的质控，它不能检测能够影响测量血液时表现出的仪器某种故障，

本产品作为质控物质能帮助评价实验室仪器的性能表现，并不能作为校准品来使用，也不能取代一个系统质控程序的其他方面，

贮存
18~25摄氏度保存，避免冷冻或放置与30度以上的温度中，放置于4~25摄氏度中也无不良影响，

靶值范围
附在盒中每个质控物质的靶值范围表是任选同一个批号安瓿瓶多次测量的结果，列出的每个仪器测量结果范围代表这些安瓿瓶在23摄氏度测量的结果（注释：pO_2值会在温度每偏离23摄氏度1度时，结果以相反的方向偏离1%），

靶值范围仅作为评价仪器性能表现的参考指导，由于仪器的设计和操作条件可能会有变化，每个实验室应建立自己的靶值及范围，平均值应在靶值表范围内，

Русский

Способ применения:
MISSION CONTROL ™ Анализ газов крови и электролитов - это проверенный контроль качества материалов, применяемый для мониторинга измерения pH, pCO_2, pO_2 в аппарате для анализа газа крови, а также натрия, калия, хлорида, лития, ионизированного кальция и всего углекислого газа в электролитных анализаторах ISE.

Описание продукта:
Этот контрольный материал применяется для мониторинга анализируемых характеристик. Он упаковывается в запаянные стеклянные ампулы, каждая из которых содержит приблизительно 1.8 мл раствора. Ампулы упаковываются по 10 штук на лотке и по 3 лотка в коробке, значит всего по 30 штук в коробке.

Активные ингредиенты:
MISSION CONTROL ™ - это буферезированный раствор электролитов (Na+, K+, Cl-, Ca++, Li+, $HCO_3/CO_{3,2}$). Он сбалансирован на специальном уровне CO_2, O_2 и N_2. Этот анализ не содержит материалов на базе человеческого органзима.

Инструкции по использованию:
Срочно передать жидкость из ампулы на анализатор, соблюдая инструкции производителя прибора для образцов контрольного материала. Использовать прямую аспирацию, шприц или капилярный метод.

Ограничение:
1. Этот анализ чувствителен ко многим факторам, связанным с приборами, влияющими на аналитические результаты. Поскольку это материал не на основе крови, невозможно обнаружение точных дисфункций, которые влияют на анализ крови.

2. Этот продукт используется как контрольный материал на качество и может помочь в оценке характеристики лабораторных приборов. Он не используется для калибровки эталонов и не может заменить другой подход к выполнению контроля качества.

Хранение:
Хранить при 18-25°C. Избегать замерзания и повышения температуры свыше 30°C. Может быть храним при температуре 4-25°C без появления неблагоприятного эффекта.

Ожидаемые диапазоны:
Величины для каждого контрольного анализа внесены в Диаграмму Ожидаемых Диапазонов, основанную на множестве определений характеристик случайно выбраных образцов из каждой серии. Запись для каждого прибора представляет ожидаемый диапозон для ампул, тестированных при 23 °C. (Примечание: величина pO_2 будет отличаться инверсно около одного процента (1%) на каждый градус С при изменении температуры ампулы от 23 °C).

Ожидаемые Диапозоны в качестве индикатора при оценке характеристики анализатора. С тех пор как дизайн и условия работы прибора могут меняться, каждая лаборатория должна устанавливать свою собственную ожидаемую величину и контрольные лимиты. Значение ожидаемой величины должно попадать в Ожидаемый Диапозон, указанный на диаграмме.

DIAMOND®
DIAGNOSTICS

PACK INSERT
Mission Control Level 2

REF DD-92002 | CE | IVD | 2019/04 | LOT 1605168

English

Intended Use:
MISSION CONTROL ™ Blood Gas and Electrolyte Control is an assayed quality control material intended for monitoring the measurements of pH pCO_2, pO_2 in blood gas analyzers and sodium, potassium, chloride, lithium, ionized calcium and total carbon dioxide in ISE electrolyte analyzers.

Product Description:
This control material is provided for monitoring analyzer performance. It is packaged in sealed glass ampules, each containing approximately 1.8 ml of solution. Ampules are packaged 10 per tray with each box containing 3 trays, for a total of 30 ampules per box.

Active Ingredients:
MISSION CONTROL ™ is a buffered solution of electrolytes (Na+, K+, Cl-, Ca++, Li+, HCO_3-/CO_{3-2}). It has been equilibrated with specific levels of CO_2, O_2, and N_2. This control contains no human-based materials.

Directions for Use
Immediately introduce the liquid from the ampule to the analyzer, following the instrument manufacturer's instructions for sampling a control material. Use direct aspiration, syringe transfer, or capillary mode techniques.

Limitation:
1. This control is sensitive to many instrument related factors that affect analytical results. Because it is not a blood-based material, it may not detect certain malfunctions, which would affect the testing of blood.

2. This product is intended for use as a quality control material and can assist in evaluating the performance of laboratory instruments. It is not for use as a calibration standard and its use should not replace other aspects of a complete quality control program.

Storage:
Store at 18-25°C. Avoid freezing and exposure to temperatures greater than 30°C. You may also store at 4-25°C without adverse effect.

Expected Ranges:
The values for each control analyte on the enclosed Expected Ranges Chart are based on multiple determinations performed on randomly selected samples from each lot. The listing for each instrument represents the expected range for these ampules when tested at 23°C. (Note: pO_2 values will vary inversely by about one percent (1%) per degree C that the temperature of the ampules varies from 23°C).

The Expected Ranges are provided as a guide in evaluating analyzer performance. Since instrument design and operating conditions may vary, each laboratory should establish its own expected values and control limits. The mean value established should fall within the Expected Ranges shown on the chart.

DEUTSCH

Vorgesehener Gebrauch:
MISSION CONTROL ™ Blutgas-und Elektrolyt-Kontrolle ist eine Qualitätskontrollprüfung, die zur Überwachung der Messungen des pH-Wertes pCO_2, pO_2 in Blutgasanalysatoren und Natrium, Kalium, Chlorid, Lithium, ionisiertes Calcium und Total-Kohlendioxid in ISE-Elektrolyt-Analysatoren dient.

Produktbeschreibung:
Diese Kontrolle dient für die Überwachung der Analysatorleistung. Es ist in verschlossenen Glasampullen verpackt mit jeweils etwa 1.8 ml Lösung. Ein Karton beinhaltet 3 Fächer mit jeweils 10 Ampullen. Es sind insgesamt 30 Ampullen pro Karton.

Aktive Inhaltsstoffe:
MISSION CONTROL ™ ist eine gepufferte Lösung von Elektrolyten (Na +, K +, Cl-, Ca + +, Li +, HCO_3-/CO_{3-2}). Diese wurde mit bestimmten Ebenen von CO_2, O_2 und N_2 äquilibriert. Diese Kontrolle enthält keine menschlichen Grundmaterialien.

Gebrauchsanweisung:
Nach dem Öffnen, führen Sie sofort die Flüssigkeit aus der Ampulle in den Analysator ein und folgen Sie den Hersteller-Anweisungen für die Probenahme des Kontrollmaterials. Verfahren Sie mit Direkteinführung, Spritzentransfer oder Kapillar-Modus-Techniken.

Begrenzung:
1. Diese Kontrolle ist auf viele instrument-bezogenen Faktoren empfindlich, die das analytische Ergebniss verfälschen kann. Da es kein echtes Blutmaterial ist, kann es daher keine Störungen, die sich in der Untersuchung von richtigem Blut zeigt, erkennen.

2. Dieses Produkt dient als Qualitätskontrolle und soll als Bewerter fuer die Leistung von Laborgeräten eingesetzt werden. Es ist kein Kalibrierstandard und dessen Verwendung sollte nicht an Stelle von anderen kompletten Qualitätskontroll-Programmen Ersatz leisten.

