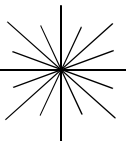


ABBOTT

CELL-DYN SYSTEM



RETICULOCYTE REAGENT

Retikulozytenreagenz / Réactif réticulocytes

Reactivo de reticulocitos / Reagente per reticolociti

REF 03H40-01

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PN 9155192A

NOTES

NAMECELL-DYN **RETICULOCYTE REAGENT****INTENDED USE****IVD** For in vitro diagnostic use.

CELL-DYN **RETICULOCYTE REAGENT** when used in combination with CELL-DYN Ruby CELL-DYN 3200, or CELL-DYN 3700 reticulocyte software, enables a whole blood specimen to be analyzed for reticulocytes.

SUMMARY AND EXPLANATION OF THE TEST

Reticulocytes are defined as transitional red cells between nucleated red cells and the so-called mature erythrocytes^[1]. The CELL-DYN reticulocyte assay enables determination of the percentage of reticulocytes using a whole blood specimen. If an RBC count is available, a reticulocyte absolute number is also derived. The method is based on light scatter measurements of stained cells.

BIOPHYSICAL AND BIOCHEMICAL PRINCIPLES OF THE PROCEDURE

In contrast to mature RBCs, reticulocytes contain ribosomal RNA. This RNA can be seen with certain supravital, cationic dyes that simultaneously stain and precipitate the polyanion to form a network or reticulum^[2]. The CELL-DYN Ruby, CELL-DYN 3200, and CELL-DYN 3700 reticulocyte method uses the thiazine dye New Methylene Blue N. Sample preparation is performed manually by diluting a small volume of blood into the pre-measured staining solution. At room temperature, staining of reticulum is complete within approximately 15 minutes. The stained sample is aspirated in the Open Mode and analyzed in the WBC Optical Count (WOC) channel. After the stained sample is aspirated, it is diluted with Reagent (WBC Lyse for CELL-DYN Ruby and CELL-DYN 3200 or Sheath for CELL-DYN 3700). Once diluted, the RBCs sphere due to the influence of the nonionic detergent incorporated into the staining solution. Sphering is necessary to eliminate optical orientational noise that would otherwise be introduced into the scatter measurements^[3]. The usual lytic action of the reagent (WBC Lyse for CELL-DYN Ruby and CELL-DYN 3200 or Sheath for CELL-DYN 3700) is prevented by electrolytes contained in the staining solution and the lack of the usual incubation period used in this channel during WBC analysis. Also the high New Methylene Blue concentration in the staining reagent exerts a stabilizing effect on RBCs.

During data acquisition, 0, 10, and 90 degree scatter are collected for up to 30,000 events. The 0 degree threshold is set high enough to exclude most platelets. Histogram data are used to differentiate reticulocytes, mature RBCs, platelet clumps and nucleated cells. Reticulocytes have similar 10 degree scatter to mature RBCs, but differ from them by exhibiting greater 90 degree scatter.

REAGENT

100 Tubes (3.7mL each) CELL-DYN Reticulocyte Reagent: Phosphate buffered saline solution containing New Methylene Blue, potassium oxalate and n-dodecyl β -D-maltoside. Preservative: Antimicrobial agent.

WARNINGS AND PRECAUTIONS**IVD** In Vitro Diagnostic Medical Device.**CAUTION:**


This product requires the handling of human specimens. It is recommended that all human sourced materials be considered potentially infectious and handled in accordance with the OSHA Standard on Bloodborne Pathogens^[6], Biosafety Level 2^[7] or other appropriate biosafety practices^{[8],[9]} should be used for materials that contain or are suspected of containing infectious agents.

Safety Data Sheets are available at www.abbottdiagnostics.com or contact your local representative.

Handling Precautions**CAUTION:**

When using the reticulocyte reagent, avoid contact with skin and clothing. This reagent contains New Methylene Blue, which will stain skin, clothing, and many other surfaces.

Storage Instructions

 Do not place in the refrigerator. For long term storage protect from light.

PROCEDURE**Instrument Requirements**

The following software revisions must be installed on the CELL-DYN Ruby, CELL-DYN 3200, or CELL-DYN 3700 prior to performing the reticulocyte analysis:

CELL-DYN Ruby: Version 1.0 or higher.
CELL-DYN 3200: Version 2.0 or higher.
CELL-DYN 3700: Version 1.1 or higher.

Please contact your local Abbott representative if your CELL-DYN System is not using one of these versions or higher.

Materials Provided

REF 03H40-01 CELL-DYN Reticulocyte Reagent Kit, containing: 100 reticulocyte reagent tubes.

