SCS™-1000

EN

Identification of the IVD reagent
SCS™-1000

Intended use
The SCS-1000 is a calibrator for Sysmex haematology analysers. It is designed for the calibration and calibration verification of WBC, RBC, HGB, HCT/MCV, PLT and RET*.

Warnings and precautions
Do not inject or ingest.
All human source material used to manufacture this product was non-reactive for antigens to Hepatitis B (HBsAg), negative by tests for antibodies to HIV (HIV-1/HIV-2) and Hepatitis C (HCV), non-reactive for HIV-1 RNA and HCV RNA by licensed NAT, and non-reactive to Serological Test for Syphilis (STS) using techniques specified by the U.S. Food and Drug Administration. Because no known test method can assure complete absence of human pathogens, this product should be handled with appropriate precautions.

Components
SCS-1000 contains stabilised human red blood cells, fixed mammalian white blood cells, and a platelet component in a medium containing preservatives.

Storage and shelf life of unopened product
SCS-1000 vials should be stored at 2-8°C. Avoid freezing this material. When stored properly the unopened product can be used until the expiration date stated on the label of the vial. Storage outside the recommended temperature range causes damage to the product. Do not use damaged material for calibration and calibration verification.

Storage and shelf life after first opening
Opened vials should be used within 4 hours. Afterwards opened vials should be discarded.

Additional required equipment
SCS-1000 is intended only for use on Sysmex instruments and reagents. The SCS-1000 acceptable limits were established by solely using Sysmex instruments and reagents and are thus comparable only with values likewise established.

Calibration procedure
Precalibration validation
1. Do not use SCS-1000 if the ambient room temperature exceeds 30°C.
2. Instrument power should be on for at least 30 minutes prior to calibration.
3. Please make sure that you have entered the lot numbers and expiration dates of all reagents used on the analyzer in the instrument's log.
4. Verify that maintenance of the instrument has been performed according to the manufacturer's recommendations.
5. Perform Auto Rinse and verify that backgrounds are within specified limits.
6. Review the recent internal quality control data to ensure that the analyser performance is stable.
7. Verify that the lot number and expiration date on the SCS-1000 vials match the data provided on the assay sheet.

Analyser precision verification
1. Analyse a normal fresh whole blood sample in the open whole blood mode 11 consecutive times. Discard the first result and calculate the Coefficient of Variation (CV‰) for all parameters being calibrated using results two (2) to eleven (11).
2. Verify that the instrument performs within “precision limits” as stated in the instructions for use.

Selection of the mode
Select the following mode dependant upon the instrument type.

Instrument	Mode		
	Whole blood Mode	Maintenance Mode / Special Mode / Control Blood Mode	Maintenance Mode / Special Mode / Calibrator Mode
K-800	X		
K-1000	X		
K-4500	X		
KX-21/XP-Series			X
pocH-100i			X
XS-Series		X (CTR3)	
XT-Series			X
XE-Series			X

Preparation of the calibrator
Since SCS-1000 calibrator is a product containing minimal stabilised cells, utmost care is to be exercised in handling the material. Slight haemolysis indicated by a slightly coloured supernatant is normal. A strong coloured supernatant is an indication for excessive haemolysis which could be the result of exposure to temperature extremes. In this case the product should be discarded.

Please follow the following procedure exactly, because it is critical for the correct calibration and calibration verification.

1. Take a SCS-1000 vial from the refrigerator and leave it at room temperature (18-25°C) for 30 minutes.
2. Mix the vial by gentle rolling between the palms of the hands for 20 seconds in the upright position, invert and roll for a further 20 sec.
3. Complete mixing by gently inverting the vial end-to-end 12 times and make sure that all cells are visibly suspended.
4. Allow the vial to rest on a flat surface 15 seconds prior to analysis to allow for the dispersion of bubbles.
5. Remove the vial cap and analyse in the open mode 6 consecutive times. Do not mix between the 6 measurements.
6. After completing 6 analyses wipe the threads of both the vial and the cap with a clean, lint-free tissue or gauze. Replace the cap.

Calculate mean and check data
1. Discard the first of the 6 results.
2. Calculate the mean of remaining 5 results for each parameter and check if the mean (analyser mean) lies within the acceptable limits.