Lagerung:
Bei 18-25°C aufbewahren. Vermeiden Sie Einfrierung und Aussetzung bei Temperaturen von mehr als 30°C. Die Lagerung bei 4-25°C ist ohne negative Auswirkung.

Wertbereiche:
Die Werte für jeden Kontrollanalyt auf der beiliegenden Werbereichtabelle basieren auf mehreren Ermittlungen, die von zufällig ausgewählten Proben von jeder Partie stammen. Die Liste für jedes Instrument beschreibt das erwartete Resultat für die jeweilige Ampulle bei der Prüfung bei 23°C. (Hinweis: pO_2 Werte variieren umgekehrt um rund ein Prozent (1%) pro Grad C, die Temperatur der Ampulle variiert um 23° C).

Die erwarteten Wertbereiche sollen als Leitfaden bei der Bewertung der Leistung von Analysiergeräten dienen. Da die Instrumentausführung und Betriebsbedingungen variieren können, sollte jedes Labor seine eigenen Werterwartungen und Kontrollbeschränkungen erstellen. Der selbst-erstellte Mittlwert sollte dem auf der vorgegebenen Wertbereichtabelle entsprechen.

FRANÇAIS

Utilisation prévue :
MISSION CONTROL ™ Contrôle de gaz et d'électrolyte de sang est un matériel pour analyse de contrôle de qualité destiné à surveiller les mesures de pH pCO_2, pO_2 en analyseurs et sodium de gaz de sang, potassium, chlorure, lithium, calcium ionisé et anhydride carbonique total dans des analyseurs d'électrolyte d'ISE.

Description de produit :
Ce matériel de contrôle est donné pour surveiller l'exécution d'analyseur. Il est empaqueté dans les ampules de verre scellés, chaque contient approximativement 1.8 ml de solution. Les ampules sont empaquetés par 10 par plateau avec chaque boîte contenant 3 plates.

Substances actives :
MISSION CONTROL ™ est une solution tampon des électrolytes (Na+, K+, Cl, Ca++, Li+, HCO_3-/CO_{3-2}). Elle a été équilibrée avec les niveaux spécifiques du CO_2, de l'O_2, et du N_2. Ce contrôle ne contient aucun matériaux humain-basé.

Notices d'emploi
Introduire immédiatement le liquide de l'ampule à l'analyseur, suivez les instructions du fabricant d'instrument pour prélever un matériel de contrôle. Utilisez l'aspiration directe, le transfert de seringue, ou les techniques de mode capillaire.

Limitation :
1. Ce contrôle est sensible à beaucoup de facteurs reliés par instrument qui affectent des résultats analytiques. Puisque ce n'est pas un matériel sang-basé, il peut ne pas détecter certains défauts de fonctionnement, qui affecteraient l'essai du sang.

2. Ce produit est prévu pour l'usage comme matériel de contrôle de qualité et peut aider à évaluer l'exécution des instruments de laboratoire. Il ne sert pas car un calibrage standard et son utilisation ne devraient pas remplacer d'autres aspects d'un pr

Stockage :
Stock à la température 18-25°C. Évitez de geler et exposer aux temperatures plus hautes que 30C°. Vous pouvez également stocker 4-25°C sans effet adverse.

Gammes prévues :
Les valeurs pour chaque analyte de contrôle sur le diagramme de gammes inclus sont basées sur des déterminations multiples effectuées sur les échantillons aléatoirement choisis provenant de chaque sort. La liste pour chaque instrument représente la gamme prévue pour ces ampules une fois examinée à 23°C. (Note : les valeurs pO2 changeront inversement par environ un pour cent (1%) par degré C que la température des ampules change de 23°C).

Les gammes prévues sont fournies comme guide dans l'évaluation de performance d'analyseur. Comme la conception d'instrument et les conditions de fonctionnement peut changer, chaque laboratoire devrait établir ses propres valeurs et limites de commande. La valeur moyenne établie devrait faire partie des marges prévues montrées sur le diagramme.

ESPAÑOL

Uso:
MISSION CONTROL ™ para Gases Arteriales y Electrólitos es un material aprobado para el control de calidad en el monitoreo de mediciones de pH, pCO2, PO2 en analizadores de gases arteriales y de sodio, potasio, cloro, litio, calcio ionizado y dioxido de carbono en analizadores de electrólitos.

Descripción del Producto:
Este material de control es suministrado para monitorear el funcionamiento del analizador. El paquete sellado contiene ampolletas de vidrio, cada una con aproximadamente 1.8 ml de solución. Las ampolletas estan empacadas de a 10 unidades por bandeja y cada caja contiene 3 bandejas, para un total de 30 ampolletas por [illegible]

Ingredientes Activos:
MISSION CONTROL ™ es una solución buffer de electrólitos (Na+, K+, Cl-, Ca++, Li+, HCO3-/CO3-2). Esta ha sido calibrada con niveles específicos de CO2, O2 y N2. Esta solución de control no contiene ingredientes de base humana.

Instrucción para su uso:
Introduzca el líquido directamente al analizador, a través de la ampolleta, siguiendo las instrucciones del fabricante para el muestreo de material de control. Utilízelo con aspiración directa, transferencia por jeringa o técnicas capilares.

Limitaciones:
1. Este control es sensible a muchos factores relativos al instrumento que pueden afectar los resultados analíticos. Debido a que este material no tiene base sanguínea, no podrá detectar algunas anomalías que podrian afectar los resultados de pruebas de sangre.

2. La intención de este producto es que sea usado como material de control de calidad y pueda asistir en la evaluación del funcionamiento de intrumentos de laboratorio. Esta solución no es para ser usada como un estandar de calibración y no puede ser remplazado en otros aspectos del programa de control de calidad.

Almacenamiento:
Almacenar entre 18-25°C. Evite su congelamiento y la exposición a altas temperaturas, mayores a 30°C. Usted puede tambien almacenarlo entre 4-25°C sin presentar efectos adversos.

Rangos Esperados:
El inserto con los valores esperados para cada parámetro se ha basado en múltiples determinaciones hechas con muestras seleccionadas aleatoriamente por cada lote. El listado para cada instrumento representa el rango esperado por prueba usando ampolletas a temperatura de 25°C. (Nota: Los valores de pO2 pueden variar inversamente en un uno porciento (1%) por cada grado Celsius en proporción a la variación de la temperatura desde los 23°C).

Los rangos esperados se suministran como una guía en la evaluación del funcionamiento de los analizadores. Las condiciones pueden haber variado desde que los instrumentos fueron diseñados y cada laboratorio debera de establecer su propio criterio de aceptación de valores.

PORTUGUÊS

Uso pretendido:
MISSION CONTROL ™ Gás de sangue e Controle do eletrólito é um material analisado do controle da qualidade pretendido para monitorar as medidas de pH pCO2, pO2 em analisadores de gás do sangue e o sódio, potássio, cloreto, lítio, ionizou o cálcio e dióxido de carbono total em analisadores do eletrólito de ISE.

Descrição de produto:
Este material do controle é fornecido para o desempenho do analisador da monitoração. É empacotado em ampola do vidro selado, cada contenção de aproximadamente 1.8 ml da solução. As ampola são empacotadas 10 por a bandeja com cada caixa que contem 3 bandejas, para um total de 30 ampola por a caixa.

Ingredientes ativos:
MISSION CONTROL ™ é uma solução protegida de eletrólitos (Na+, K+, Cl-, Ca++, Li+, HCO_3-/CO_{3-2}). Foi equilibrado com níveis específicos de CO_2, O_2, and N_2. Este controle não contem nenhum material humano-baseado.

Sentidos para o uso
Introduza imediatamente o líquido da ampola ao analisador, depois do instrumento manufacturer' instruções para provar um material do controle. Aspiração direta do uso, transferência da seringa, ou técnicas capilares da modalidade.

Limitação:
1. Este controle é sensível a muitos proveja os fatores relacionados que afetam resultados analíticos. Porque não é um material sangue-baseado, não pode detectar determinados maus funcionamentos, qual afetaria o teste do sangue.

