

REF 48559

IVD 15°C 30°C CE

Stat Profile® pHox Ultra/Critical Care Xpress CO-Oximeter Calibrator Cartridge with Bilirubin and Deproteinizing Solution

Kalibrator-Patrone mit Bilirubin und Deproteinisierungslösung, Πλακέτα θερμονομητή με χολερυθίνη και διάλυμα αποπρωτεΐνισμού, Cartucho de calibrador con bilirrubina y solución desproteinizante, Cartouche de calibrateur avec bilirubine et solution de déprotéinisation, Cartuccia calibratore con bilirubina e soluzione deproteinizzante, Cartucho de calibrador com solução de desproteinização e bilirrubina, ビリルビンおよび除蛋白液付きキャリブレータ・カートリッジ, Calibrator Cartridge 와 빌리루빈 및 단백질 제거액, 含有胆红素和去蛋白溶液的定标品盒

LOT 24004059

2025-01-04

tHb CALIBRATOR ≥70mL	DIL ≥180mL	SOLN F ≥620mL	Deproteinizing Solution ≥90mL	WASTE CONTAINER W
Dye, Viscosity Enhancers, Preservatives in an Aqueous Salt Solution. Farbstoff, Viskositätsverstärker, Konservierungsmittel in einer wässrigen Salzlösung. Χρωστικό, ενισχυτικά ιώδη ρύπανσης σε ένα οιδικό υγρό. Colorant, viscosity enhancers in solution salt in aqueous. Colorant, mejoradores de la viscosidad, conservantes en solución salina acuosa. Colorant, activadores de la viscosidad, agentes de conservación en solución en agua salina.	Colorante, migratori della viscosità, conservanti in soluzione salina acuosa. Corriente, intensificadores de viscosidad, conservantes en solución salina acuosa. 색소 및 윤활제, 염색제, 염화물 용액(�액ous Salt Solution)의 염료, 침침 강제제, 염부제.	Deionized Water, Surfactant, Buffers, Preservatives, Deionat, Tensid, Puffer, Konservierungsmittel, Αποιωνισμένο νερό, επιφανειοδραστικό μέσο, ρυθμιστικά διαλύματα, συντηρητικά, Agua desionizada, surfactante, tampones, conservantes, Eau désionisée, agent de surface, tampons, agents de conservation, Acqua deionizzata, surfattante, tamponi, conservanti, Água desionizada, Surfactante, Tampões, Conservantes.	Deionized Water, Surfactant, Preservatives, Deionat, Tensid, Konservierungsmittel, Αποιωνισμένο νερό, επιφανειοδραστικό μέσο, συντηρητικά, Agua desionizada, surfactante, conservantes, Eau désionisée, agent de surface, agents de conservation, Acqua deionizzata, surfattante, conservanti, Água desionizada, Surfactante, Conservantes,	Deproteinizing Solution Deproteinisierungslösung Διάλυμα αποπρωτεΐνισμού Solução de desproteinização Solution de déprotéinisation Soluzione deproteinizzante Solução de desproteinização 除蛋白液 단백질 제거액 去蛋白溶液
Units	X			
g/dL	16.1			
g/L	161			
mmol/L	10.0			
Colorante, migratori della viscosità, conservanti in soluzione salina acuosa. Corriente, intensificadores de viscosidad, conservantes en solución salina acuosa. 색소 및 윤활제, 염색제, 염화물 용액(�액ous Salt Solution)의 염료, 침침 강제제, 염부제.	Deionized Water, Surfactant, Buffers, Preservatives, Deionat, Tensid, Puffer, Konservierungsmittel, Αποιωνισμένο νερό, επιφανειοδραστικό μέσο, ρυθμιστικά διαλύματα, συντηρητικά, Agua desionizada, surfactante, tampones, conservantes, Eau désionisée, agent de surface, tampons, agents de conservation, Acqua deionizzata, surfattante, tamponi, conservanti, Água desionizada, Surfactante, Tampões, Conservantes.	Deionized Water, Surfactant, Preservatives, Deionat, Tensid, Konservierungsmittel, Αποιωνισμένο νερό, επιφανειοδραστικό μέσο, συντηρητικά, Agua desionizada, surfactante, conservantes, Eau désionisée, agent de surface, agents de conservation, Acqua deionizzata, surfattante, conservanti, Água desionizada, Surfactante, Conservantes,	Deproteinizing Solution Deproteinisierungslösung Διάλυμα αποπρωτεΐνισμού Solução de desproteinização Solution de déprotéinisation Soluzione deproteinizzante Solução de desproteinização 除蛋白液 단백질 제거액 去蛋白溶液	NaOCl 0.4 mol/L