Materials Required but not provided

- CELL-DYN Reticulocyte Controls (Refer to the instrument specific CELL-DYN Systems Operator's Manual for list numbers of reticulocyte control products.)
- Pipettor Eppendorf type
- Pipettor tips
- Timer
- Tube rocker (optional)
- Tube rack
- Marker pen

Abbott Laboratories

CELL-DYN **RETICULOCYTE REAGENT**

Sample Collection

Use only whole blood specimens anticoagulated with EDTA. Do not run hemolyzed specimens, as hemolysis may cause inaccurate reticulocyte values.

Specimens may be run up to 8 hours after collection time without refrigeration.

Specimens older than eight (8) hours and up to 72 hours after collection may be processed if they have been stored in the refrigerator during that time. If refrigerated specimens are used, allowing them to come to room temperature before mixing will avoid damage to any fragile cells.

If a specimen is >8 hours old and the CBC was processed on the CELL-DYN System more than 8 hours ago, rerun the specimen to obtain the RBC value and to collect data that will be used during the flagging analysis. (The reticulocyte package will only select RBC values for specimens processed within the last 8 hours.)

For the Absolute Reticulocyte calculation, it is recommended that the RBC value used be selected from the same sample chosen for the Reticulocyte count and that it be run on the same analyzer.

See the appropriate System's Operator's Manual for complete instructions.

Staining Procedure

1. Label a tube of CELL-DYN Reticulocyte Reagent for each patient.
2. Verify that the whole blood specimen is warmed to room temperature and well mixed prior to sampling.
3. Pipette 20 µL of the whole blood specimen into each labeled tube of reticulocyte reagent.
4. Incubate the stained reticulocyte specimens on the tube rocker for 15 minutes or in a rack after fully inverting the stained specimens five (5) times. Incubation must be done at a room temperature of 15°–30°C.

NOTE: The stained reticulocyte specimens (specimen age <8 hours) may incubate for 15 minutes to 2 hours prior to processing on the CELL-DYN System. This timing will allow the reticulocyte specimens to be processed for STAT requests (15 minute incubation plus the one minute run time). Reticulocyte specimens can also be grouped and run in batches provided the 2-hour incubation time limit is not exceeded. For normal specimens, there is no clinically significant difference on samples up to 8 hours old that have been stained from 15 minutes to 2 hours.

The reticulocyte package is available for use only in the Open Sampler Mode.

Reagent Background Count Procedure

For background counts, a tube of reticulocyte reagent is run without an aliquot of whole blood, to check for particulate material in the reagent and system.

Quality Control Procedures

CELL-DYN reticulocyte control materials should be properly warmed and mixed according to the manufacturer's recommendations. Patient reticulocyte controls should be handled according to the laboratory's protocol. Refer to the reticulocyte quality control procedures provided in the appropriate CELL-DYN Operator's Manual.

RESULTS

CELL-DYN Reticulocyte results are acquired using information from the 0, 10, and 90 degree scatter channels. The reticulocytes are differentiated from mature red blood cells due to their scattering in the 90 degree channel. Reticulocytes are reported as a percentage of RBCs. If the RBC value is available, the Absolute Reticulocyte value is also reported.

FLAGS

Information pertaining to flagged results is displayed in the Flags field. For a description of the flags that may appear in this field, refer to the CELL-DYN System Operator's Manual, Reticulocyte Section. If ERL flagging is observed, re-run the sample and decrease incubation time to 15 minutes.

LIMITATIONS OF THE PROCEDURE

The CELL-DYN Ruby, CELL-DYN 3200, and CELL-DYN 3700 Reticulocyte method is a nucleic acid staining method. Therefore, other substances that contain nucleic acids could potentially be enumerated by the instrument as reticulocytes. If these interfering substances are present in sufficient numbers, they may interfere with the dynamic thresholds used to obtain the CELL-DYN reticulocyte count.

The information in the following table, based on NCCLS Document H44-A2^[1], indicates substances that are known or potential interferents. The CELL-DYN Ruby, CELL-DYN 3200, and CELL-DYN 3700 Reticulocyte method is designed to minimize some common interferents, including high WBC counts and NRBCs.

Potentially Interfering Substances

Cellular Elements	Cellular Inclusions	Miscellaneous
Platelet clumps	Howell-Jolly bodies	Abnormal red cells
Basophilic stippling	Heinz bodies	Paraproteins
Giant platelets	Pappenheimer bodies	Cold agglutinins
Leukocytes and leukocyte fragments	Parasites (malaria, babesia)	Platelet/erythrocyte coincidence
Nucleated erythrocytes		Hemolysis

EXPECTED VALUES

Bloods from healthy Abbott employees were tested on CELL-DYN Systems. Distributions of reticulocyte percentage results were calculated. The resultant means and standard deviations were used to determine the 95% normal distribution ranges (± 2 standard deviations). Across the CELL-DYN Systems these ranges were 0.88–2.37% for adults.^[2]

SPECIFIC PERFORMANCE CHARACTERISTICS

Refer to the CELL-DYN Ruby Operator's Manual for the instrument specific system performance results.