2. Este produto é pretendido para o uso como um material do controle da qualidade e pode ajudar em avaliar o desempenho de instrumentos do laboratório. Não é para o uso como um padrão da calibração e seu uso não deve substituir outros aspectos de um programa de controle completo da qualidade.

Armazenamento:
Lugar em 18-25°C. Evite congelar-se e exposição às temperaturas maiores do que 30°C. Você pode igualmente lugar em 4-25°C sem efeito adverso.

Escalas previstas:
Os valores para cada analyte do controle na carta de escalas prevista incluida são baseados em determinações múltiplas executado em amostras aleatória selecionadas de cada lote. A lista para cada instrumento representa a escala prevista para estas ampola quando testado em 23°C. (Nota: os valores pO_2 variarão inversa por aproximadamente um por cento (1%) por o grau C que a temperatura das ampola varia de 23°C).

As escalas previstas são fornecidas como um guia no desempenho de avaliação do analisador. Desde o instrumento as condições do projeto e de funcionamento podem variar cada laboratório deve estabeleça seus próprios valores previstos e limites de controle. O valor médio estabeleceu deve cair dentro das escalas previstas mostradas na carta.

CHINESE

用途
MISSION CONTROL
™血气和电解质质控是用于监测血气分析仪测量的pH, pCO_2, pO_2以及电解质分析仪测量的钠，钾，氯，锂，离子钙和总二氧化碳结合力分析质控物质。

产品介绍
本质控物质用于监测仪器的性能表现，它是密封在玻璃安瓿瓶里，每瓶约含有2毫升的溶液，每板由10个安瓿瓶，每盒3板共30个安瓿瓶。

活性成份
MISSION CONTROL ™是电解质离子(Na+, K+, Cl-, Ca++, Li+, HCO_3-/CO_{3-2})缓冲液，并由特殊水平的CO_2, O_2和N_2平衡而成的，本质控不含有人血清成份。

使用方法
打开后应立即应用于分析仪，按照仪器生产商要求测试质控物质，可从用盖膜加样获取，或用注射器转移，应用毛细管方法。

局限性
本质控对能影响分析结果很多仪器相关因素敏感，
因为不是血清基质的质控，它不能检测能够影响测量血液时表现出的仪器某种故障。

贮存
18-25摄氏度贮存，避免冷冻或放置与30度以上的温度中，放置于4-25摄氏度中也无不良影响。

靶值范围
附在盒中每个质控物质的靶值范围表是任选同一个批号安瓿瓶多次测量的结果，列出的每个仪器测量结果范围代表这些安瓿被在23摄氏度测量的结果（注释：pO_2值会在温度每偏离23摄氏度1度时，结果以相反的方向偏离1%），

靶值范围仅作为评价仪器性能表现的参考指导，由于仪器的设计和操作条件可能会有变化，每个实验室应建立自己的靶值及范围，平均值应在靶值表范围内。

Русский

Способ применения:
MISSION CONTROL ™ Анализ газов кр
электролитов - это проверенный контрс
качества материалов, применяемый дл
мониторинга измерения pH, pCO_2, pO_2
для анализа газа крови, а также натрия
хлорида, лития, ионизированного кальц
углекислого газа в электролитных анал
ISE.

Описание продукта:
Этот контрольный материал применяет
мониторинга анализируемых характери
упаковывается в запаянные стеклянны
каждая из которых содержит приблизит
мл раствора. Ампулы упаковываются п
лотке и по 3 лотка в коробке, значит все
штук в коробке.

Активные ингредиенты:
MISSION CONTROL ™ - это буферезир
раствор электролитов (Na+, K+, Cl-, Ca-
HCO_3-/CO_{3-2}). Он сбалансирован на сп
уровне CO_2, O_2 и N_2. Этот анализ не со
материалов на базе человеческого орга

Инструкции по использованию:
Срочно передать жидкость из ампулы н
анализатор, соблюдая инструкции прои
прибора для образцов контрольного ма
Использовать прямую аспирацию, шпри
капиляpный метод.

Ограничение:
1. Этот анализ чувствителен ко многим
связанным с приборами, влияющими н
аналитические результаты. Поскольку э
материал не на основе крови, невозмож
обнаружение точных дисфункций, котор
на анализ крови.

2. Этот продукт используется как контр
материал на качество и может помочь в
характеристики лабораторных приборо
используется для калибровки эталонов
заменить другой подход к выполнению
качества.

Хранение:
Хранить при 18-25 ° C. Избегать замора
повышения температуры свыше 30°C. М
храним при температуре 4-25°C без пос
неблагоприятного эффекта.

Ожидаемые диапазоны:
Величины для каждого контрольного ан
внесены в Диаграмму Ожидаемых Диап
основанную на множестве определений
характеристик случайно выбранных обра
каждой серии. Запись для каждого прил
представляет ожидаемый диапазон для
тестированных при 23 °C. (Примечание
pO_2 будет отличаться инверсно около с
процента (1%) на каждый градус С при
температуры ампулы от 23°C).

Ожидаемые Диапозоны в качестве инду
оценке характеристики анализатора. С
дизайн и условия работы прибора могу
каждая лаборатория должна устанавли
собственную ожидаемую величину и ко
лимиты. Значение ожидаемой величин
попадать в Ожидаемый Диапозон, указа
диаграмме.

DIAMOND®
DIAGNOSTICS

PACK INSERT
Mission Control Level 3

REF DD-92003 | CE | IVD | 2019/04 | LOT 1605165

English

Intended Use:
MISSION CONTROL ™ Blood Gas and Electrolyte Control is an assayed quality control material intended for monitoring the measurements of pH pCO_2, pO_2 in blood gas analyzers and sodium, potassium, chloride, lithium, ionized calcium and total carbon dioxide in ISE electrolyte analyzers.

Product Description:
This control material is provided for monitoring analyzer performance. It is packaged in sealed glass ampules, each containing approximately 1.8 ml of solution. Ampules are packaged 10 per tray with each box containing 3 trays, for a total of 30 ampules per box.

Active Ingredients:
MISSION CONTROL ™ is a buffered solution of electrolytes (Na+, K+, Cl-, Ca++, Li+, HCO_3-/CO_{3-2}). It has been equilibrated with specific levels of CO_2, O_2, and N_2. This control contains no human-based materials.

Directions for Use
Immediately introduce the liquid from the ampule to the analyzer, following the instrument manufacturer's instructions for sampling a control material. Use direct aspiration, syringe transfer, or capillary mode techniques.

Limitation:
1. This control is sensitive to many instrument related factors that affect analytical results. Because it is not a blood-based material, it may not detect certain malfunctions, which would affect the testing of blood.

2. This product is intended for use as a quality control material and can assist in evaluating the performance of laboratory instruments. It is not for use as a calibration standard and its use should not replace other aspects of a complete quality control program.

Storage:
Store at 18-25°C. Avoid freezing and exposure to temperatures greater than 30°C. You may also store at 4-25°C without adverse effect.

Expected Ranges:
The values for each control analyte on the enclosed Expected Ranges Chart are based on multiple determinations performed on randomly selected samples from each lot. The listing for each instrument represents the expected range for these ampules when tested at 23°C. (Note: pO_2 values will vary inversely by about one percent (1%) per degree C that the temperature of the ampules varies from 23°C).

The Expected Ranges are provided as a guide in evaluating analyzer performance. Since instrument design and operating conditions may vary, each laboratory should establish its own expected values and control limits. The mean value established should fall within the Expected Ranges shown on the chart.

DEUTSCH

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MISSION CONTROL ™ Blutgas-und Elektrolyt-Kontrolle ist eine Qualitätskontrollprüfung, die zur Überwachung der Messungen des pH-Wertes pCO_2, pO_2 in Blutgasanalysatoren und Natrium, Kalium, Chlorid, Lithium, ionisiertes Calcium und Total-Kohlendioxid in ISE-Elektrolyt-Analysatoren dient.

