Parashar Micro Measurement Pvt. Ltd.

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Website : www.pmmpl.in, www.parashar.info
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CC - 2795

Calibration Certificate

ULR - CC279521000033849F			Page 1 of 1
Certificate Number : PMM/14360/3		Date of Request	11.12.2021
Calibrated For	M/s. Pathology Lab. District Women Hospital. Pelibhit.	Calibrated on	11.12.2021
		Valid Upto	10.12.2022
		Cert. Issue Date	15.12.2021

Description of Equipments

Nomenclature	Fridge (Dig. Temp. Indicator With Sensor)	Accuracy/Class	Not Mentioned
		Condition of UUC	Physically Ok
Range	0 to 50 ° C	Serial No.	20068026
Resolution / Least Count	0.1 ° C	Party ID Mark No.	---------
Make & Model No.	Labtop Instrument Pvt.Ltd./ LB4 - 600/P	Location	---------
Material / Type	--------		

Master Equipment / Standard Used

Sr. No.	Nomenclature	Make & Model	Serial No. / I/D Mark	Calibrated From	Certificate No.	Due Date of Calibration
1	Dig. Temp Indicator With RTD Sensor	Tempsens YCT	PMM/RTD/02 PMM/RTDTHM/01	PMMPL, Noida	PMM/TH/DTIWS/1225	05.02.2022

Standard used for calibration are traceable to National Standards through unbroken chain of calibration.

Calibration Performed at	Site	Environmental	Temperature = 25 ± 5° C
Calibration Procedure No.	CP/T/S/04	Condition(s)	Humidity = 30 to 75 % RH
Reference Standard / Guideline	IS:2806 - 1992 Conversion Table ITS-90		

Thermal Calibration

CALIBRATION RESULTS

S.N.	Nominal Value in UUC (in ° C)	Actual Observed Value in Std. (in ° C)	Error (in ° C)
1	2.0	2.11	-0.11
2	4.2	4.35	-0.15
3	8.3	8.51	-0.21

UUC - Unit Under Calibration
Std. - Standard Instrument
Uncertainty of Measurement (at approx 95% Confidence Level with Coverage factor k = 2) = ± 0.47 ° C

Calibrated By : Sudhir Kumar
Designation : Calibration Engineer

Approved By : Jai Prakash
Designation : Tech. Manager / Auth. Sign.

Conditions : 1. This certificate refers only to the particular item submitted for calibration.
2. The calibration result reported in this certificate are valid at the time of and under the stated conditions of measurement.
3. This particular certificate can not be reproduced except in full, without prior permission of chief executive officer of the lab.

District Women Hospital Pilibhit

To whom so ever it may concern

This is to bring to your kind notice that we, Pathology lab, are using refrigerator for 2-8 degree Celsius to store control, calibrator and reagents and as per manufacturer instructions regarding stability and storage, it is written in the literature that we can store the control, calibrator and reagents on 2-8 degree Celsius.

Enclosure:- Manufacturer pack insert for reference.

Dr. Afzal Husain
Pathologist
District Women Hospital
Pilibhit, Uttar Pradesh

चिकित्सा अधिकारी
संयुक्त जिला चिकित्सालय
पीलीभीत

Q-Line S TRIGLYCERIDES SL

TRGS0240PS 12 x 20 mL

INTENDED USE

Q-Line® S Clinical Systems TRIGLYCERIDES SL is intended for the quantitative *in vitro* diagnostic determination of triglycerides in human serum and plasma.

CLINICAL SIGNIFICANCE [1-2]

Triglycerides constitute 95% of tissue storage fat and their main role is to provide energy for the cell. They are synthesized both in the intestine from dietary fats and in liver from dietary carbohydrates, and are then transported in blood by chylomicrons and VLDL.

High serum triglyceride levels are associated with important risks of atherosclerosis. They can be due to diseases like different lipid metabolism disorders (hyperlipoproteinemia, lipase activity deficiency, apolipoprotein C-II deficiency), but also to diabetes, renal or endocrine disorders.

METHOD [3]

Enzymatic (GPO-PAP) - colorimetric.
End point.