- RETC_Background (Count)
- Reproducibility (Precision)
- Analytical Measurement Range
- Comparability (Correlation)
- Carryover

For CELL-DYN 3700 and CELL-DYN 3200 Systems, refer to the performance specifications indicated below:

Background Counts

Daily background counts were run over an extended period using tubes from different lots of CELL-DYN Reticulocyte Reagent. In all cases, the total background count/count cycle did not exceed 100 during the study.

Reticulocyte Background Counts: ≤ 100 Counts

Precision

Replicate precision was quantified by running sets of normal specimens as $N=31$ and $N=20$ replicate runs. Paired precision was also run.

CV $\leq 15.0\%$.

Accuracy

Accuracy specifications are determined by correlation to a reference instrument using specimens from healthy donors and hospital patients. The CELL-DYN 3700 was correlated to the Becton Dickinson FACScan and CELL-DYN 4000 with specimens in the range of 0.1–40%. The CELL-DYN 3200 was correlated to a CELL-DYN 4000 with specimens in the range of 0.5–23%.

Each specimen was run twice ($N=2$) using 15-minute staining reagent incubation times. Multiple lots of CELL-DYN Reticulocyte Reagent were used during the specimen acquisition period. The methods described in the reference were used for the analysis^[4].

Correlation Coefficient ≥ 0.90 .

Linearity

CELL-DYN 3700: Linearity was quantified by running six (6) levels of reticulocyte-containing material prepared by using varying concentrations of two stock preparations. The general method described in the referenced NCCLS Standard^[5] was used. Specifically, six concentration levels were run in quadruplicate, and the method of least-squares regression was used for analysis of the reticulocyte percentage result.

CELL-DYN 3200: Linearity was determined by analyzing dilutions of a linearity material that contained no interfering substances and did not display any suspect parameter flags. Specifications were determined by taking multiple measurements on each dilution. The reticulocyte percentage limits were determined by regression analysis.

Linearity Range

For CELL-DYN 3700:

0–30% $\pm 7\%$ or 1.1 absolute

For CELL-DYN 3200:

0.50–23.00% $\pm 7\%$ or 1.1 absolute

Carryover

Carryover was determined by running samples with high proportions of reticulocytes or high RBC concentrations. Each sample was run in triplicate followed by three background cycles.

Refer to the appropriate CELL-DYN Operator's Manual for the formula to calculate % carryover.

Carryover $\leq 0.5\%$

BIBLIOGRAPHY

- [1] Clinical and Laboratory Standards Institute/NCCLS. *Methods for Reticulocyte Counting (Automated Blood Cell Counters, Flow Cytometry, and Supravital Dyes)*; Approved Guideline—Second Edition. CLSI/NCCLS document H44-A2 [ISBN 1-56238-527-5]. Clinical and Laboratory Standards Institute/NCCLS, 940 West Valley Road, Suite 1400, Wayne, PA, 2004.
- [2] Marshall, PN. *Reticulation, Polychromasia and Stippling of Erythrocytes - Review*. *Microscopica Acta* 1978; 81:89-106.
- [3] Kim, YR, Ornstein, L. *Isovolometric Sphering of Erythrocytes for More Accurate and Precise Cell Volume Measurement by Flow Cytometry*. *Cytometry* 1983; 3:419-427.
- [4] Clinical and Laboratory Standards Institute/NCCLS. *Method Comparison and Bias Estimation Using Patient Samples*; Approved Guideline—Second Edition. CLSI/NCCLS document EP9-A2 [ISBN 1-56238-472-4]. Clinical and Laboratory Standards Institute/NCCLS, 940 West Valley Road, Suite 1400, Wayne, PA, 2002.
- [5] Clinical and Laboratory Standards Institute/NCCLS. *Evaluation of the Linearity of Quantitative Measurement Procedures; a Statistical Approach*; Approved Guideline. CLSI/NCCLS document EP6-A [ISBN 1-56238-498-8]. Clinical and Laboratory Standards Institute/NCCLS, 940 West Valley Road, Suite 1400, Wayne, PA, 2003.
- [6] US Department of Labor, Occupational Safety and Health Administration, 29 CFR Part 1910.1030, Bloodborne pathogens.
- [7] US Department of Health and Human Services. *Biosafety in Microbiological and Biomedical Laboratories*. 5th ed. Washington, DC: US Government Printing Office; December 2009.