Produktbeschreibung:
Diese Kontrolle dient für die Überwachung der Analysatorleistung. Es ist in verschlossenen Glasampullen verpackt mit jeweils etwa 1.8 ml Lösung. Ein Karton beinhaltet 3 Fächer mit jeweils 10 Ampullen. Es sind insgesamt 30 Ampullen pro Karton.

Aktive Inhaltsstoffe:
MISSION CONTROL ™ ist eine gepufferte Lösung von Elektrolyten (Na+, K+, Cl-, Ca++, Li+, HCO_3-/CO_{3-2}). Diese wurde mit bestimmten Ebenen von CO_2, O_2 und N_2 äquilibriert. Diese Kontrolle enthält keine menschlichen Grundmaterialien.

Gebrauchsanweisung:
Nach dem Öffnen, führen Sie sofort die Flüssigkeit aus der Ampulle in den Analysator ein und folgen Sie den Hersteller-Anweisungen für die Probenahme des Kontrollmaterials. Verfahren Sie mit Direkteinführung, Spritzentransfer oder Kapillar-Modus-Techniken

Begrenzung:
1. Diese Kontrolle ist auf viele instrument-bezogenen Faktoren empfindlich, die das analytische Ergebnis verfälschen kann. Da es kein echtes Blutmaterial ist, kann es daher keine Störungen, die sich in der Untersuchung von richtigem Blut zeigt, erkennen.

2. Dieses Produkt dient als Qualitätskontrolle und soll als Bewerter fuer die Leistung von Laborgeräten eingesetzt werden. Es ist kein Kalibrierstandard und dessen Verwendung sollte nicht an Stelle von anderen kompletten Qualitätskontroll-Programmen Ersatz leisten.

Lagerung:
Bei 18-25 ° C aufbewahren. Vermeiden Sie Einfrierung und Aussetzung bei Temperaturen von mehr als 30 ° C. Die Lagerung bei 4-25 ° C ist ohne negative Auswirkung.

Wertbereiche:
Die Werte für jeden Kontrollanalyt auf der beiliegenden Werbereichtabelle basieren auf mehreren Ermittlungen, die von zufällig ausgewählten Proben von jeder Partie stammen. Die Liste für jedes Instrument beschreibt das erwartete Resultat für die jeweilige Ampulle bei der Prüfung bei 23°C. (Hinweis: pO_2 Werte varieren umgekehrt um rund ein Prozent (1%) pro Grad C, die Temperatur der Ampulle variiert um 23°C).

Die erwarteten Wertbereiche sollen als Leitfaden bei der Bewertung der Leistung von Analysiergeräten dienen. Da die Instrumentausführung und Betriebsbedingungen variieren können, sollte jedes Labor seine eigenen Werterwartungen und Kontrollbeschränkungen erstellen. Der selbst-erstellte Mittlwert sollte dem auf der vorgegebenen Wertbereichtabelle entsprechen.

FRANÇAIS

Utilisation prévue :
MISSION CONTROL ™ Contrôle de gaz et d'électrolyte de sang est un matériel pour analyse de contrôle de qualité destiné à surveiller les mesures de pH pCO_2, pO_2 en analyseurs et sodium de gaz de sang, potassium, chlorure, lithium, calcium ionisé et anhydride carbonique total dans des analyseurs d'électrolyte d'ISE.

Description de produit :
Ce matériel de contrôle est donné pour surveiller l'exécution d'analyseur. Il est empaqueté dans les ampules de verre scellés, chaque contient approximativement 1.8 ml de solution. Les ampules sont empaquetés par 10 par plateau avec chaque boîte contenant 3 plates.

Substances actives :
MISSION CONTROL ™ est une solution tampon des électrolytes (Na+, K+, Cl-, Ca++, Li+, HCO_3-/CO_{3-2}). Elle a été équilibrée avec les niveaux spécifiques du CO_2, de l'O_2, et du N_2. Ce contrôle ne contient aucun matériaux humain-basé.

Notices d'emploi
Introduire immédiatement le liquide de l'ampule à l'analyseur, suivez les instructions du fabricant d'instrument pour prélever un matériel de contrôle. Utilisez l'aspiration directe, le transfert de seringue, ou les techniques de mode capillaire.

Limitation :
1. Ce contrôle est sensible à beaucoup de facteurs reliés par instrument qui affectent des résultats analytiques. Puisque ce n'est pas un matériel sang-basé, il peut ne pas détecter certains défauts de fonctionnement, qui affecteraient l'essai du sang.

2. Ce produit est prévu pour l'usage comme matériel de contrôle de qualité et peut aider à évaluer l'exécution des instruments de laboratoire. Il ne sert pas car un calibrage standard et son utilisation ne devraient pas remplacer d'autres aspects d'un pr

Stockage :
Stock à la température 18-25°C. Évitez de geler et exposer aux temperatures plus hautes que 30°C. Vous pouvez également stocker 4-25°C sans effet adverse.

Gammes prévues :
Les valeurs pour chaque analyte de contrôle sur le diagramme de gammes inclus sont basées sur des déterminations multiples effectuées sur les échantillons aléatoirement choisis provenant de chaque sort. La liste pour chaque instrument représente la gamme prévue pour ces ampules une fois examinée à 23°C. (Note : les valeurs pO_2 changeront inversement par environ un pour cent (1%) par degré C que la température des ampules change de 23°C).

Les gammes prévues sont fournies comme guide dans l'évaluation de performance d'analyseur. Comme la conception d'instrument et les conditions de fonctionnement peut changer, chaque laboratoire devrait établir ses propres valeurs et limites de commande. La valeur moyenne établie devrait faire partie des marges prévues montrées sur le diagramme.

ESPAÑOL

Uso:
MISSION CONTROL ™ para Gases Arteriales y Electrólitos es un material aprobado para el control de calidad en el monitoreo de mediciones de pH, pCO2, PO2 en analizadores de gases arteriales y de sodio, potasio, cloro, litio, calcio ionizado y dióxido de carbono en analizadores de electrólitos.

Descripción del Producto:
Este material de control es suministrado para monitorear el funcionamiento del analizador. El paquete sellado contiene ampolletas de vidrio, cada una con aproximadamente 1.8 ml de solución. Las ampolletas estan empacadas de a 10 unidades por bandeja y cada caja contiene 3 bandejas, para un total de 30 ampolletas por caja.

Ingredientes Activos:
MISSION CONTROL ™ es una solución buffer de electrólitos (Na+, K+, Cl-, Ca++, Li+, HCO3-/CO3-2). Esta ha sido calibrada con niveles especificos de CO2, O2 y N2. Esta solución de control no contiene ingredientes de base humana.

Instrucción para su uso:
Introduzca el líquido directamente al analizador, a través de la ampolleta, siguiendo las instrucciones del fabricante para el muestreo de material de control. Utilizelo con aspiración directa, transferencia por jeringa o técnicas capilares.

Limitaciones:
1. Este control es sensible a muchos factores relativos al instrumento que pueden afectar los resultados analíticos. Debido a que este material no tiene base sanguínea, no podrá detectar algunas anomalías que podrian afectar los resultados de pruebas de sangre.

2. La intención de este producto es que sea usado como material de control de calidad y pueda asistir en la evaluación del funcionamiento de intrumentos de laboratorio. Esta solución no es para ser usada como un estandar de calibración y no puede ser remplazado en otros aspectos del programa de control de calidad.

Almacenamiento:
Almacenar entre 18-25°C. Evite su congelamiento y la exposición a altas temperaturas, mayores a 30°C. Usted puede tambien almacenarlo entre 4-25°C sin presentar efectos adversos.

Rangos Esperados:
El inserto con los valores esperados para cada parámetro se ha basado en múltiples determinaciones hechas con muestras seleccionadas aleatoriamente por cada lote. El listado para cada instrumento representa el rango esperado por prueba usando ampolletas a temperatura de 25°C. (Nota: Los valores de pO2 pueden variar inversamente en un uno porciento (1%) por cada grado Celsius en proporción a la variación de la temperatura desde los 23°C).