Description

For use in calibrating the CO-Oximeter on the Stat Profile pHox Ultra/Critical Care Xpress (CCX) Analyzer. The above table lists the concentrations of the constituents for the calibrator flush, deproteinizing and diluent solutions contained in the Calibrator Cartridge. Contains the following aqueous solutions with individual bagged bags placed in a cardboard box: flush solution, deproteinizing solution, diluent, and a flexible waste bag. The exposed bag flaps are arranged in a line along the rear of the cartridge box. The septa are pierced during the insertion of the cartridge into the analyzer.

Indented Use

For the quantitative determination of total hemoglobin, oxyhemoglobin, carboxyhemoglobin, methemoglobin, deoxyhemoglobin, and total bilirubin in human blood using the Stat Profile pHox Ultra/Critical Care Xpress CO-Oximeter Analyzer.

Methodology

Refer to Stat Profile pHox Ultra/Critical Care Xpress Analyzer Instructions for Use Manual for Test Methodologies and Principles.

Composition

Solution volumes are listed in the table above. Contains no constituents of human origin, however good laboratory practice should be followed during handling of these materials. (REF. NCLS DOCUMENT M29-T2).

Warnings and Caution

Intended for in vitro diagnostic use. Refer to the Stat Profile pHox Ultra/Critical Care Xpress Analyzer Instructions for Use Manual for complete directions for installation of the cartridge. Follow all laboratory practices for handling laboratory reagents. Discard Calibrator Cartridges in accordance with local guidelines. Waste bag contains Preservative (eye, skin and respiratory irritant).

Storage

Store at 15°C - 30°C. Expiration date is printed on the front of the cartridge.

Directions for Use

Refer to the Stat Profile pHox Ultra/Critical Care Xpress Analyzer Instructions for Use Manual for complete directions for installation of the cartridge. Cartridge is ready for use.

Limitations

For use on Nova Biomedical Analyzers only.

If not stored at room temperature and out of direct sunlight, the solution may deteriorate. Indications of deterioration may be high or low of range control values or a noticeable change in coloration or both. Cloudiness or particulate matter may be a sign of possible deterioration.

This product is warranted to perform as described in this product insert, and Nova Biomedical disclaims any liability or merchantability or fitness for any other purpose, and in no event shall Nova Biomedical be liable for any consequential damages arising out of the aforesaid expressed warranty.

Traceability of Standards

Traceable to precise hemoglobin measurement using the reference cyanmethemoglobin method.

Reference

ICSH, Recommendations for Haemoglobinometry in Human Blood. British Journal of Haematology, 13 (suppl) pp 71-75, 1967.

Beschreibung

Zur Vorbereitung beim Kalibrieren des CO-Oximeters im Stat Profile pHox Ultra/Critical Care Xpress (CCX) Analyzer. Die obige Tabelle zeigt die Bestandteilkonzentrationen für den Flusshahn, Deproteinisierung und Verdünnungslösungen, die im Kalibrator-Kartuschen enthalten sind. Enthält die folgenden wässrigen Lösungen: Spülung, Verdunstern, Deproteinisierung, Kalibrator sowie entsprechende Entzerrungslösungen. Die folgenden Einzelheiten im Karton verpackten wässrigen Lösungen: Spülung, Verdunstern, Deproteinisierung, Kalibrator sowie entsprechende Entzerrungslösungen. Die entsprechenden Beutelabschlüsse sind rückseitig am Patronenbehälter aufgerollt. Beim Einfügen der Patrone in den Analyzer werden die Septa durchtrennt.

Aufbewahrung

Zur quantitativen Bestimmung der Gesamthämoglobin, Oxyhämoglobin, Carboxyhämoglobin, Methemoglobin, Deoxyhämoglobin und Gesamt-Bilirubin im menschlichen Blut unter Verwendung des Stat Profile pHox Ultra/Critical Care Xpress CO-Oximeter Analytors.