PRINCIPLE [3]

Enzymatic determination of triglycerides according to the following reactions:

$$\text{Triglycerides} + H_2O \xrightarrow{\text{Lipoprotein lipase}} \text{Glycerol} + \text{Fatty acids}$$

$$\text{Glycerol} + \text{ATP} \xrightarrow{\text{Glycerol kinase}} \text{Glycerol-3-Phosphate} + \text{ADP}$$

$$\text{Glycerol-3-Phosphate} + O_2 \xrightarrow{\text{GPO}} H_2O_2 + \text{Dihydroxyacetone-P}$$

$$H_2O_2 + \text{4-AAP} + p\text{-Chlorophenol} \xrightarrow{\text{Peroxidase}} \text{Quinoneimine}$$

GPO = Glycerol-3-phosphate oxidase
DHA-P = Dihydroxyacetone-P
4-AAP = Amino-4-antipyrine

REAGENT COMPOSITION

Reagent: R

Pipes buffer, pH 7.00		50	mmol/L
Mg^{2+}		14.8	mmol/L
p-Chlorophenol		2.7	mmol/L
ATP		3.15	mmol/L
Potassium ferrocyanide		10	µmol/L
Amino-4-antipyrine		0.31	mmol/L
Lipoprotein lipase	≥	2000	U/L
Glycerol kinase	≥	500	U/L
Glycerol-3-phosphate oxidase	≥	4000	U/L
Peroxidase	≥	500	U/L
Sodium azide	<	0.1	%

MATERIALS REQUIRED BUT NOT PROVIDED

- CALI0550ET ELICAL 2 4 x 3 mL
- CONT0060ET ELITROL I 10 x 5 mL
- CONT0160ET ELITROL II 10 x 5 mL
- Normal saline solution (NaCl 9 g/L).
- General Laboratory equipment.
- Do not use materials that are not required as indicated above.

WARNINGS AND PRECAUTIONS

- This reagent is for professional *in vitro* diagnostic use only.
- The reagent R contains sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of these reagents always flush with copious amounts of water to prevent azide build up.
- Take normal precautions and adhere to good laboratory practice.
- Use clean or single use laboratory equipment only to avoid contamination.
- For more information, Safety Data Sheet (SDS) is available on request for professional user.

STABILITY OF REAGENTS

Store at 2-8 °C and protect from light. Do not freeze.
Do not use after expiration dates indicated on the vial labels.
On board stability:
The on-board stability is specific for each analyzer.
(Refer to § PERFORMANCE DATA).

PREPARATION

The reagent is ready to use.

REAGENT DETERIORATION

- The reagent solution should be clear. Cloudiness would indicate deterioration.
- Do not use the product if there is visible evidence of biological, chemical or physical deterioration.

DAMAGED PACKAGING

Do not use the reagent if the damages of packaging might have an effect on the product performance(leakages, pierced vial).

SAMPLES [4]

Specimen
- Serum or lithium heparinized plasma from fasting patients (≥ 12 hours).
- Do not use icteric or hemolyzed samples.
- Do not use other specimens.

Warnings and precautions
- According to Good Laboratory Practice, venepuncture should be performed prior to the administration of drugs. A venipuncture could lead to false results if performed during or immediately after the administration of some drugs.
- Collect the samples in tubes and stoppers free of glycerol.
- Separate from cells within 2 hours.
- To reduce biological variability, collection of samples should follow standardized conditions as recommended by NCEP.

Storage and stability
- Samples are stable 5 to 7 days if stored at 2-8 °C, 3 months at -15 to -20 °C and several years at -70 °C. Avoid repeated freezing and thawing.

REFERENCE VALUES [2]

The NCEP (American National Cholesterol Education Program) has established the following classification for total cholesterol levels according to the risk of developing coronary heart diseases:

Risk Classification	Level (mg/dL)	Level (mmol/L)
Normal	< 150	< 1.69
Borderline high	150 - 199	1.69 - 2.25
High	200 - 499	2.26 - 5.64
Very High	≥ 500	5.65

Note: *The quoted range should serve as a guide only. It is recommended that each laboratory verifies this range or establishes a reference interval for the intented population.*

PROCEDURE

For ELITech Clinical Systems Selectra Analyzers
applications are available on request.
Wavelength : 505 nm
Temperature : 37 °C
Read against reagent blank.