Evaluation of results
Analyser mean values deviating from the acceptable limits indicate the need for recalibration. However, before changing calibration settings the results of the internal quality control (using Sysmex control bloods) and of the external quality control (Sysmex IQAS, SNCS - IQAS ONLINE or external third-party inter-laboratory test) have to be taken into account. If results are contradicting it is to be checked that the calibrator is intact. The justification for recalibration shall be given careful consideration.

Calculate new calibration settings
1. Calculate new calibration settings using this formula:

$$\text{New calibration factor} = \text{Current calibration factor} \times \frac{\text{Assay Target}}{\text{Analyser Mean}}$$

2. After calibration settings have been changed, verify the changes by repeating the calibration procedure. Analyser mean values which lie within the acceptable limits confirm the accurate calibration status of the instrument.

Metrological traceability
The assigned values for SCS-1000 are determined by multiple analyses on Sysmex haematology analysers who are calibrated with fresh human blood against the following international conventional reference measurement procedures:

WBC: Reference method for the enumeration of erythrocytes and leucocytes, ICSH Expert Panel on Cytometry, Clin Lab Haematol. 1994; 16, 131-138.
Counts on 1:500 dilutions performed on SCC (Semi-automated Single Channel counter), a volumetric manometer semi-automated electronic impedance cell counter.

RBC: Reference method for the enumeration of erythrocytes and leucocytes, ICSH Expert Panel on Cytometry, Clin Lab Haematol. 1994; 16, 131-138.
Counts on 1:50,000 dilutions performed on SCC (Semi-automated Single Channel counter), a volumetric manometer semi-automated electronic impedance cell counter.

HGB: Recommendations for reference method for haemoglobinometry in human blood (ICSH standard 1995) and specifications for international haemiglobincyanide standard (4th edition), ICSH Expert Panel on Haemoglobinometry, J Clin Pathol 1996; 49: 271-274.
CLSI H15-A3: Reference and selected procedures for the quantitative determination of hemoglobin in blood; Approved Standard - Third edition (2000).
Photometry on 1:250 dilutions with appropriate reagent (recommended by van Kampen, Zijlstra).

HCT: CLSI H7-A3: Procedure for Determining Packed Cell Volume by the Microhematocrit Method; Approved Standard - Third edition (2000).

PLT: Platelet Counting by the RBC/Platelet Ratio Method – A Reference Method, ICSH Expert Panel on Cytometry and ISLH Task Force on Platelet Counting, Am J Clin Pathol 2001; 115: 460-464.
Determined from the RBC/PLT ratio performed by fluorescence flow cytometry with platelets labeled with monoclonal antibodies.

RET*: Methods for Reticulocyte Counting (Automated Blood Cell Counters, Flow Cytometry, and Supravital Dyes); Approved Guideline – Second Edition Manual method CLSI H44-A2 (2004).

Limitations of the examination procedure
The use of this product is validated on specific devices to optimize product performance and meet product specifications. Please refer to the Instructions for Use of your device to confirm that the use of this product is authorized by Sysmex. Sysmex cannot take the responsibility for patient results obtained from the use of Sysmex products on unauthorized devices. It is the responsibility of the user to validate modifications to these instructions or use of the product on devices other than those specified by Sysmex.

Manufacturer
Sysmex Corporation
1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073, Japan

“Producer” on OEM-Basis:
STRECK, Inc.
7002 S. 109th Street La Vista, NE 68128, U.S.A.

Authorized representatives
Europe, Middle East and Africa:
EC REP **Sysmex Europe GmbH**
Bornbarch 1, 22848 Norderstedt, Germany

Americas: **Sysmex America, Inc.**
577 Aptakisic Road, Lincolnshire, IL 60069, U.S.A.