Los rangos esperados se suministran como una guía en la evaluación del funcionamiento de los analizadores. Las condiciones pueden haber variado desde que los instrumentos fueron diseñados y cada laboratorio debera de establecer su propio criterio de aceptación de valores.

PORTUGUÊS

Uso pretendido:
MISSION CONTROL ™ Gás de sangue e Controle do eletrólito é um material analisado do controle da qualidade pretendido para monitorar as medidas de pH, pCO^2, pO^2 em analisadores de gás do sangue e o sódio, potássio, cloreto, lítio, ionizou o cálcio e dióxido de carbono total em analisadores do eletrólito de ISE.

Descrição de produto:
Este material do controle é fornecido para o desempenho do analisador da monitoração. É empacotado em ampola do vidro selado, cada contenção de aproximadamente 1.8 ml da solução. As ampola são empacotadas 10 por a bandeja com cada caixa que contem 3 bandejas, para um total de 30 ampola por a caixa.

Ingredientes ativos:
MISSION CONTROL ™ é uma solução protegida de eletrólitos (Na+, K+, Cl-, Ca++, Li+, HCO_3-/CO_{3-2}). Foi equilibrado com níveis específicos de CO_2, O_2, and N_2. Este controle não contem nenhum material humano-baseado.

Sentidos para o uso
Introduza imediatamente o líquido da ampola ao analisador, depois do instrumento manufacturer' instruções para provar um material do controle. Aspiração direta do uso, transferência da seringa, ou técnicas capilares da modalidade.

Limitação:
1. Este controle é sensível a muitos proveja os fatores relacionados que afetam resultados analíticos. Porque não é um material sangue-baseado, não pode detectar determinados maus funcionamentos, qual afetaria o teste do sangue.

2. Este produto é pretendido para o uso como um material do controle da qualidade e pode ajudar em avaliar o desempenho de instrumentos do laboratório. Não é para o uso como um padrão da calibração e seu uso não deve substituir outros aspectos de um programa de controle completo da qualidade.

Armazenamento:
Lugar em 18-25°C. Evite congelar-se e exposição às temperaturas maiores do que 30°C. Você pode igualmente lugar em 4-25°C sem efeito adverso.

Escalas previstas:
Os valores para cada analyte do controle na carta de escalas prevista incluida são baseados em determinações múltiplas executado em amostras aleatória selecionadas de cada lote. A lista para cada instrumento representa a escala prevista para estas ampola quando testado em 23°C. (Nota: os valores pO_2 variarão inversa por aproximadamente um por cento (1%) por o grau C que a temperatura das ampola varia de 23°C).

As escalas previstas são fornecidas como um guia no desempenho de avaliação do analisador. Desde o instrumento as condições do projeto e de funcionamento podem variar cada laboratório deve estabeleça seus próprios valores previstos e limites de controle. O valor médio estabeleceu deve cair dentro das escalas previstas mostradas na carta.

CHINESE

用途
MISSION CONTROL ™血气和电解质质控是用于监测血气分析仪测量的pH, pCO_2, pO_2以及电解质分析仪测量的钠，钾，氯，锂，离子钙和总二氧化碳结合力分析质控物质。

产品介绍
本质控物质用于监测仪器的性能表现，它是密封在玻璃安瓿瓶里，每瓶约含有1.8毫升的溶液，每板由10个安瓿瓶，每盒3板共30个安瓿瓶。

活性成份
MISSION CONTROL ™是电解质离子(Na+, K+, Cl-, Ca++, Li+, HCO_3-/CO_{3-2})缓冲液，并由特殊水平的CO_2, O_2和N_2平衡而成的，本质控不含有人血清成份。

使用方法
打开后应立即应用于分析仪，按照仪器生产商要求测试质控物质，可以用直接加样吸取，或用注射器转移，应用毛细管方法。

局限性
本质控对能影响分析结果很多仪器相关因素敏感，
因为不是血清基质的质控，它不能检测能够影响测量血液时表现出的仪器某种故障。

本产品作为质控物质能帮助评价实验室仪器的性能表现，并不能作为校准品来使用，也不能取代一个系统质控程序的其他方面。

贮存
18~25摄氏度保存，避免冷冻或放置与30度以上的温度中，放置于4~25摄氏度中也无不良影响，

靶值范围
附在盒中每个质控物质的靶值范围表是任选同一个批号安瓿瓶多次测量的结果，列出的每个仪器测量结果范围代表这些安瓿瓶在23摄氏度测量的结果（注释：pO_2值会在温度每偏离23摄氏度1度时，结果以相反的方向偏离1%）。

靶值范围仅作为评价仪器性能表现的参考指导，由于仪器的设计和操作条件可能会有变化，每个实验室应建立自己的靶值及范围，平均值应在靶值表范围内。

Русский

Способ применения:
MISSION CONTROL ™ Анализ газов крови и электролитов - это проверенный контроль качества материалов, применяемый для мониторинга измерения pH, pCO_2, pO_2 в аппарате для анализа газа крови, а также натрия, калия, хлорида, лития, ионизированного кальция и всего углекислого газа в электролитных анализаторах ISE.

Описание продукта:
Этот контрольный материал применяется для мониторинга анализируемых характеристик. Он упаковывается в запаянные стеклянные ампулы, каждая из которых содержит приблизительно 1.8 мл раствора. Ампулы упаковываются по 10 штук на лотке и по 3 лотка в коробке, значит всего по 30 штук в коробке.

Активные ингрединенты:
MISSION CONTROL ™ - это буферезированный раствор электролитов (Na+, K+, Cl-, Ca++, Li+, HCO_3-/CO_{3-2}). Он сбалансирован на специальном уровне CO_2, O_2 и N_2. Этот анализ не содержит материалов на базе человеческого организма.

Инструкции по использованию:
Срочно передать жидкость из ампулы на анализатор, соблюдая инструкции производителя прибора для образцов контрольного материала. Использовать прямую аспирацию, шприц или капилярный метод.

Ограничение:
1. Этот анализ чувствителен ко многим факторам, связанным с приборами, влияющими на аналитические результаты. Поскольку это материал не на основе крови, невозможно обнаружение точных дисфункций, которые влияют на анализ крови.

2. Этот продукт используется как контрольный материал на качество и может помочь в оценке характеристики лабораторных приборов. Он не используется для калибровки эталонов и не может заменить другой подход к выполнению контроля качества.

Хранение:
Хранить при 18-25°C. Избегать замерзания и повышения температуры свыше 30°C. Может быть храним при температуре 4-25°C без появления неблагоприятного эффекта.

Ожидаемые диапазоны:
Величины для каждого контрольного анализа внесены в Диаграмму Ожидаемых Диапазонов, основанную на множестве определений характеристик случайно выбраных образцов из каждой серии. Запись для каждого прибора представляет ожидаемый диапозон для ампул, тестированных при 23 °C. (Примечание: величина pO_2 будет отличаться инверсно около одного процента (1%) на каждый градус C при изменении температуры ампулы от 23 °C).

Ожидаемые Диапозоны в качестве индикатора при оценке характеристики анализатора. С тех пор как дизайн и условия работы прибора могут меняться, каждая лаборатория должна устанавливать свою собственную ожидаемую величину и контрольные лимиты. Значение ожидаемой величины должно попадать в Ожидаемый Диапозон, указанный на диаграмме.

DIAMOND®
DIAGNOSTICS

PACK INSERT
Mission Control Level 1-2-3
Blood Gas and Electrolyte Analyzer
DD-92123

Manufacturer and Product Information

Diamond Diagnostics Inc., 333 Fiske Street, Holliston, MA. 01746 USA
For Technical Assistance call:
Diamond Diagnostics Technical Services at 1-508-429-0450

Intended Use: MISSION CONTROL™ Level 1-2-3, DD-92123, Blood Gas and Electrolyte Control is an assayed quality control material intended for monitoring the measurements of pH pCO2, pO2 in blood gas analyzers and sodium, potassium, chloride, lithium, ionized calcium and total carbon dioxide in ISE electrolyte analyzers.