	Blank	Calibrator	Test
Reagent R	300 µL	300 µL	300 µL
Distilled water	3 µL	-	-
Calibrator	-	3 µL	-
Sample	-	-	3 µL

Mix and read the absorbances (A) after an incubation of 11 minutes and 30 seconds.
- Triglycerides SL reagent can be contaminated by Cholesterol HDL SL 2G reagent.

In order to avoid contamination on Selectra ProM, ProXL, E and XL, program incompatibilities as follows:

Software	Menu	Parameter
TouchPro	Probe incompatibilities	Link/Cholesterol HDL SL 2G –Acid Solution
Other	Needle Incompatibility	Cholesterol HDL SL 2G <<HCl

For other instruments, repeat any absurd results after programming a needle wash.

- Lipase SL reagent is strongly contaminated by Triglycerides SL reagent.

In order to avoid cuvette contamination on Selectra instruments, program the following incompatibilities:

Software	Menu	Parameter
TouchPro	Test incompatibilities	Link / Triglycerides SL –Acid Solution
Other	Cuvette incompatibility	Triglycerides SL << Hcl

In order to avoid needle contamination on Selectra instruments, do not program Lipase SL and Triglycerides SL in the same run. Ensure the instrument goes back to "stand-by" status before launching a run containing Lipase SL.

CALCULATION

$$\frac{A_{Sample}}{A_{Calibrator}} \times n$$

where n = calibrator concentration

Conversion factor: mg/dL x 0.0113 = mmol/L
mg/dL x 0.01 = g/L

CALIBRATION

For calibration, multiparametric calibrator ELICAL 2 must be used. Its value is traceable to the reference method ID-MS (Isotope Dilution - Mass Spectrometry).

Calibration frequency: The calibration is specific for each analyser. (Refer to § PERFORMANCE DATA).

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sanitaires compétentes.
- Prendre des précautions lors de la manipulation de flacons de verre brisés, car les bords tranchants peuvent blesser l'utilisateur.
- Ces produits contiennent de l'azide de sodium qui peut réagir avec le plomb ou le cuivre et former des azides métalliques potentiellement explosifs. Lors de l'élimination de ces réactifs toujours rincer abondamment avec de l'eau pour éviter l'accumulation d'azides.
- Respecter les précautions d'usage et les bonnes pratiques de laboratoire.
- Utiliser du matériel de laboratoire propre ou à usage unique afin d'éviter toute contamination.
- Consulter la fiche de données de sécurité (FDS) pour une manipulation appropriée.

☛TRAITEMENT DES DÉCHETS
L'élimination de tous les déchets doit être effectuée conformément aux exigences réglementaires locales, d'état et fédérales (veuillez-vous référer à la fiche de données de sécurité (FDS)).

☛PRÉPARATION
- Ouvrir avec précaution le flacon en évitant la perte de poudre lyophilisée.
- Ajouter **précisément 3 mL d'eau distillée ou désionisée**.
- Reboucher le flacon avec soin et dissoudre le contenu complètement dans les 30 minutes en remuant délicatement le flacon et en évitant la formation de mousse.

☛DÉTÉRIORATION DU PRODUIT
- Le produit peut présenter un aspect légèrement trouble après reconstitution. Cela n'a aucun effet sur les performances du produit. Toute présence de particules serait le signe d'une détérioration.
- Ne pas utiliser le produit s'il y a des signes évidents de détérioration biologique ou chimique (ex : particules après reconstitution).
- Un flacon endommagé peut avoir un impact sur les performances du produit. Ne pas utiliser le produit si les flacons présentent des signes physiques de détérioration (par exemple, fuite).

☛STABILITÉ
Avant reconstitution :
- Stocker à 2-8 °C et à l'abri de la lumière.
- Ne pas utiliser après la date d'expiration indiquée sur l'étiquette du flacon.