[8] World Health Organization. *Laboratory Biosafety Manual*. 3rd ed. Geneva: World Health Organization; 2004.

[9] Clinical and Laboratory Standards Institute. *Protection of Laboratory Workers from Occupationally Acquired Infections: Approved Guideline—Third Edition*. CLSI Document M29-A3. Wayne, PA: Clinical and Laboratory Standards Institute; 2005.

Key to symbols used



Consult instructions for use.



Authorized Representative



In Vitro Diagnostic Medical Device



Manufacturer



Catalog Number



Batch Code



Reagent



Reticulocyte Reagent



Temperature Limitation



Exp

Use by

CELL-DYN *Enzymatic Cleaner Concentrate*

PRODUCT INFORMATION SHEET

ABBOTT

CELL-DYN SYSTEMS



INTENDED USE

CELL-DYN Enzymatic Cleaner Concentrate is a special cleaning agent for use on CELL-DYN Hematology Analyzers. Analyzers should be cleaned on the schedule recommended in the appropriate CELL-DYN Operator's Manual, or whenever a repeated clog or obstructed aperture is suspected. CELL-DYN Enzymatic Cleaner Concentrate was specifically developed for the removal of protein buildup and debris (clogs) in counting orifices, flow cells, and associated analyzer tubing. CELL-DYN Enzymatic Cleaner Concentrate is less harmful to delicate plastic and ceramic parts than is bleach (sodium hypochlorite).

INGREDIENTS

Subtilisin	<5.0%	Anti-Microbial Agent	<1.0%
Buffer	<25.0%	Stabilizer	<3.0%
Polyoxyethylene Ether	<10.0%		

PRECAUTIONS

IVD For *in vitro* diagnostic use.

The following warnings and precautions apply to the CELL-DYN Enzymatic Cleaner Concentrate:



DANGER: Contains subtilisin and tris hydroxymethyl aminomethane.

H334 May cause allergy or asthma symptoms or breathing difficulty if inhaled.

H318 Causes serious eye damage.

H315 Causes skin irritation.

H335 May cause respiratory irritation.

Prevention

P261 Avoid breathing mist / vapours / spray.

P280 Wear protective gloves / protective clothing / eye protection.

Safety Data Sheets are available at www.abbottdiagnostics.com or contact your local representative.

STORAGE INSTRUCTIONS

8°C Protect from freezing or excessive heat. Cloudiness from cold storage or color change from lot to lot (yellow–dark brown) will not affect the effectiveness of CELL-DYN Enzymatic Cleaner Concentrate.

2°C

PROCEDURES

Bring cleaner to room temperature before use.

Refer to CELL-DYN Operator's manual for specific instructions on how to clean your automated CELL-DYN analyzer.

Instruments with Exposed Transducers - Place 10 drops (0.5 mL) of enzymatic cleaner concentrate in a sample cup, add 10 mL of lukewarm (not hot) water and mix. Place cup on sample stage and press RUN button. After cycle completes, allow cleaner to work for 5–10 minutes. Remove vial, rinse outside of transducer with the appropriate diluent and place a new cup containing 20 mL of fresh diluent (only) on sample stage. Cycle instrument a minimum of 3 times.

Instruments with Internal Transducers - Consult the appropriate CELL-DYN Operator's Manual.

LIMITATIONS OF THE PROCEDURE

- This product is intended to be used as a cleaner for CELL-DYN hematology analyzers and should not be considered to have disinfectant properties.
- Diluted concentrate should be discarded after six hours.
- CELL-DYN Enzymatic Cleaner Concentrate solution must be thoroughly removed from the analyzer before running specimens.**
- Ensure the Wash Block and/or the Probe are free from Enzymatic Cleaner after completion of the Auto Clean and Extended Auto Clean. Consult Operator's Manual for cleaning instructions, if appropriate for your system.**
- Do not use product beyond expiration date.

ORDERING INFORMATION

REF 99644-01 CELL-DYN Enzymatic Cleaner Concentrate 2 x 50 mL quantity.

VERWENDUNGSZWECK

CELL-DYN Enzymatic Cleaner Concentrate ist ein spezielles Reinigungsmittel für CELL-DYN Hämatologie-Analysengeräte. Die Reinigung des Analysengerätes ist gemäß dem in der entsprechenden CELL-DYN Bedienungsanleitung empfohlenen Wartungsplan durchzuführen. Darüber hinaus ist eine Reinigung bei wiederholter Verstopfung oder bei Verdacht auf eine verstopfte Messöffnung erforderlich. Das CELL-DYN Enzymatic Cleaner Concentrate wurde speziell zum Entfernen von Eiweißablagerungen und Gerinnseln (Verstopfungen) in Messöffnungen, Durchflussküvetten und dem Schlauchsystem der Analysengeräte entwickelt. Im Vergleich zu Bleichmittel (Natriumhypochlorit) ist das CELL-DYN Enzymatic Cleaner Concentrate schonender gegenüber den empfindlichen Kunststoff- und Keramiktteilen der Geräte.