Asia-Pacific: **Sysmex Asia Pacific Pte Ltd.**
9 Tampines Grande #06-18, Singapore 528735

Product information
SCS-1000 2.0 mL x 3 vials

Date of issue or revision
07/2020

* Not available for all countries

REF Catalogue number

IVD In vitro diagnostic medical device

Manufacturer

EC REP Authorised Representative in the European Community

Consult instructions for use

Temperature limitation

Use by

LOT Batch code

Biological Risks

SCS™-1000

BG

Предупреждения и предпазни мерки
Да не се инжектира или поглъща.
Всички изходни човешки материали, използвани за произвеждането на този продукт, са нереактивни за антигени към хепатит B (HBsAg), с отрицателен резултат от тестове за антитела към HIV (HIV-1/HIV-2) и хепатит C (HCV), нереактивни към HIV-1 RNA и HCV RNA, изследвани чрез лицензирани NAT, и нереактивни на серологичен тест за сифилис (STS) при използване на техники, посочени от Агенцията по храните и лекарствата (FDA) на САЩ. Тъй като никой познат метод за тестване не може да гарантира пълна липса на човешки патоген, с този продукт трябва да се работи с подходящи предпазни мерки.

CS

Varování a bezpečnostní opatření
Neaplikujte injekčně ani nepolykejte.
Veškerý materiál humánního původu použitý při výrobě tohoto výrobku byl prokázán jako nereaktivní na antigen hepatitidy B (HBsAg), jako negativní při testech na protilátky proti HIV (HIV-1/HIV-2) a hepatitidě C (HCV), nereaktivní pro HIV-1 RNA a HCV RNA licencovaným NAT a nereagoval ani v sérologickém testu na syfilis (STS), a to za použití metod specifikovaných americkým Úřadem pro potraviny a léčiva (FDA). Jelikož žádná známá testovací metoda nemůže zaručit absolutní nepřítomnost humánních patogenů, měla by být při manipulaci s tímto výrobkem dodržována odpovídající bezpečnostní opatření.

DA

Advarsler og sikkerhedsforanstaltninger
Må ikke injiceres eller indtages.
Alt humant kildemateriale, der er anvendt til at fremstille dette produkt, er testet ikke-reaktivt for antigener mod Hepatitis B (HBsAg), negativ ved tests for antistoffer mod HIV (HIV-1/HIV-2) og Hepatitis C (HCV), ikke-reaktivt for HIV-1 RNA og HCV RNA ved en licenseret NAT og ikke-reaktivt mod serologisk test for syfilis (STS) med teknikker, der er fastlagt af de amerikanske fødevare- og medicinalmyndigheder (FDA). Da der ikke findes en kendt testmetode, der kan sikre et fuldkommen fravær af humane patogener, skal dette produkt håndteres med egnede forholdsregler.

DE

Warnhinweise und Vorsichtsmaßnahmen
Nicht injizieren oder einnehmen.
Sämtliches Material humanen Ursprungs, das zur Herstellung dieses Produkts verwendet wurde, war nicht reaktiv für Antigene von Hepatitis B (HBsAg), negativ in Tests auf Antikörper gegen HIV (HIV-1/HIV-2) und Hepatitis C (HCV), nicht reaktiv für HIV-1 RNA und HCV RNA in zugelassenen NAT-Tests und nicht reaktiv für den serologischen Test auf Syphilis (STS) mit Verfahren, die von der US-Bundesbehörde der Lebens- und Arzneimittelüberwachung vorgeschrieben sind. Da keine bekannte Testmethode die völlige Abwesenheit von humanpathogenen Erregern sichern kann, sollte dieses Produkt unter Ergreifung der entsprechenden Vorsichtsmaßnahmen gehandhabt werden.

EL

Προφυλάξεις και προειδοποιήσεις
Ακατάλληλο για ένεση και λήψη.
Όλα τα υλικά που προέρχονται από τον άνθρωπο για την παρασκευή αυτού του προϊόντος ήταν μη αντιδραστικά για αντιγόνα σε Ηπατίτιδα B (HBsAg), αρνητικά σε ελέγχους για αντισώματα σε HIV (HIV-1/HIV-2) και Ηπατίτιδα C (HCV), μη αντιδραστικά για HIV-1 RNA και HCV RNA από εγκεκριμένο NAT και μη αντιδραστικά σε Ορολογικούς Ελέγχους για Σύφιλη (STS) χρησιμοποιώντας τεχνικές που ορίζονται από τον Οργανισμό Τροφίμων και Φαρμάκων των Η.Π.Α. Επειδή καμία γνωστή μέθοδος ελέγχου δεν μπορεί να εξασφαλίσει ολοκληρωτική απουσία των ανθρώπινων παθογόνων, πρέπει να χειριστείτε αυτό το προϊόν με τις κατάλληλες προφυλάξεις.