Après reconstitution :
- *Ces produits doivent être immédiatement et correctement refermés afin d'éviter toute contamination ou évaporation.*

- Stabilité des constituants :
Entre 15 et 25 °C : 8 heures
Entre 2 et 8 °C : 2 jours
Entre -25 et -15 °C : 4 semaines (ne congeler qu'une seule fois)

Exceptions :
- Stabilité de la bilirubine totale (à conserver à l'abri de la lumière) :
Entre 15 et 25 °C : 6 heures
Entre 2 et 8 °C : 1 jour
Entre -25 et -15 °C : 2 semaines (ne congeler qu'une seule fois)
- Stabilité de la bilirubine directe (à conserver à l'abri de la lumière) :
Entre 15 et 25 °C : 3 heures
Entre 2 et 8 °C : 8 heures
Entre -25 et -15 °C : 2 semaines (ne congeler qu'une seule fois)

***Note** : Conserver les flacons bien fermés et à l'abri de la lumière.*

☛INTENDED USE
This *in vitro* diagnostic device is intended for the calibration of ELITech Clinical Systems quantitative tests listed in the value sheet.
This *in vitro* diagnostic device is for professional use only.

☛COMPOSITION
- Lyophilized product prepared from human serum spiked with chemical and biological additives.
- Sodium azide < 0.1 % (w/w)
- Concentrations for each analyte to test are lot-specific.

☛MATERIALS REQUIRED BUT NOT PROVIDED
- ELITech Clinical Systems reagents listed in the value sheet.
- General Laboratory equipment.

☛TRACEABILITY
The traceability is indicated in the value sheet enclosed in the kit.

☛PRECAUTIONS FOR USE AND WARNINGS
- Each unit of human blood used in the manufacture of these products was tested and found to be negative/non-reactive for the presence of HbsAg, HCV and HIV1/2. The methods used were FDA approved or cleared in compliance with European Directive 98/79/EC, Annex II, List A. Nevertheless, since the risk of infection cannot be fully excluded these products must be handled as potentially infectious. In case of exposure, follow the guidelines of the competent health authorities.
- Take precautions when handling broken glass vials as sharp edges can injure the user.
- These products contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of these reagents always flush with copious amounts of water to prevent azide buildup.
- Take normal precautions and adhere to good laboratory practice.
- Use clean or single use laboratory equipment only to avoid contaminations.
- Consult Safety Data Sheet (SDS) for a proper handling.

☛WASTE MANAGEMENT
Disposal of all waste material should be in accordance with local, state and federal regulatory requirements (please refer to the Safety Data Sheet (SDS)).

☛PREPARATION
- Carefully open the vial, avoiding the loss of lyophilizate.
- Add **in exactly 3 mL of distilled or deionized water**.
- Carefully close the vial and dissolve the contents completely within 30 minutes by occasional gentle stirring avoiding the formation of foam.

☛PRODUCT DETERIORATION
- The product may present a slightly hazy appearance after reconstitution. This has no effect on the performances of the product. All presence of particules would indicate deterioration.
- Do not use the product if there is visible evidence of contamination or damage (e.g. particle matter after reconstitution).
- Damage to the container may impact on product performance. Do not use the product if there is physical evidence of deterioration (e.g. leakages).

☛STABILITY
Before reconstitution :
- Store at 2-8 °C and protect from light.
- Do not use beyond the expiration date indicated on the vial label.

After reconstitution :
- *These products must be immediately and correctly closed to avoid contamination and evaporation.*

- Stability of components :
Between 15 and 25 °C : 8 hours
Between 2 and 8 °C : 2 days
Between -25 and -15 °C : 4 weeks (do not freeze more than once)

Exceptions :
- Stability of total bilirubin (protect from light) :
Between 15 and 25 °C : 6 hours
Between 2 and 8 °C : 1 day
Between -25 and -15 °C : 2 weeks (do not freeze more than once)
- Stability of direct bilirubin (protect from light) :
Between 15 and 25 °C : 3 hours
Between 2 and 8 °C : 8 hours
Between -25 and -15 °C : 2 weeks (do not freeze more than once)

***Note** : Keep vials well closed and protected from light.*

☛VALUES
The concentrations are indicated in the value sheet enclosed in the kit.
For users of Selectra instruments allowing data import for tests, calibrators and controls, use corresponding barcode, available on the value sheet.