BESTANDTEILE

Subtilisin	<5,0 %	Bakteriostatikum	<1,0 %
Puffer	<25,0 %	Stabilisator	<3,0 %
Polyoxyethylenether	<10,0 %		

VORSICHTSMASSNAHMEN

IVD Zur Verwendung als In-vitro-Diagnostikum.

Die folgenden Gefahren- und Sicherheitshinweise gelten für das CELL-DYN Enzymatic Cleaner Concentrate:



GEFAHR: Enthält Subtilisin und Tris-Hydroxymethyl-Aminomethan.

H334 Kann bei Einatmen Allergie, asthmaartige Symptome oder Atembeschwerden verursachen.

H318 Verursacht schwere Augenschäden.

H315 Verursacht Hautreizungen.

H335 Kann die Atemwege reizen.

Prävention

P261 Einatmen von Nebel/Dampf/Aerosol vermeiden.

P280 Schutzhandschuhe/Schutzkleidung/Augenschutz tragen.

P284 Atemschutz tragen.

Sicherheitsdatenblätter sind unter www.abbottdiagnostics.com oder über den Kundendienst erhältlich.

LAGERUNG

8°C Vor Frost- und starker Hitze einwirkung schützen. Eine Trübung durch gekühlte Lagerung oder farbliche Veränderungen von Charge zu Charge (gelb - dunkelbraun) beeinträchtigen nicht die Wirksamkeit des CELL-DYN Enzymatic Cleaner Concentrate.

2°C

VERFAHREN

Reinigungsmittel vor Gebrauch auf Raumtemperatur bringen.

Ausführliche Hinweise zur Reinigung Ihres automatischen CELL-DYN-Analysengerätes finden Sie in Ihrer CELL-DYN Bedienungsanleitung.

Geräte mit externem Transducer - 10 Tropfen (0,5 ml) Enzymatisches Reinigungskonzentrat in einen Probenbecher geben, 10 ml lauwarmes (nicht heißes) Wasser zugeben und mischen. Den Probenbecher auf die dafür vorgesehene Fläche stellen und die Start-Taste (RUN) drücken. Nach Beendigung des Waschzyklus das Reinigungsmittel 5 bis 10 Minuten einwirken lassen. Den Probenbecher entfernen, den Transducer von außen mit dem dafür vorgesehenen Verdünnungsmittel spülen und einen weiteren Probenbecher mit 20 ml (ausschließlich) frischem Verdünnungsmittel auf die Probenstellfläche stellen. Mindestens 3 Waschzyklen durchführen.

Geräte mit internem Transducer - Informationen entnehmen Sie bitte der entsprechenden CELL-DYN Bedienungsanleitung.

GRENZEN DES VERFAHRENS

- Dieses Produkt ist als Reinigungsmittel für CELL-DYN Hämatologie-Analysengeräte bestimmt. Es darf nicht als Desinfektionsmittel verwendet werden.
- Verdünntes Konzentrat ist nach 6 Stunden zu verwerfen.
- Die CELL-DYN Enzymatic Cleaner Concentrate Lösung ist vor Messung der Proben vollständig aus dem Gerät zu entfernen.**
- Nach der automatischen Reinigung (Auto Clean) und der erweiterten automatischen Reinigung (Extended Auto Clean) sicherstellen, dass der Waschblock und/oder die Nadel frei von enzymatischem Reinigungsmittel sind. Anweisungen zur Reinigung enthält die jeweilige Bedienungsanleitung (wenn für das System zutreffend).**
- Das Produkt nicht über das Verfallsdatum hinaus verwenden.

BESTELLINFORMATION

REF 99644-01 CELL-DYN Enzymatic Cleaner Concentrate, 2 x 50 ml.

DOMAINE D'APPLICATION

Le CELL-DYN Enzymatic Cleaner Concentrate est un agent de nettoyage spécial destiné à être utilisé sur les analyseurs d'hématologie CELL-DYN. Les analyseurs doivent être nettoyés conformément au calendrier de maintenance recommandé dans le Manuel Technique CELL-DYN correspondant ou en cas d'obstruction répétée ou d'orifice bouché. Le CELL-DYN Enzymatic Cleaner Concentrate a été spécialement conçu pour éliminer les dépôts protéiques et les débris (obstructions) accumulés dans les orifices de comptage, les cellules de mesure et dans les tubulures de l'analyseur correspondant. Le CELL-DYN Enzymatic Cleaner Concentrate endommage moins les éléments délicats en plastique et céramique que l'eau de Javel (hypochlorite de sodium).