ES

Advertencias y precauciones
No inyectar ni ingerir.
Todo el material de origen humano utilizado para fabricar este producto se mostró no reactivo a antígenos de Hepatitis B (HBsAg), dio negativo en ensayos de anticuerpos de HIV (HIV-1/HIV-2) y Hepatitis C (HCV), se mostró no reactivo a HIV-1 RNA y HCV RNA mediante el sistema NAT con licencia y no reactivo al Test serológico para sífilis (STS) utilizando las técnicas especificadas por la Administración de alimentos y fármacos de EE.UU. Ya que ningún método de prueba puede asegurar una ausencia completa de patógenos humanos, este producto se debe manipular con la debida precaución.

ET

Hoiatused ja ettevaatusabinõud
Ärge süstige ega neelake.
Kõik selle toote valmistamiseks kasutatud inimmaterjalid olid mittereageerivad B-hepatiidi (HBsAg) antikehadele, negatiivsed HIV (HIV-1/HIV-2) ja C-hepatiidi (HCV) antikehade suhtes, mittereageerivad litsentsitud NAT HIV-1 RNA ja HCV RNA suhtes ning mittereageerivad USA Toidu- ja Ravimiameti määratud tehnikaid kasutades süüfilise seroloogilise testi suhtes (STS). Kuna ükski tuntud testimismeetod ei saa tagada inimpatogeenide täielikku puudumist, siis tuleks seda toodet käsitseda vastavate ettevaatusabinõudega.

FI

Varoitukset ja varotoimet
Älä injisoi tai niele.
Tämän tuotteen valmistuksessa käytetty ihmisperäinen materiaali on testattu kokonaisuudessaan ja todettu Yhdysvaltain elintarvike- ja lääkeviranomaisen määrittämiä tekniikoita käyttämällä vasta-ainetestien perusteella ei-reaktiiviseksi B-hepatiitti-vasta-aineille (HBsAg), testien perusteella HIV (HIV-1/HIV-2)- ja hepatiitti C (HCV) -vasta-ainenegatiiviseksi, NAT perusteella ei-reaktiiviseksi HIV-1-RNA:lle ja HCV-RNA:lle ja serologisen tutkimuksen (STS) perusteella ei-reaktiiviseksi syfilikselle. Koska mikään tunnettu testausmenetelmä ei voi täysin sulkea pois ihmispatogeenien mahdollisuutta, tämän tuotteen käsittelyssä on noudatettava asianmukaisia varotoimia.

FR

Avertissements et mesures de précaution
Ne pas injecter ni ingérer.
Tous les matériaux d'origine humaine utilisés pour fabriquer ce produit sont non réactifs à l'antigène de l'hépatite B (HBsAg), négatifs aux tests d'anticorps du HIV (HIV-1/HIV-2) et de l'hépatite C (HCV), non réactifs à HIV-1 RNA et HCV RNA par NAT homologué et non réactifs aux tests sérologiques de la syphilis (TSS) utilisant les techniques indiqués par l'Administration des Aliments et Médicaments (FDA) des États-Unis. Cependant, aucune méthode d'examen ne peut permettre de garantir l'absence totale d'agents pathogènes humains. Ce produit doit donc être manipulé avec une extrême précaution.

HR

Upozorenja i mjere opreza
Ne ubrizgavajte i ne gutajte.
Nijedan od ljudskih izvornih materijala koji se koriste za proizvodnju ovog proizvoda nije bio reaktivan za antigene na hepatitis B (HBsAg), svi su bili negativni na testove na antitijela za HIV (HIV-1/HIV-2) i hepatitis C (HCV), nisu bili reaktivni na HIV-1 RNA i HCV RNA uporabom licencirane NAT metode, niti na serološki test za sifilis (STS) uporabom metoda propisanih od strane Američke agencije za hranu i lijekove. Budući da nijedan poznati test ne može jamčiti potpunu odsutnost ljudskih patogena, ovim proizvodom treba rukovati uz odgovarajuće mjere opreza.