☛DECLARATION OF SERIOUS INCIDENT
Please notify the manufacturer (through your distributor) and competent authority of the Member State of the european union in which the user and/or the patient is established, of any serious incident that has occurred in relation to the device. For other jurisdictions, the declaration of serious incident should be in accordance with local, state and federal regulatory requirements. By reporting a serious incident, you provide information that can contribute to the safety of *in vitro* medical devices.

☛ASSISTANCE TECHNIQUE
Contact your local distributor or ELITech Clinical Systems SAS (CCsupport@elitechgroup.com).

Español - ES

☛USO PREVISTO
Este dispositivo de diagnóstico *in vitro* está diseñado para la calibración de las pruebas cuantitativas ELITech Clinical Systems listadas en la hoja de valores.
Este dispositivo de diagnóstico *in vitro* esta destinado unicamente para los profesionales.

☛COMPOSICIÓN
- Producto liofilizado preparado a partir de suero humano enriquecido con aditivos químicos y biológicos.
- Azida sódica < 0.1 % (p/p)
- Las concentraciones de cada analito a analizar son específicas a cada lote.

☛MATERIALES REQUERIDOS PERO NO INCLUIDOS
- Reactivos ELITech Clinical Systems listados en la hoja de valores.
- Equipo de laboratorio de uso general.

☛TRAZABILIDAD
La trazabilidad se indica en la ficha de valores incluida en el kit.

☛PRECAUCIONES DE USO Y ADVERTENCIAS
- Cada unidad de sangre humana utilizada en la fabricación de estos productos fue analizada y resultó ser negativa / no reactiva ante la presencia de HbsAg, VHC y VIH1/2. Los métodos utilizados fueron aprobados de conformidad por la FDA y con la Directiva Europea 98/79 / CE, Anexo II, Lista A. Sin embargo, dado que el riesgo de infección no puede excluirse por completo, estos productos deben manejarse como potencialmente infecciosos. En caso de exposición, siga las indicaciones de las autoridades sanitarias competentes.
- Tenga precauciones al manipular viales de vidrio roto, ya que los bordes afilados pueden dañar al usuario.
- Los productos contienen azida sódica que puede reaccionar con el plomo o el cobre de la tubería y potencialmente formar azidas metálicas explosivas. Cuando se eliminen los reactivos, enjuague con agua abundantemente para prevenir la acumulación de azidas.
- Respetar las precauciones de uso y las buenas prácticas de laboratorio.

☛PREPARACIÓN
- Abra con cuidado el vial, evitando la pérdida de liofilizado.
- Añadir **exactamente 3 mL de agua destilada o desionizada**.
- Cierre con cuidado el vial y disuelva el contenido completamente en 30 minutos mediante agitación suave ocasional evitando la formación de espuma.

☛DETERIORO DEL PRODUCTO
- El producto puede presentar un aspecto ligeramente turbio después de la reconstitución. Esto no tiene efecto sobre el rendimiento del producto. Todo presencia de partículas indicaría deterioro.
- No use el producto si hay evidencia visible de contaminación o daño (por ejemplo, partículas después de la reconstitución).
- El daño al envase puede afectar el rendimiento del producto. No use el producto si hay evidencia física de deterioro (por ejemplo, fugas).

☛ESTABILIDAD
Antes de reconstitución :
- Conservar a 2-8 °C y proteger de la luz.
- No usar después de la fecha de caducidad indicada en la etiqueta del vial.

Después de reconstitución :
- Estos productos deben ser bien cerrados de inmediato para evitar contaminación y evaporación.

- Estabilidad de los componentes:
Entre 15 y 25 °C : 8 horas
Entre 2 y 8 °C : 2 días
Entre -25 y -15 °C : 4 semanas (no congelar más de una vez)

Excepciones:
- Estabilidad de la bilirrubina total (proteger de la luz) :
Entre 15 y 25 °C : 6 horas
Entre 2 y 8 °C : 1 día
Entre -25 y -15 °C : 2 semanas (no congelar más de una vez)
- Estabilidad de la bilirrubina directa (proteger de la luz) :
Entre 15 y 25 °C : 3 horas
Entre 2 y 8 °C : 8 horas
Entre -25 y -15 °C : 2 semanas (no congelar más de una vez)

***Nota** : Conservar los frascos bien cerrados y protegidos de la luz.*

☛PROCEDIMIENTO
Para utilizar ELICAL 2, siga el procedimiento descrito en el inserto del reactivo ELITech Clinical Systems utilizado.