COMPOSANTS

Subtilisine	< 5,0 %	Agent antimicrobien	< 1,0 %
Tampon	< 25,0 %	Stabilisant	< 3,0 %
Ether de polyoxyéthylène	< 10,0 %		

PRECAUTIONS

IVD Pour diagnostic *in vitro*.

Les mises en garde et précautions suivantes s'appliquent au CELL-DYN Enzymatic Cleaner Concentrate :



DANGER : Contient de la subtilisine et du tris-hydroxyméthyl-aminométhane.

H334 Peut provoquer des symptômes allergiques ou d'asthme ou des difficultés respiratoires par inhalation.

H318 Provoque des lésions oculaires graves.

H315 Provoque une irritation cutanée.

H335 Peut irriter les voies respiratoires.

Prévention

P261 Éviter de respirer les brouillards / vapeurs / aérosols.

P280 Porter des gants de protection / des vêtements de protection / un équipement de protection des yeux.

P284 Porter un équipement de protection respiratoire.

P264 Se laver les mains soigneusement après manipulation.

Conservation

P403 + P233 Stocker dans un endroit bien ventilé. Maintenir le récipient fermé de manière étanche.

Élimination

P501 Éliminer le contenu / récipient conformément aux réglementations locales.

Les fiches de données de sécurité sont disponibles sur www.abbottdiagnostics.com ou auprès du Service Clients Abbott.

CONDITIONS DE CONSERVATION

8°C Ne pas congeler ni chauffer excessivement. L'aspect trouble imputable à une conservation au réfrigérateur ou une couleur différente d'un lot à l'autre (jaune - marron foncé) n'influent pas sur l'efficacité du CELL-DYN Enzymatic Cleaner Concentrate.

PROCÉDURES

Amener le détergent à température ambiante avant l'emploi.

Pour des instructions spécifiques concernant le nettoyage de votre analyseur automatique CELL-DYN, se référer au Manuel Technique CELL-DYN.

Instruments à transducteur externe - Distribuer 10 gouttes (0,5 ml) du concentré de détergent enzymatique dans un godet-échantillon, ajouter 10 ml d'eau tiède (pas chaude) et mélanger. Placer le godet sur le plateau des échantillons, puis appuyer sur la touche RUN (analyse). Après l'exécution d'un cycle complet, laisser agir le détergent pendant 5 à 10 minutes. Retirer le godet, rincer l'extérieur du transducteur avec un diluant approprié et placer un autre godet-échantillon contenant (exclusivement) 20 ml de diluant frais sur le plateau des échantillons. Laisser l'analyseur effectuer au moins 3 cycles de lavage.

Instruments à transducteur interne - Voir le Manuel Technique CELL-DYN correspondant.

LIMITES DE LA METHODE

- Ce produit est destiné à être utilisé en tant que détergent pour les analyseurs d'hématologie CELL-DYN. Ne pas l'utiliser comme désinfectant.
- Jeter le concentré dilué au bout de six heures.
- La solution de CELL-DYN Enzymatic Cleaner Concentrate doit être éliminée du système avec soin avant d'analyser des échantillons.**
- Veiller à ce que le bloc de lavage et/ou la sonde soient exempts de détergent enzymatique après l'auto-nettoyage et l'auto-nettoyage étendu. Pour de plus amples informations sur le nettoyage du système, consulter le Manuel Technique pour les systèmes concernés.**
- Ne pas utiliser le produit au-delà de la date de péremption.

INFORMATIONS DE COMMANDE

REF 99644-01 CELL-DYN Enzymatic Cleaner Concentrate 2 flacons (50 ml chacun).



FINALIDAD DE USO

CELL-DYN Enzymatic Cleaner Concentrate (limpiador enzimático concentrado) es un agente limpiador especial para los analizadores de hematología CELL-DYN. Los analizadores deben limpiarse en los intervalos recomendados en el Manual de operaciones CELL-DYN correspondiente o siempre que se produzca una obstrucción repetida o se bloquee el orificio de recuento. El limpiador enzimático concentrado CELL-DYN ha sido diseñado especialmente para eliminar los restos de proteínas y los residuos (coágulos) de los orificios de recuento, de las celdas de flujo y de los conductos del analizador. El limpiador enzimático concentrado CELL-DYN es menos dañino que la lejía (hipoclorito de sodio) para los componentes delicados de plástico o cerámica.