HU

Figyelmeztetések és óvintézkedések
Ne fecskendezze be és ne nyelje le!
A termék elkészítéséhez használt egyik humán forrásanyag sem volt reaktív a hepatitisz B antigénekre (HBsAg) nézve, a HIV (HIV-1/HIV-2) és a hepatitisz C (HCV) antitestek vizsgálatára szolgáló tesztek negatívak voltak, a jóváhagyott nukleinsav teszttel (NAT) végzett vizsgálat HIV-1 RNA-ra és HCV RNA-ra nézve nem volt reaktív, valamint az Amerikai Egyesült Államok Élelmiszer- és Gyógyszerellenőrző Hivatala (Food and Drug Administration) által meghatározott technikákat alkalmazó szifilisz szerológiai teszt (STS) sem volt reaktív. Mivel egyetlen ismert tesztmódszer sem biztosíthatja a humán patogének teljes hiányát, a terméket kellő elővigyázatossággal kell kezelni.

IT

Avvertenze e precauzioni
Non iniettare né ingerire.
Tutto il materiale di origine umana utilizzato nella produzione di questo prodotto non ha evidenziato alcuna reattività agli antigeni dell'epatite B (HBsAg), si è rivelato negativo ai test degli anticorpi anti-HIV (HIV-1/HIV-2) e anti-epatite C (HCV), non ha mostrato alcuna reattività all'HIV-1 RNA e HCV RNA tramite test NAT autorizzato, nè al test sierologico per la sifilide (STS), utilizzando le tecniche specificate dall'agenzia americana Food and Drug Administration. Poiché nessun metodo di analisi conosciuto è in grado di assicurare la completa assenza di agenti patogeni umani, questo prodotto deve essere manipolato con le opportune precauzioni.

LT

Įspėjimai ir atsargumo priemonės
Negalima įšvirkšti ar nuryti.
Visos šio gaminio gamybai naudojamos žmogaus kilmės medžiagos nereagavo su hepatito B (HBsAg) antigenais, neigiami rezultatai gauti tiriant antikūnius prieš ŽIV (HIV-1/HIV-2) ir hepatitą C (HCV), nereagavo su HIV-1 RNA ir HCV RNA (testai atlikti licencijuota NAT), nereagavo į serologinius sifilio (STS) testus naudojant JAV maisto ir vaistų administracijos apibrėžtus metodus. Šis produktas turi būti naudojamas laikantis atitinkamų atsargumo priemonių, nes jokie žinomi tyrimų metodai negali užtikrinti, kad nebus jokių žmogaus patogenų.

LV

Brīdinājumi un piesardzības pasākumi
Neinjicēt un nenorīt.
Visi no cilvēkiem iegūtie materiāli, kas izmantoti šā produkta ražošanā, nereaģēja uz B hepatīta (HBsAg) antigēniem, uzrādīja negatīvus rezultātus HIV (HIV-1/HIV-2) un C hepatīta (HCV) antivielu testos, nereaģēja uz HIV-1 RNA un HCV RNA ar licencētu NAT, kā arī nereaģēja uz seroloģisko pārbaudi sifilisa (STS) noteikšanai, izmantojot ASV Pārtikas un zāļu pārvaldes noteiktās metodes. Tā kā neviena zināma metode nevar nodrošināt cilvēka patogēnu pilnīgu neesamību, ar šo izstrādājumu jārīkojas, atbilstīgi piesargoties.

NL

Waarschuwingen en voorzorgsmaatregelen
Niet injecteren of inslikken.
Al het materiaal van menselijke oorsprong dat is gebruikt voor het produceren van dit product reageerde niet voor antigenen op Hepatitis B (HBsAg), was negatief voor tests voor antilichamen op HIV (HIV-1/HIV-2) en Hepatitis C (HCV), reageerde niet voor HIV-1 RNA en HCV RNA door gelicentieerde NAT, en reageerde niet op Serologische Test voor Syfilis (STS) met behulp van technieken die zijn gespecificeerd door de U.S. Food and Drug Administration (Amerikaanse organisatie ter controle op voedingswaren en geneesmiddelen). Omdat geen bekende testmethode volledige afwezigheid van menselijke pathogenen kan verzekeren, moet dit product met de gepaste voorzorgsmaatregelen worden behandeld.