☛LIMITACIONES
El uso de ELICAL 2 ha sido validado con los sistemas ELITech (equipos y reactivos enumerados en la hoja de valores).
El uso de cualquier otro sistema debe ser validado por el laboratorio.

☛VALORES
Las concentraciones son indicadas en la ficha de valores incluida en el kit.
Para usuarios de los equipos Selectra que permiten la importación de pruebas, calibradores y controles, use el código de barras correspondiente, disponible en la hoja de valores.

☛DECLARACIÓN DE INCIDENTES GRAVES
Por favor notifique al fabricante (por medio de su distribuidor) y autoridad competente del Estado miembro de la Unión Europea en donde el usuario o paciente radique, de cualquier incidente grave que se produzca con relación al dispositivo.
Para otras jurisdicciones, la declaración de incidentes graves debe realizarse
de acuerdo con los requisitos regiamentarios locales, estatales y federales.
Reportando incidentes graves usted contribuye a proporcionar más información sobre la seguridad del dispositivo médico de diagnóstico *in vitro*.

☛ASISTENCIA TÉCNICA
Contacte a su distribuidor local o con ELITech Clinical Systems SAS (CCsupport@elitechgroup.com).

Português - PT

☛UTILIZAÇÃO PREVISTA
Este dispositivo de diagnóstico *in vitro* é destinado a calibração dos testes quantitativos ELITech Clinical Systems listados na folha de valores.
Este dispositivo de diagnóstico *in vitro* é apenas para uso profissional.

ELITechGroup
EMPOWERING IVD

ELITROL I
ELITROL II

Références/References/Referencias
Referências/Κωδικοί:
CONT - 0060 *ELITROL I*
CONT - 0160 *ELITROL II*

Composition du coffret/ Kit composition/Composición del kit
Conteúdo da embalagem/Περιεχόμενα συσκευασίας:
Control *: 10 x 5 mL*
Control *: 10 x 5 mL*

CE

FTCE-CONT-5-v5 (12/2018)

Français - FR

☞USAGE PRÉVU
Ces dispositifs de diagnostic *in vitro* sont destinés au contrôle qualité des performances des tests quantitatifs ELITech listés dans la fiche de valeur.

☞COMPOSITION
ELITROL I et II sont des sérums de contrôle lyophilisés à base de sérum humain.

MATÉRIELS REQUIS MAIS NON FOURNIS
- Equipement général de laboratoire

AVERTISSEMENTS ET PRÉCAUTIONS
- Ces contrôles sont uniquement destinés aux professionnels du diagnostic *in vitro*.
- Ces contrôles sont préparés à partir de produits d'origine humaine examinés selon des méthodes approuvées par la FDA et trouvés non réactifs pour l'antigène de surface du virus de l'Hépatite B (AgHBs), pour les anticorps anti-HCV (Hépatite C) et pour les anticorps anti-VIH1/VIH2. Il est toutefois recommandé de les considérer comme potentiellement infectieux et de les manipuler avec les précautions d'usage.
- Respecter les précautions d'usage et les bonnes pratiques de laboratoire.
- Utiliser du matériel de laboratoire propre ou à usage unique afin d'éviter toute contamination.
- Pour plus d'information, la fiche de données de sécurité (FDS) est disponible sur demande pour les professionnels.

TRAITEMENT DES DÉCHETS
L'élimination de tous les déchets doit être effectuée conformément aux exigences réglementaires locales, d'état et fédérales.

☞PRÉPARATION
- Tapoter doucement le flacon pour que le matériel de contrôle soit en bas du flacon.
- Ouvrir avec précaution le flacon en évitant la perte de poudre lyophilisée.
- **Ajouter précisément 5 mL d'eau distillée ou d'eau désionisée**
- Reboucher le flacon avec soin. Dissoudre le contenu complètement par retournements successifs du flacon pendant une durée de 30 minutes.
- Ne pas agiter afin d'éviter la formation de mousse.