Methodik

Siehe Testmethodik und -prinzip im Anleitungshandbuch für den Stat Profile pHox Ultra/Critical Care Xpress Analyzer.

Zusammensetzung

Die Lösungsvolumen sind in der oben Tabelle angegeben. Enthält keine Bestandteile menschlichen Ursprungs, doch ist bei Handhabung dieser Materialien unter Einhaltung guter Labortypen zu verfahren. (s. NCLS DOKUMENT M29-T2).

Warn- und Vorsichtshinweise

Nur für In-Vivo-Diagnose vorgesehen. Siehe komplette Anweisungen im Anleitungshandbuch für den Stat Profile pHox Ultra/Critical Care Xpress Analyzer. Beim Umgang mit Laborreagenzien ist die übliche Laborhandhabung einzuhalten. Die Kalibrator-Patronen sind genau den örtlichen Vorschriften zu entsprechen. Der Abfallbeutel enthält Konservierungsmittel (Augen-, Haut- und Atemwegs-Reizstoff).

Lagerung

Bei 15°C - 30°C lagern. Das Verfallsdatum ist vorne an der Patrone vermerkt.

Gebrauchsanleitung

Siehe komplette Patronen-Einbauanweisungen im Benutzerhandbuch für den Stat Profile pHox Ultra/Critical Care Xpress Analyzer. Die Patrone ist verwendungsbereit.

Einschränkungen

Ausschließlich zur Verwendung mit Nova Biomedical Analytoren.

Wird die Lösung nicht bei Raumtemperatur und vor direkter Sonneninstrahlung geschützt gelagert, kann sie verderben. Verfallsanzeichen bestehen z.B. aus Bereichsüber- oder unterschreitenden Kontrollwerten und/oder einer wahrnehmbaren Eichabweichung. Trübung oder Partikel deutet auf möglichen Vorfall.

Dieses Produkt unterliegt einer Leistungsgarantie entsprechend den Angaben in diesem Beilogg. Nova Biomedical stellt keinerlei gefolgte oder stöchiometrische Garantie oder Gewährleistung für Maßnahmen oder Eignung für andere Zwecke und auf Nebenfall. Fall ist Nova Biomedical haftbar für Folgeschäden aus der Vorgehensweise aus derartigen Garantien.

Nachweisbarkeit von Eichnormen

Nachweisbar genauer Hämoglobinmessung unter Anwendung des Cyanmethemoglobin-Verfahrens.

Bezugschrift

ICSH, Empfehlungen für Hämoglobinmetrie im menschlichen Blut. British Journal of Haematology, 13 (Nachr.) S. 71-75, 1967.

Properties

For use in calibrating the CO-Oximeter on the analisys STP pHox Ultra/Critical Care Xpress (CCX). Το πλακέτα πίνακας περιέχει τις συγκεντρώσεις των συστατικών για το θερμονομητή, τα διάλυμα αποπρωτεΐνισμού και συστατικού που βρίσκεται στα πλακέτα πίνακας. Η πλακέτα πίνακας περιέχει τις συγκεντρώσεις των συστατικών για την πλακέτα πίνακας εκμετάλλευσης ακόμα και σε ένα φάρμακο. Βιδούλια εκκίνησης διάλυμα αποπρωτεΐνισης και (και εύκαρπος) άλικος απορρυπάντιμος. Το εκτιθέμενα εξαρτώματα είναι εύα. Επιπλέοντα σε στατικά κατά μήκος του πινόνιου των ποντικών του πλακέτα πίνακα. Το διαστηματικό διατύπωμα είναι στην επιφάνεια του πλακέτα πίνακα.

Storage conditions

For the quantitative determination of total hemoglobin, Oxyhemoglobin, Carboxyhemoglobin, Methemoglobin, Deoxyhemoglobin, and Total Bilirubin in human blood using the Stat Profile pHox Ultra/Critical Care Xpress CO-Oximeter Analyzer.

Methodology

According to the instructions for use of the Stat Profile pHox Ultra/Critical Care Xpress CO-Oximeter Analyzer.

Composition

The contents of the table above. Contains no constituents of human origin, however good laboratory practice should be followed during handling of these materials. (REF. NCLS DOCUMENT M29-T2).

Warnings and Caution

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