COMPONENTES

Subtilisina	<5,0%	Agente antimicrobiano	<1,0%
Tampón	<25,0%	Estabilizante	<3,0%
Éter de polioxietileno	<10,0%		

PRECAUCIONES

IVD Para uso en diagnóstico *in vitro*.

Las siguientes advertencias y precauciones se aplican al limpiador enzimático concentrado CELL-DYN:



PELIGRO: contiene subtilisina y tris(hidroximetil)

aminometano.

H334 Puede provocar síntomas de alergia o asma o

dificultades respiratorias en caso de inhalación.

H318 Provoca lesiones oculares graves.

H315 Provoca irritación cutánea.

H335 Puede irritar las vías respiratorias.

Prevención

P261 Evitar respirar la niebla/los vapores/el aerosol.

P280 Llevar guantes/prendas/gafas de protección.

P284 Llevar equipo de protección respiratoria.

P264 Lavarse las manos concienzudamente tras la manipulación.

Las fichas de datos de seguridad están disponibles en la página web www.abbottdiagnostics.com o a través de la Asistencia Técnica de Abbott.

INSTRUCCIONES DE ALMACENAMIENTO

8°C Evítese la congelación o la exposición al calor excesivo. El aspecto turbio debido al almacenamiento en el refrigerador o los cambios de color de un lote a otro (amarillo - marrón oscuro) no afectan al rendimiento del limpiador enzimático concentrado CELL-DYN.

2°C

PROCEDIMIENTOS

Deje que el limpiador alcance la temperatura ambiente antes de su uso.

Si desea más información sobre la limpieza del analizador automatizado CELL-DYN, consulte el Manual de operaciones del sistema CELL-DYN específico.

Instrumentos con transductor externo - Dispense 10 gotas (0,5 ml) de limpiador enzimático concentrado en una copa de muestra, añada 10 ml de agua tibia (no caliente) y mézclelo. Coloque la copa en el área prevista para la muestra y pulse el botón RUN (botón para procesar). Una vez finalizado el ciclo, deje actuar el agente limpiador durante 5–10 minutos. Retire el frasco, lave el exterior del transductor con el diluyente apropiado y coloque una nueva copa con 20 ml de diluyente recién preparado (únicamente) en el área de la muestra correspondiente. Deje que el instrumento realice como mínimo 3 ciclos de lavado.

Instrumentos con transductor interno - Consulte el Manual de operaciones del sistema CELL-DYN correspondiente.

LIMITACIONES DEL PROCEDIMIENTO

- Este producto sólo se debe utilizar como agente limpiador para los analizadores de hematología CELL-DYN y no debe considerarse como un desinfectante de uso general.
- El concentrado diluido deberá eliminarse transcurridas 6 horas desde su preparación.
- La solución del limpiador enzimático concentrado CELL-DYN se debe eliminar meticulosamente del analizador antes de procesar muestras de pacientes.**
- Asegúrese de que no queda limpiador enzimático en el bloque de lavado o en la sonda una vez finalizada la limpieza automática y la limpieza automática ampliada. Consulte las instrucciones sobre la limpieza en el Manual de operaciones (si procede para su sistema).**
- No utilice este producto una vez transcurrida la fecha de caducidad.

INFORMACIÓN PARA LOS PEDIDOS

REF 99644-01 CELL-DYN Enzymatic Cleaner Concentrate (limpiador enzimático concentrado); cantidad 2 x 50 ml.

FINALITÀ D'USO

CELL-DYN Enzymatic Cleaner Concentrate è un detergente speciale da usare con gli analizzatori per ematologia CELL-DYN. Pulire gli analizzatori secondo gli intervalli raccomandati nel Manuale d'Impiego CELL-DYN appropriato o se si sospettano ripetuti coaguli od ostruzioni all'orifizio di conteggio. Il CELL-DYN Enzymatic Cleaner Concentrate è stato sviluppato appositamente per eliminare depositi di proteine ed altri residui (coaguli) rimasti negli orifizi di conteggio, nelle cellette di flusso e nei tubi dell'analizzatore. Il CELL-DYN Enzymatic Cleaner Concentrate è meno dannoso di un candeggiante (ipoclorito di sodio) nei confronti di parti delicate in plastica e ceramica.

COMPONENTI

Subtilisina	<5,0%	Agente antimicrobico	<1,0%
Tampone	<25,0%	Stabilizzante	<3,0%
Etere di poliessietilene	<10,0%		

PRECAUZIONI

IVD Per uso diagnostico *in vitro*.

Le seguenti avvertenze e precauzioni si riferiscono al CELL-DYN Enzymatic Cleaner Concentrate:



PERICOLO: contiene subtilisina e tris idrossimetil

amminometano.