Remarque importante : Pour réactiver la phosphatase alcaline, laissez reposer le flacon reconstitué à 15 - 25 °C pendant une heure.

☞DÉTÉRIORATION DU PRODUIT
- Le contrôle peut présenter un aspect légèrement trouble après reconstitution. Cela n'a aucun effet sur les performances du produit. Toute présence de particules serait le signe d'une détérioration.
- Ne pas utiliser le produit s'il y a des signes évidents de détérioration biologique, chimique ou physique.
- Ne pas utiliser le contrôle si les dommages de l'emballage peuvent avoir un effet sur les performances du produit (fuites).

STABILITÉ ET CONSERVATION
Avant reconstitution :
- Stocker à 2-8 °C et à l'abri de la lumière.
- Ne pas utiliser après la date d'expiration indiquée sur l'étiquette

English - EN

☞INTENDED USE
These *in vitro* diagnostic devices are intended for the quality control of the performances of ELITech quantitative tests listed in the value sheet.

☞COMPOSITION
ELITROL I and ELITROL II are lyophilised control sera prepared from human serum.

MATERIALS REQUIRED BUT NOT PROVIDED
- General Laboratory equipment.

WARNINGS AND PRECAUTIONS
- These controls are for professional *in vitro* diagnostic use only.
- These controls are prepared from human material tested by FDA approved methods and found to be non reactive for HbsAg, anti-HCV antibody and anti-HIV1&2 antibodies. However as no test method can rule out the potential risk of infection with absolute certainty, handle cautiously as potentially infectious.
- Take normal precautions and adhere to good laboratory practice.
- Use clean or single use laboratory equipment only to avoid contaminations.
- For more information, Safety Data Sheet (SDS) is available on request for professional user.

WASTE MANAGEMENT
Disposal of all waste material should be in accordance with local, state and Federal regulatory requirements.

☞PREPARATION
- Gently tap the vial so that the control material can be at the bottom of the vial.
- Carefully open the vial, avoiding the loss of lyophilizate.
- Add **in exactly 5 mL of distilled/deionized water**.
- Carefully close the vial and dissolve the contents completely by occasional gentle swirling during 30 minutes.
- Do not shake to avoid the formation of foam.

Important: To reactivate the alkaline phosphatase, allow the reconstituted control serum to stand for one hour at 15–25 °C.

☞PRODUCT DETERIORATION
- The control may present a slightly hazy appearance after reconstitution. This has no effect on the performances of the product. All presence of particules would indicate deterioration.
- Do not use the product if there is visible evidence of biological, chemical or physical deterioration.
- Do not use the control if the damages of packaging might have an effect on the product performance (leakages).

STABILITY AND STORAGE
Prior to reconstitution :
- Stored at 2-8 °C and protected from light.
- Do not use after expiration date indicated on the vial label.

☞ After reconstitution :

- Stability of the components:

Between 2 and 8 °C	:	5 days
Between -25 and -15 °C	:	4 weeks (when frozen once)

Español - ES

☞USO PREVISTO
Estos dispositivos de diagnóstico *in vitro* están diseñados para el control de calidad del rendimiento de las pruebas cuantitativas ELITech listadas en la hoja de valores.

☞COMPOSICIÓN
ELITROL I y II son sueros de control liofilizados de origen humano.

MATERIALES REQUERIDOS PERO NO INCLUIDOS
- Equipo de laboratorio de uso general.

ATENCIÓN Y PRECAUCIONES
- Estos controles son solamente para uso profesional en el diagnóstico *in vitro*.
- Los controles se prepararon a partir de productos de origen humano examinados de acuerdo con métodos aprobados por la FDA y han resultado no reactivos para el antigeno de superficie del virus de la Hepatitis B (AgHBs), para los anticuerpos anti-HCV (Hepatitis C) y para los anticuerpos anti-VIH1/ VIH2. Sin embargo, se recomienda considerarlos como potencialmente infecciosos y manipularlos con precaución.
- Respetar las precauciones de uso y las buenas prácticas de laboratorio.
- Para evitar contaminaciones utilizar equipo nuevo o completamente limpio.
- Para más información, la ficha de datos de seguridad (FDS) está disponible a solicitud para uso profesional.