Summary And Principle: This product is intended to serve as a functional equivalent to pre-existing material distributed by the Original Equipment Manufacturer (OEM). Diamond Diagnostics calibrators have defined electrolyte concentrations that provide internal calibration points against which samples are measured by direct Ion Selective Electrode Methods.

Contents: Buffered solution of electrolytes (Na+, K+, Cl-, Ca++, Li+, HCO3-/CO3-2). It has been equilibrated with specific levels of CO2, O2, and N2. This control contains no human-based materials.

For *in vitro* diagnostic use only

Cautions: Exercise normal laboratory precautions. If contact occurs with skin, rinse affected area with water. If contact with eyes occurs, immediately rinse with copious amount of clean water or eye rinse. In cases of accidental ingestion, contact a physician immediately.

Stability: Package stability (expiration date) is listed on the product label. Do not use open or closed reagent beyond this date. Store upright at room temperature, 18°-25 °C.

Procedure

Procedure: The product is manufactured in a ready to use form. It is intended to serve as a direct replacement to pre existing materials distributed by the OEM. For a detailed description of the use of this material, refer to the Instrument Operator's Manual.

Quality Control: Diamond Diagnostics suggests the use of commercially available control material with results assayed for the instrument used. Controls should be run at Normal and Abnormal levels. Diamond Diagnostics suggests measuring controls before patient samples are run and following instrument maintenance.

Limitations

Limitations: If the instrument fails calibration or controls do not measure within acceptable range when Diamond Diagnostics products are used, Diamond Diagnostics suggests the following:

Verify that the internal calibrators used to standardize the instrument are correct for the instrument, have adequate expiration, and do not contain visually evident contamination.

Follow the procedures delineated within the Operator's Manual listed under Troubleshooting.

Ensure that all appropriate Maintenance Procedures, as listed in the Operator's Manual, have been performed.

CE

If problems still exist, contact Diamond Diagnostics' Technical Service Department.

DIAMOND®
DIAGNOSTICS

PACK INSERT
Fluid Pack
Diamond PROLYTE, Menarini SpotLyte, IL ILyte Electrolyte Analyzers
IL-2121D & MN-2121D

Manufacturer and Product Information

Diamond Diagnostics, 333 Fiske Street, Holliston, MA.
For Technical Assistance call:
Diamond Diagnostics Technical Service at 1-508-429-0450

Intended Use: To provide calibration points for Na^+, K^+, Cl^- and Li^+ electrodes.

Summary And Principle: This product is intended to serve as a functional equivalent to pre-existing material distributed by the Original Equipment Manufacturer (OEM). Diamond Diagnostics calibrators have defined electrolyte concentrations which provide internal calibration points against which samples are measured.

Reagents: MN-2121D (Na/K, Na/K/Cl, Na/K/Li, 800 mL Pack)
IL-2121D (Na/K, Na/K/Cl, Na/K/Li, 800 mL Pack)

Containing:
- Standard A: 140 mmol/L Na^+, 4.0 mmol/L K^+, 125 mmol/L Cl^-, 1 mmol/L Li^+, buffer and preservative
- Standard B: 35 mmol/L Na^+, 16.0 mmol/L K^+, 41 mmol/L Cl^-, 0.4 mmol/L Li^+, buffer and preservative
- Wash: 0.1 mol/L Ammonium Biflouride
- Waste Container

For *in vitro* diagnostic use only

Values Assignment: Each calibration standard is tested for each calibrating analyte. Reference is made to either an aqueous standard made with corresponding analyte NIST (National Institute of Standards and Technology) material or the OEM Calibrator.

Cautions: Exercise normal laboratory precautions. If contact occurs with skin, rinse affected area with water. If contact with eyes occurs, immediately rinse with copious amounts of clean water or eye rinse. In cases of accidental ingestion, contact a physician immediately.

Stability: Package stability (expiration date) is listed on the product label. Do not use open or closed reagent beyond this date. Store upright at room temperature, 18°- 25 °C.

Procedure

Procedure: The product is manufactured in a ready to use form. It is intended to serve as a direct replacement to pre-existing materials distributed by the OEM. For a detailed description of the use of this reagent, refer to the Instrument's Operator Manual.

Quality Control: Diamond Diagnostics suggests the use of commercially available control material with results assayed for the instrument used. Controls should be run at Normal and Abnormal levels. Diamond Diagnostics suggests measuring controls before patient samples are run and following instrument maintenance.

Limitations

Limitations: If the instrument fails calibration or controls do not measure within acceptable range when Diamond Diagnostics products are used, Diamond Diagnostics suggests the following:

Verify that the reagents and internal calibrators used to standardize the instrument are correct for the instrument, have adequate expiration, and do not contain visually evident contamination.

Follow the procedures delineated within the Operator's Manual listed under Troubleshooting.

Ensure that all appropriate Maintenance Procedures, as listed in the Operator's Manual, have been performed.

If problems still exist, contact Diamond Diagnostics' Technical Service Department.

CE

DIAMOND®
DIAGNOSTICS

PACK INSERT
800mL Na/K/Ca/pH Pack
MEDICA EasyLyte or IL ILyte Analyzers
ME-2123D & IL-2123D

Manufacturer and Product Information

Diamond Diagnostics, 333 Fiske Street, Holliston, MA.
For Technical Assistance call:
Diamond Diagnostics Technical Services at 1-508-429-0450

Intended Use: To provide calibration points for Na^+, K^+, Ca^{++} & pH electrodes.

Summary And Principle: This product is intended to serve as a functional equivalent to pre existing material distributed by the Original Equipment Manufacturer (OEM). Diamond Diagnostic calibrators have defined electrolyte concentrations which provide internal calibration points against which samples are measured.

Reagents: Na/K/Ca/pH Fluid Pack, ME-2123D, 800 mL
Na/K/Ca/pH Fluid Pack, IL-2123D, 800 mL

Containing:
- Standard A: 145 mmol/L Na, 4.0 mmol/L K, 1.25 mmol/L Ca buffer for a pH of 7.40 and preservative
- Standard B: 80 mmol/L Na, 10.0 mmol/L K, 2.20 mmol/L Ca buffer for a pH of 6.80 and preservative
- Wash: 0.1 mol/L Ammonium Biflouride

For *in vitro* diagnostic use only

Values Assignment: Each calibration standard is tested for each calibrating analyte. Reference is made to either an aqueous standard made with corresponding analyte NIST (National Institute of Standards and Technology) material or the OEM Calibrator.

Cautions: Exercise normal laboratory precautions. If contact occurs with skin, rinse affected area with water. If contact with eyes occurs, immediately rinse with copious amounts of clean water or eye rinse. In cases of accidental ingestion, contact a physician immediately.

Stability: Package stability (expiration date) is listed on the product label. Do not use open or closed reagent beyond this date. Store upright at room temperature, 18°-25 °C.

Procedure

Procedure: The product is manufactured in a ready to use form. It is intended to serve as a direct replacement to pre-existing materials distributed by the OEM. For a detailed description of the use of this reagent, refer to the Instrument's Operator Manual.

Quality Control: Diamond Diagnostics suggests the use of commercially available control material with results assayed for the instrument used. Controls should be run at Normal and Abnormal levels. Diamond Diagnostics suggests measuring controls before patient samples are run and following instrument maintenance.

Limitations

Limitations: If the instrument fails calibration or controls do not measure within acceptable range when Diamond Diagnostics products are used, Diamond Diagnostics suggests the following:

Verify that the reagents and internal calibrators used to standardize the instrument are correct for the instrument, have adequate expiration, and do not contain visually evident contamination.

Follow the procedures delineated within the Operator's Manual listed under Troubleshooting.