NO

Advarsler og sikkerhetsregler
Må ikke injiseres eller svelges.
Alle menneskelige råmaterialer som ble brukt i fremstillingen av dette produktet, har vært testet og funnet ikke-reaktive for antigener til hepatitt B (HBsAg), negative for antistoffer til HIV (HIV-1/HIV-2) og hepatitt C (HCV), ikke-reaktive for HIV-1 RNA og HCV RNA ved godkjent NAT, og ikke-reaktive ved serologisk test for syfilis (STS) i henhold til metoder spesifisert av U.S. Food and Drug Administration. Ettersom ingen kjente testmetoder kan garantere fullstendig mangel på menneskelige patogener, må det tas hensiktsmessige forholdsregler ved håndtering av dette produktet.

PL

Ostrzeżenia i środki ostrożności
Nie wstrzykiwać ani nie połykać.
Wszystkie materiały pochodzenia ludzkiego użyte do wytworzenia tego produktu były niereaktywne pod względem antygenów wirusa zapalenia wątroby typu B (HBsAg), jak również uzyskały wynik ujemny w testach na obecność przeciwciał przeciwko wirusowi HIV (HIV-1/HIV-2) i przeciwko wirusowi zapalenia wątroby typu C (HCV), a także były niereaktywne pod względem HIV-1 RNA i HCV RNA w testach przeprowadzonych z zastosowaniem licencjonowanych technik amplifikacji kwasu rybonukleinowego (NAT, Nucleic Acid Amplification Technology) oraz niereaktywne w badaniu serologicznym pod kątem syfilisu (STS, Serological Test for Syphilis) przeprowadzonym z zastosowaniem technik określonych przez Amerykański Urząd ds. Żywności i Leków. Ponieważ żadna znana metoda badań nie gwarantuje całkowitego wykluczenia obecności patogenów ludzkich, podczas stosowania produktu należy zachować odpowiednie środki ostrożności.

PT

Advertências e precauções
Não injectar nem ingerir.
Todos os materiais de origem humana utilizados no fabrico deste produto são não reactivos aos antigénios de Hepatite B (HBsAg), são negativos aos testes de anticorpos a HIV (HIV-1/HIV-2) e Hepatite C (HCV), são não reactivos a HIV-1 RNA e HCV RNA por NAT autorizado, e são não -reactivos ao Teste Serológico de Sífilis (STS) usando as técnicas especificadas pela U.S. Food and Drug Administration. Uma vez que nenhum método de teste conhecido pode assegurar a ausência total de elementos patogénicos humanos, este produto deve ser manuseado com precauções adequadas.

RO

Avertismente şi măsuri de precauţie
A nu se injecta sau ingera.
Toate materialele care provin din surse umane şi care au fost folosite la realizarea acestui produs au fost testate, rezultatele negative indicând absenţa antigenilor de hepatită B (HBsAg), anticorpilor pentru HIV (HIV-1/HIV-2) şi Hepatită C (HCV), absenţa HIV-1 RNA şi HCV RNA fiind indicată prin tehnici brevetate de amplificare a acizilor nucleici (NAT), rezultatele fiind negative şi la testul serologic pentru sifilis (STS) realizat prin utilizarea tehnicilor specificate de Food and Drug Administration din SUA. Deoarece nicio metodă de testare cunoscută nu poate asigura absenţa completă a agenţilor patogeni umani, acest produs trebuie manevrat luând toate măsurile de precauţie corespunzătoare.

RU

Предупреждения и предосторожности
Не впрыскивать и не глотать.
Все материалы человеческого происхождения, использованные в производстве этого продукта, не содержали антигенов к гепатиту B (HBsAg), давали отрицательные результаты в тестах на содержание антител к HIV (HIV-1/HIV-2) и гепатиту C (HCV), не давали реакции на HIV-1 RNA и HCV RNA в лицензированном методе NAT, а также не давали реакции в серологических тестах на сифилис (STS) при использовании методов, соответствующих требованиям Управления по контролю за продуктами и лекарствами США (FDA). Однако, поскольку ни один из известных методов не может гарантировать полное отсутствие патогенов человека, с этим продуктом следует обращаться с соответствующей осторожностью.