H334 Può provocare sintomi allergici o asmatici o

dificoltà respiratorie se inalato,

H318 Provoca gravi lesioni oculari.

H315 Provoca irritazione cutanea.

H335 Può irritare le vie respiratorie.

Prevenzione

P261 Evitare di respirare la nebbia/i vapori/gli aerosol.

P280 Indossare guanti/indumenti protettivi/

Proteggere gli occhi.

Le schede di sicurezza sono disponibili sul sito www.abbottdiagnostics.com oppure contattando il Servizio Clienti Abbott.

NORME PER LA CONSERVAZIONE

8°C Proteggere da congelamento o eccessivo calore. La torbidità dovuta ad una conservazione in frigorifero oppure la diversità di colore (giallo–marrone scuro) in lotti diversi non pregiudicano la prestazione del CELL-DYN Enzymatic Cleaner Concentrate.

2°C

PROCEDURE

Portare il detergente a temperatura ambiente prima dell'uso.

Per le istruzioni specifiche sulla pulizia dell'analizzatore CELL-DYN automatizzato, fare riferimento al Manuale d'Impiego CELL-DYN. **Strumenti con trasduttore esterno** - Dispensare 10 gocce (0,5 ml) di detergente enzimatico concentrato in una coppetta del campione, aggiungere 10 ml di acqua tiepida (non bollente) e miscelare. Collocare la coppetta sulla piattaforma prevista per i campioni e premere il tasto RUN. Terminato il ciclo di lavaggio, lasciar agire il detergente per 5–10 minuti. Togliere il flacone, sciacquare l'esterno del trasduttore con il diluente appropriato e collocare un'altra coppetta contenente 20 ml di diluente fresco (soltanto) sulla piattaforma. Eseguire almeno 3 cicli.

Strumenti con trasduttore interno - Fare riferimento al Manuale d'Impiego CELL-DYN appropriato.

LIMITI DEL METODO

- Questo prodotto è da utilizzare come detergente per gli analizzatori di ematologia CELL-DYN e non come disinfettante.
- Eliminare la soluzione diluita dopo sei ore.
- Il CELL-DYN Enzymatic Cleaner Concentrate deve essere completamente rimosso dallo strumento prima di analizzare i campioni.**
- Assicurarsi che non rimangano residui di detergente enzimatico sul blocco di lavaggio e/o sull'ago dopo il completamento del ciclo di pulizia automatica normale ed estesa. Se appropriato per il proprio sistema, consultare il Manuale d'Impiego CELL-DYN per le istruzioni sulla pulizia del sistema.**
- Non utilizzare il prodotto oltre la data di scadenza.

INFORMAZIONI PER L'ORDINE

REF 99644-01 CELL-DYN Enzymatic Cleaner Concentrate 2 x 50 ml.

Keys to Symbols Used/Erläuterung der verwendeten Symbole/Légende des symboles utilisés/Clave de símbolos utilizados/Legenda dei simboli utilizzati

REF	Catalog Number / Bestellnummer / Référence / Número de referencia /Numero di listino
IVD	In Vitro Diagnostic Medical Device / In-vitro-Diagnostikum / Dispositif médical de diagnostic <i>in vitro</i> / Dispositivo sanitario para diagnóstico <i>in vitro</i> / Dispositivo medico-diagnostico <i>in vitro</i>
	Use by / Verwendbar bis / Date de péremption / Fecha de caducidad / Usare entro
LOT	Batch Code / Chargenbezeichnung / Numéro de lot / Número de lote / Numero di lotto
	Temperature Limitation / Temperaturbegrenzung / Conserver à / Limitación de temperatura / Limiti di temperatura
	Consult accompanying documents / Begleitdokumente beachten / Consulter les documents joints / Consulte las instrucciones de uso / Consultare i documenti allegati

ENZYMATIC CLEANER CONCENTRATE

Enzymatic Cleaner Concentrate / Enzymatisches Reinigungskonzentrat / Concentré de détergent enzymatique / Limpiador enzimático concentrado / Detergente enzimatico concentrato

EC REP

Authorized Representative in the European Community / Bevollmächtigter in der Europäischen Gemeinschaft / Mandataire au sein de la Communauté européenne / Representante autorizado en la Unión Europea / Mandatario nella Comunità Europea



Manufacturer / Hersteller / Fabricant / Fabricante / Fabbricante

MANUFACTURED FOR

Manufactured for / Hergestellt für / Fabriqué pour / Fabricado para / Fabricato per

PRODUCT OF USA

Product of USA / Produkt aus den USA / Produit aux Etats-Unis / Producto de EE. UU. / Prodotto degli USA



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