Ensure that all appropriate Maintenance Procedures, as listed in the Operator's Manual, have been performed.

If problems still exist, contact Diamond Diagnostics' Technical Service Department.

CE

DIAMOND®
DIAGNOSTICS

PACK INSERT
Flush Solution
Diamond, ILyte, Menarini Analyzers
ME-2309D

Manufacturer and Product Information

Diamond Diagnostics, 333 Fiske Street, Holliston, MA.
For Technical Assistance call:
Diamond Diagnostics Technical Services at 1-508-429-0450

Intended Use: Diamond Flush Solution is intended for in-vitro diagnostics use clean the fluid path on the analyzer.

Summary And Principle: This product is intended to serve as a functional equivalent to pre existing material distributed by the Original Equipment Manufacturer (OEM).

Reagents: 0.1 mol/L Ammonium Bifluoride

For *in vitro* diagnostic use only

Values Assignment: Each calibration standard is tested for each calibrating analyte. Reference is made to either an aqueous standard made with corresponding analyte NIST (National Institute of Standards and Technology) material or the OEM Calibrator.

Cautions: Exercise normal laboratory precautions. If contact occurs with skin, rinse affected area with water. If contact with eyes occurs, immediately rinse with copious amounts of clean water or eye rinse. In cases of accidental ingestion, contact a physician immediately.

Stability: Package stability (expiration date) is listed on the product label. Do not use open or closed reagent beyond this date. Store upright at room temperature, 18°-25 °C.

Procedure

Procedure: The product is manufactured in a ready to use form. It is intended to serve as a direct replacement to pre-existing materials distributed by the OEM. For a detailed description of the use of this reagent, refer to the Instrument's Operator Manual.

Quality Control: Diamond Diagnostics suggests the use of commercially available control material with results assayed for the instrument used. Controls should be run at Normal and Abnormal levels. Diamond Diagnostics suggests measuring controls before patient samples are run and following instrument maintenance.

Limitations

If the instrument fails calibration or controls do not measure within acceptable range when Diamond Diagnostics products are used, Diamond Diagnostics suggests the following:

Verify that the reagents and internal calibrators used to standardize the instrument are correct for the instrument, have adequate expiration, and do not contain visually evident contamination.

Follow the procedures delineated within the Operator's Manual listed under Troubleshooting.

Ensure that all appropriate Maintenance Procedures, as listed in the Operator's Manual, have been performed.

If problems still exist, contact Diamond Diagnostics' Technical Service Department.

CE

DIAMOND®
DIAGNOSTICS

PACK INSERT
Daily Rinse Kit
Diamond PROLYTE, Medica EasyLyte & IL ILyte Analyzers
ME-2118D

Manufacturer and Product Information

Diamond Diagnostics, 333 Fiske Street, Holliston, MA.
For Technical Assistance call:
Diamond Diagnostics Technical Services at 1-508-429-0450

Intended Use: To rinse and clean the sample path.

Summary And Principle: This product is intended to serve as a functional equivalent to pre existing material distributed by the Original Equipment Manufacturer (OEM). Diamond Diagnostic calibrators have defined electrolyte concentrations which provide internal calibration points against which samples are measured.

Reagent Contents: An aqueous solution containing 1 bottle – 100 ml Daily Rinse/Cleaning Diluent, 6 bottles – 0.35 g pepsin/bottle.

For *in vitro* diagnostic use only

Values Assignment: Each calibration standard is tested for each calibrating analyte. Reference is made to either an aqueous standard made with corresponding analyte NIST (National Institute of Standards and Technology) material or the OEM Calibrator.

Cautions: Exercise normal laboratory precautions. If contact occurs with skin, rinse affected area with water. If contact with eyes occurs, immediately rinse with copious amounts of clean water or eye rinse. In cases of accidental ingestion, contact a physician immediately.

Stability: Package stability (expiration date) is listed on the product label. Do not use open or closed reagent beyond this date. Store upright at room temperature, 18°-25 °C.

Procedure

Procedure: The product is manufactured in a ready to use form. It is intended to serve as a direct replacement to pre-existing materials distributed by the OEM. For a detailed description of the use of this reagent, refer to the Instrument's Operator Manual.

Quality Control: Diamond Diagnostics suggests the use of commercially available control material with results assayed for the instrument used. Controls should be run at Normal and Abnormal levels. Diamond Diagnostics suggests measuring controls before patient samples are run and following instrument maintenance.

Limitations

Limitations:

If the instrument fails calibration or controls do not measure within acceptable range when Diamond Diagnostics products are used, Diamond Diagnostics suggests the following:

Verify that the reagents and internal calibrators used to standardize the instrument are correct for the instrument, have adequate expiration, and do not contain visually evident contamination.

Follow the procedures delineated within the Operator's Manual listed under Troubleshooting.

Ensure that all appropriate Maintenance Procedures, as listed in the Operator's Manual, have been performed.

If problems still exist, contact Diamond Diagnostics' Technical Service Department.

CE

DIAMOND®
DIAGNOSTICS

PACK INSERT
800mL, Na/K/Cl Pack
MEDICA EasyLyte Analyzers
ME-2121D

Manufacturer and Product Information

Diamond Diagnostics, 333 Fiske Street, Holliston, MA.
For Technical Assistance call:
Diamond Diagnostics Technical Services at 1-508-429-0450

Intended Use: To provide calibration points for Na^+, K^+ and Cl- electrodes.

Summary And Principle: This product is intended to serve as a functional equivalent to pre existing material distributed by the Original Equipment Manufacturer (OEM). Diamond Diagnostic calibrators have defined electrolyte concentrations which provide internal calibration points against which samples are measured.

Reagents: Na/K/Cl Fluid Pack, ME-2121D, 800 mL

Containing:
- Standard A: 140 mmol/L Na, 4.0 mmol/L K, 125 mmol/L Cl, buffer and preservative
- Standard B: 35 mmol/L Na, 16.0 mmol/L K, 41 mmol/L Cl buffer and preservative
- Wash: 0.1 mol/L Ammonium Biflouride
- Waste Container

For *in vitro* diagnostic use only

Values Assignment: Each calibration standard is tested for each calibrating analyte. Reference is made to either an aqueous standard made with corresponding analyte NIST (National Institute of Standards and Technology) material or the OEM Calibrator.

Cautions: Exercise normal laboratory precautions. If contact occurs with skin, rinse affected area with water. If contact with eyes occurs, immediately rinse with copious amounts of clean water or eye rinse. In cases of accidental ingestion, contact a physician immediately.

Stability: Package stability (expiration date) is listed on the product label. Do not use open or closed reagent beyond this date. Store upright at room temperature, 18°-25 °C.

Procedure

Procedure: The product is manufactured in a ready to use form. It is intended to serve as a direct replacement to pre-existing materials distributed by the OEM. For a detailed description of the use of this reagent, refer to the Instrument's Operator Manual.

Quality Control: Diamond Diagnostics suggests the use of commercially available control material with results assayed for the instrument used. Controls should be run at Normal and Abnormal levels. Diamond Diagnostics suggests measuring controls before patient samples are run and following instrument maintenance.

Limitations

Limitations: **This Fluid Pack is not intended for use on instruments with SN# 27000 or higher.**

If the instrument fails calibration or controls do not measure within acceptable range when Diamond Diagnostics products are used, Diamond Diagnostics suggests the following:

Verify that the reagents and internal calibrators used to standardize the instrument are correct for the instrument, have adequate expiration, and do not contain visually evident contamination.

Follow the procedures delineated within the Operator's Manual listed under Troubleshooting.

Ensure that all appropriate Maintenance Procedures, as listed in the Operator's Manual, have been performed.

If problems still exist, contact Diamond Diagnostics' Technical Service Department.