TRATAMIENTO DE LOS RESIDUOS
Todos los materiales de desecho deben eliminarse de acuerdo con las requisitos reglamentarias locales, estatales, y federales.

☞PREPARACIÓN
- Golpee suavemente el frasco para que el material de control quede en el fondo del frasco.
- Destapar cuidadosamente el frasco con el fin de evitar la pérdida de material liofilizado.
- **Agregar exactamente 5 mL de agua destilada o de agua desionizada**.
- Cerrar cuidadosamente el frasco. Disolver completamente por inversión realizando movimientos giratorios ocasionales durante 30 minutos.
- No agitar para evitar la formación de espuma.

Importante: Para reactivar la fosfatasa alcalina, deje el vial reconstituido descansar a 15 - 25 ° C durante una hora.

☞DETERIORACIÓN DEL PRODUCTO
- El control puede presentar un aspecto ligeramente turbio después de reconstitución, esto no afecta el rendimiento del producto. La presencia de particulas es un signo de deterioro.
- No utilice el producto si este presenta signos evidentes de deterioración biológica, química o física.
- No utilice el control si los daños al embalaje pudiesen tener un efecto sobre el rendimiento del producto (fugas).

ESTABILIDAD Y CONSERVACIÓN
Antes de la reconstitución :
- Conservar a 2-8 °C y protegidos de la luz.
- No utilice después de la fecha de caducidad indicada en la

Português – PT

☞UTILIZAÇÃO PREVISTA
Estes dispositivos de diagnóstico *in vitro* são destinados ao controle de qualidade dos desempenhos dos testes quantitativos ELITech listados na folha de valores.

☞COMPOSIÇÃO
ELITROL I e II são soros de controlo liofilizados à base de soro humano.

MATERIAIS NECESSÁRIOS MAS NÃO FORNECIDOS
- Equipo de laboratorio de uso general.

AVISO E PRECAUÇÕES
- Estes controles são solamente para uso profissional de diagnóstico *in vitro*.
- Os controles são preparados a partir de produtos de origem humana examinados através dos métodos aprovados da FDA e que apresentaram um resultado não reativo ao antigénio de superficie do vírus da Hepatite B (AgHBs), aos anticorpos anti-HCV (Hepatite C) e aos anticorpos anti-VIH1/VIH2. No entanto, recomenda-se que sejam considerados como potencialmente infecciosos e que sejam manuseados respeitando as precauções de utilização.
- Respeitar as precauções de utilização e as boas práticas de laboratório.
- Utilizar material de laboratório limpo ou destinado a uma única utilização de modo a evitar qualquer contaminação.
- Para mais informações, a ficha de dados de segurança (FDS) está disponivel mediante pedido para os profissionais.

TRATAMENTO DOS RESÍDUOS
Todos os resíduos devem ser eliminados de acordo com as exigências locais de regulamentação, estadual e federal.

☞PREPARAÇÃO
- Bata levemente no frasco para que o material de controle possa estar no fundo do frasco.
- Abrir cuidadosamente o frasco, evitando a perda de pó liofilizado.
- **Acrescentar exactamente 5 mL de água destilada ou desionizada**.
- Fechar o frasco com cuidado. Dissolver o conteúdo completamente através de rotações sucessivas do frasco durante 30 minutos.
- Não agitar, de modo a evitar a formação de espuma.

Observação importante:
Para reativar a fosfatase alcalina, deixe o frasco reconstituído descansar a 15 - 25 °C por uma hora.

☞DETERIORAÇÃO DO PRODUCTO
- O control pode apresentar uma aparência um pouco nebulosa após a reconstituição. Isto não tem efeito sobre o desempenho do produto. A presença de particulas indica deterioração.
- Não use o produto se houver evidência visível de deterioração física, biológica ou química.
- Não utilizar o control caso haja danos na embalagem que possam causar algum efeito sobre o desempenho do produto (vazamentos).

ESTABILIDADE E CONSERVAÇÃO
Antes da reconstituição :