SK

Varovania a bezpečnostné opatrenia
Výrobok nepodávajte injekčne ani orálnou formou.
Žiadne ľudské zdrojové materiály, ktoré sa použili pri výrobe tohto výrobku, nepreukazovali reaktivitu s antigénmi hepatitídy B (HBsAg), boli negatívne pri testovaní protilátok proti HIV (HIV-1/HIV-2) a proti hepatitíde C (HCV), tiež boli nereaktívne v prípade protilátok pre HIV-1 RNA a HCV RNA, ktoré boli testované licencovaným testom nukleovej kyseliny (NAT), materiál bol negatívny aj v prípade sérologického testu na syfilis (STS), ktorý využíva technické postupy špecifikované nariadeniami Úradu na kontrolu potravín a liečiv USA. Vzhľadom na to, že táto testovacia metóda môže zaistiť úplnú absenciu ľudských patogénov, je potrebné zaobchádzať s týmto výrobkom mimoriadne opatrne.

SL

Opozorila in previdnostni ukrepi
Ne injicirajte in ne zaužijte.
Ves material človeškega izvora, ki je bil uporabljen za izdelavo tega izdelka, ni bil reaktiven za antigene hepatitisa B (HBsAg), bil je negativen pri testih za protitelesa proti HIV (HIV-1/HIV-2) in hepatitisu C (HCV), ni bil reaktiven za HIV-1 RNA in HCV RNA z licencirano metodo pomnoževanja nukleinskih kislin – NAT, in ni bil reaktiven na serološke teste za sifilis (STS) s tehnikami, ki jih določa Uprava ZDA za hrano in zdravila. Ker z nobeno znano metodo ni mogoče potrditi popolne odsotnosti človeških patogenov, so pri uporabi tega izdelka potrebni ustrezni previdnostni ukrepi.

SR

Upozorenja i mere predostrožnosti
Ne injektirajte i ne gutajte.
Nijedan od materijala ljudskog porekla koji se koriste za proizvodnju ovog proizvoda nije bio reaktivan za antigene hepatitis B virusa (HBsAg), svi su bili negativni na testove na antitela za HIV (HIV-1/HIV-2) i hepatitis C virus (HCV), nisu bili reaktivni na HIV-1 RNA i HCV RNA upotrebom licencirane NAT metode, niti na serološki test za sifilis (STS) upotrebom metoda propisanih od strane Američke agencije za hranu i lekove. Budući da nijedan poznati test ne može da garantuje potpuno odsustvo ljudskih patogena, ovim proizvodom potrebno je rukovati uz odgovarajuće mere opreza.

SV

Varningar och förebyggande åtgärder
Får inte injiceras eller intas.
Allt humant källmaterial som användes vid tillverkningen av den här produkten var icke-reaktivt för antigener mot Hepatitis B (HBsAg), negativt enligt tester för antikroppar mot HIV (HIV-1/HIV-2) och Hepatitis C (HCV), icke-reaktivt för HIV-1 RNA och HCV RNA enligt licensierad NAT, samt icke-reaktivt för STS (serologiskt test för syfilis) enligt tekniker som har angivits av FDA. Eftersom ingen känd testmetod kan garantera total avsaknad av humana patogener, bör produkten hanteras enligt lämpliga försiktighetsregler.

TR

Uyarılar ve önlemler
Enjekte etmeyiniz ve yutmayınız.
Bu ürünü üretmek için kullanılan insan kaynaklı maddelerin hiçbiri Hepatit B (HBsAg) antijenlerine karşı reaktif değildir, HIV (HIV-1/HIV-2) ve Hepatit C (HCV) antikorlarının testleri itibariyle negatiftir, ruhsatlı NAT (Nükleik Asit Testleri) itibariyle HIV-1 RNA ve HCV RNA'ya karşı reaktif değildir ve ABD Gıda ve İlaç Yönetimi (FDA) tarafından belirlenen tekniklerin kullanıldığı Sifilis için Serolojik Teste (STS) karşı reaktif değildir. Bilinen hiçbir test yöntemi insan patojenlerinin yokluğunu bütünüyle garanti etmediğinden, bu ürün gerekli önlemler alınarak kullanılmalıdır.