CE

DIAMOND®
DIAGNOSTICS

PACK INSERT
800mL Na/K/Ca/pH Pack
MEDICA EasyLyte or IL ILyte Analyzers
ME-2123D & IL-2123D

Manufacturer and Product Information

Diamond Diagnostics, 333 Fiske Street, Holliston, MA.
For Technical Assistance call:
Diamond Diagnostics Technical Services at 1-508-429-0450

Intended Use: To provide calibration points for Na^+, K^+, Ca^{++} & pH electrodes.

Summary And Principle: This product is intended to serve as a functional equivalent to pre existing material distributed by the Original Equipment Manufacturer (OEM). Diamond Diagnostic calibrators have defined electrolyte concentrations which provide internal calibration points against which samples are measured.

Reagents: Na/K/Ca/pH Fluid Pack, ME-2123D, 800 mL
Na/K/Ca/pH Fluid Pack, IL-2123D, 800 mL

Containing:
- Standard A: 145 mmol/L Na, 4.0 mmol/L K, 1.25 mmol/L Ca buffer for a pH of 7.40 and preservative
- Standard B: 80 mmol/L Na, 10.0 mmol/L K, 2.20 mmol/L Ca buffer for a pH of 6.80 and preservative
- Wash: 0.1 mol/L Ammonium Biflouride

For *in vitro* diagnostic use only

Values Assignment: Each calibration standard is tested for each calibrating analyte. Reference is made to either an aqueous standard made with corresponding analyte NIST (National Institute of Standards and Technology) material or the OEM Calibrator.

Cautions: Exercise normal laboratory precautions. If contact occurs with skin, rinse affected area with water. If contact with eyes occurs, immediately rinse with copious amounts of clean water or eye rinse. In cases of accidental ingestion, contact a physician immediately.

Stability: Package stability (expiration date) is listed on the product label. Do not use open or closed reagent beyond this date. Store upright at room temperature, 18°-25 °C.

Procedure

Procedure: The product is manufactured in a ready to use form. It is intended to serve as a direct replacement to pre-existing materials distributed by the OEM. For a detailed description of the use of this reagent, refer to the Instrument's Operator Manual.

Quality Control: Diamond Diagnostics suggests the use of commercially available control material with results assayed for the instrument used. Controls should be run at Normal and Abnormal levels. Diamond Diagnostics suggests measuring controls before patient samples are run and following instrument maintenance.

Limitations

Limitations: If the instrument fails calibration or controls do not measure within acceptable range when Diamond Diagnostics products are used, Diamond Diagnostics suggests the following:

Verify that the reagents and internal calibrators used to standardize the instrument are correct for the instrument, have adequate expiration, and do not contain visually evident contamination.

Follow the procedures delineated within the Operator's Manual listed under Troubleshooting.

Ensure that all appropriate Maintenance Procedures, as listed in the Operator's Manual, have been performed.

If problems still exist, contact Diamond Diagnostics' Technical Service Department.

CE

PACK INSERT
Urine Diluent
Diamond, AVL pH/Blood Gas Analyzers
AV-BP0344D

Manufacturer and Product Information

Diamond Diagnostics, 333 Fiske Street, Holliston, MA.
For Technical Assistance call:
Diamond Diagnostics Technical Services at 1-508-429-0450

Intended Use: Diamond Urine Diluent is intended for in-vitro diagnostics use to dilute Urine samples.

Summary And Principle: This product is intended to serve as a functional equivalent to pre existing material distributed by the Original Equipment Manufacturer (OEM).

Reagents: Aqueous Solution

Containing: An aqueous solution containing 120 mmol/L Na+, 128 mmol/L Cl-, buffer and preservative.

For *in vitro* diagnostic use only

Values Assignment: Each calibration standard is tested for each calibrating analyte. Reference is made to either an aqueous standard made with corresponding analyte NIST (National Institute of Standards and Technology) material or the OEM Calibrator.

Cautions: Exercise normal laboratory precautions. If contact occurs with skin, rinse affected area with water. If contact with eyes occurs, immediately rinse with copious amounts of clean water or eye rinse. In cases of accidental ingestion, contact a physician immediately.

Stability: Package stability (expiration date) is listed on the product label. Do not use open or closed reagent beyond this date. Store upright at room temperature, 18°-25 °C.

Procedure

Procedure: The product is manufactured in a ready to use form. It is intended to serve as a direct replacement to pre-existing materials distributed by the OEM. For a detailed description of the use of this reagent, refer to the Instrument's Operator Manual.

Quality Control: Diamond Diagnostics suggests the use of commercially available control material with results assayed for the instrument used. Controls should be run at Normal and Abnormal levels. Diamond Diagnostics suggests measuring controls before patient samples are run and following instrument maintenance.

Limitations

If the instrument fails calibration or controls do not measure within acceptable range when Diamond Diagnostics products are used, Diamond Diagnostics suggests the following:

Verify that the reagents and internal calibrators used to standardize the instrument are correct for the instrument, have adequate expiration, and do not contain visually evident contamination.

Follow the procedures delineated within the Operator's Manual listed under Troubleshooting.

Ensure that all appropriate Maintenance Procedures, as listed in the Operator's Manual, have been performed.

If problems still exist, contact Diamond Diagnostics' Technical Service Department.

CE

DIAMOND®
DIAGNOSTICS

PACK INSERT
Fluid Pack
Diamond PROLYTE, Menarini SpotLyte, IL ILyte Electrolyte Analyzers
IL-2121D & MN-2121D

Manufacturer and Product Information

Diamond Diagnostics, 333 Fiske Street, Holliston, MA.
For Technical Assistance call:
Diamond Diagnostics Technical Service at 1-508-429-0450

Intended Use: To provide calibration points for Na^+, K^+, Cl^- and Li^+ electrodes.

Summary And Principle: This product is intended to serve as a functional equivalent to pre-existing material distributed by the Original Equipment Manufacturer (OEM). Diamond Diagnostics calibrators have defined electrolyte concentrations which provide internal calibration points against which samples are measured.

Reagents: MN-2121D (Na/K, Na/K/Cl, Na/K/Li, 800 mL Pack)
IL-2121D (Na/K, Na/K/Cl, Na/K/Li, 800 mL Pack)

Containing:
- Standard A: 140 mmol/L Na^+, 4.0 mmol/L K^+, 125 mmol/L Cl^-, 1 mmol/L Li^+, buffer and preservative
- Standard B: 35 mmol/L Na^+, 16.0 mmol/L K^+, 41 mmol/L Cl^-, 0.4 mmol/L Li^+, buffer and preservative
- Wash: 0.1 mol/L Ammonium Biflouride
- Waste Container

For *in vitro* diagnostic use only

Values Assignment: Each calibration standard is tested for each calibrating analyte. Reference is made to either an aqueous standard made with corresponding analyte NIST (National Institute of Standards and Technology) material or the OEM Calibrator.

Cautions: Exercise normal laboratory precautions. If contact occurs with skin, rinse affected area with water. If contact with eyes occurs, immediately rinse with copious amounts of clean water or eye rinse. In cases of accidental ingestion, contact a physician immediately.

Stability: Package stability (expiration date) is listed on the product label. Do not use open or closed reagent beyond this date. Store upright at room temperature, 18°- 25 °C.

Procedure

Procedure: The product is manufactured in a ready to use form. It is intended to serve as a direct replacement to pre-existing materials distributed by the OEM. For a detailed description of the use of this reagent, refer to the Instrument's Operator Manual.

Quality Control: Diamond Diagnostics suggests the use of commercially available control material with results assayed for the instrument used. Controls should be run at Normal and Abnormal levels. Diamond Diagnostics suggests measuring controls before patient samples are run and following instrument maintenance.

Limitations

Limitations: If the instrument fails calibration or controls do not measure within acceptable range when Diamond Diagnostics products are used, Diamond Diagnostics suggests the following:

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Follow the procedures delineated within the Operator's Manual listed under Troubleshooting.

Ensure that all appropriate Maintenance Procedures, as listed in the Operator's Manual, have been performed.

If problems still exist, contact Diamond Diagnostics' Technical Service Department.

CE