

K960894

510(k) Summary of Safety and Effectiveness

510(k) Submitter:

Streck Laboratories, Inc.
14306 Industrial Road
Omaha, Nebraska 68144

MAY 24 1996

Official Correspondent:

Theodore Heise, Ph.D.
Quality Assurance/Regulatory Affairs Manager
(402) 691-7465

Date Prepared:

May 13, 1996

Names of Device:

Trade Name: CD-Chex PLUS (K960894)
Common Name: Immunophenotyping control
Classification Name: White cell control (§864.8625)

Predicate Device:

CD-Chex (K920997) manufactured by Streck Laboratories

Description: CD-Chex PLUS is a suspension of stabilized human red blood cells and human white cells packaged in glass vials containing 2.5 or 4.0 mL volumes. Closures are polypropylene screw-top caps. The vials are packaged in polystyrene jars.

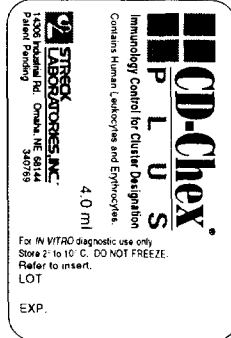
Intended Use: CD-Chex PLUS is intended to be used as a control for evaluating monoclonal antibody binding by flow cytometry. CD-Chex PLUS control cells possess surface antigens detectable with monoclonal antibodies. When these cells are stained with fluorescent antibodies and analyzed by flow cytometry they provide a reference for normal peripheral blood leukocytes. CD-Chex PLUS is designed for use on Becton Dickinson and Coulter flow cytometry systems

Comparison with Predicate Device: Like CD-Chex CD-Chex PLUS is intended to enable the user to verify satisfactory performance of flow cytometry systems. Both devices contain control cells which possess surface antigens detectable with monoclonal antibodies. Unlike CD-Chex, CD-Chex PLUS contains stabilized human red cells. This allows the user to verify proper performance of the red cell lysing step which gives the user a true positive procedural control.

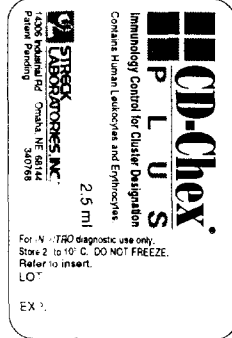
Discussion of Tests and Test Results: Four studies of CD-Chex PLUS were conducted: I) Lot to Lot Reproducibility and Comparison to Whole Blood ; II) Site to Site Reproducibility and Comparison to Predicate Device; III) Long Term Stability; and IV) Open Vial Stability. Study results showed CD-Chex PLUS to be consistently reproducible, substantially equivalent to the predicate product, and stable for the entire product dating.

Conclusions Drawn from Tests: CD-Chex PLUS is a safe and effective control for immunophenotyping when used as instructed in the product package insert.

4.0 mL Vial Label



2.5 mL Vial Label



FRANÇAIS Contrôle d'immunologie pour la Détermination des Classes de Différenciation. Disponible en Niveau normal. Contient des Leucocytes Humains. Uniquement pour diagnostic IN VITRO. Conserver entre 2°C et 10°C. NE PAS CONGELER. Se référer à la notice de la boîte. LE MATÉRIEL HUMAIN, DUQUEL CE PRODUIT A ÉTÉ DÉRIVÉ, A ÉTÉ TROUVÉ NON-REACTIF POUR L'ANTIGÈNE DE SURFACE DE L'HÉPATITE B, POUR LE VIRUS DE L'HÉPATITE C (HCV) ET L'ANTICORPS VIH EN UTILISANT DES TECHNIQUES SPÉCIFIÉES PAR LA FDA.

DEUTSCH Kontrolle zur immunologischen Clusterbestimmung. Mit normalem Anteil erhältlich. Enthält humane Leukozyten. Zur IN VITRO Diagnose ausschließlich bei 2-10°C lagern. NICHT EINFRIEREN. Packungsbeilage beachten. DAS HUMANE AUSGANGSMATERIAL, AUS DEM DIESES PRODUKT HERGESTELLT WURDE, WURDE MIT VON DER FDA VORGESCHRIEBENEN METHODEN UNTERSUCHT. HINSICHTLICH HEPATITIS B OBERFLÄCHENANTIGEN, HEPATITIS C VIRUS (HCV) UND HIV ANTIKÖRPER WURDEN KEINE REAKTIONEN FESTGESTELLT.

ITALIAN Controllo immunologico per la Definizione del Cluster. Disponibile a Espressione Normale. Contiene Leucociti Umani. NR. Richiesta di Brevetto. Solo per uso diagnostico IN VITRO. Conservare a 2-10°C. NON CONGELARE. Consultare Foglietto illustrativo. QUESTO PRODOTTO È STATO COSTITUITO CON MATERIALE DI ORIGINE UMANA CHE NON È RISULTATO POSITIVO AL VIRUS DELL'EPATITE B C (HCV) E ALL'ANTI-CORPO HIV SECONDO LE METODICHE CONSIGLIATE DALLA FDA.

ALL HUMAN SOURCE MATERIAL USED IN THE MANUFACTURE OF THIS PRODUCT HAS BEEN TESTED AND FOUND TO BE NON-REACTIVE FOR HEPATITIS B VIRUS (HBsAg), HEPATITIS C VIRUS (HCV ANTIBODY), AND HUMAN IMMUNODEFICIENCY VIRUS (HIV-1/HIV-2 ANTIBODIES) USING TECHNIQUES LICENSED BY THE U.S. FOOD AND DRUG ADMINISTRATION. BECAUSE NO KNOWN TEST METHOD CAN OFFER COMPLETE ASSURANCE THAT THESE PATHOGENS ARE ABSENT, THIS PRODUCT SHOULD BE HANDLED IN ACCORDANCE WITH GOOD LABORATORY PRACTICES USING APPROPRIATE PRECAUTIONS.



ESPAÑOL Control inmunológico para la determinación del Cluster. Disponible para recuentos normales. Contiene leucocitos humanos. Unicamente para el diagnóstico IN VITRO. Mantener entre 2-10°C. NO CONGELAR. Ver especificaciones en el prospecto adjunto. MATERIAL DE ORIGEN HUMANO. NO PRESENTA REACTIVIDAD CRUZADA CON EL ANTIGENO DEL VIRUS DE LA HEPATITIS B, DEL VIRUS DE LA HEPATITIS C (VHC) Y HIV. ANALISIS REALIZADO SEGUN LAS ESPECIFICACIONES TECNICAS DE LA FDA.

CATALOG # / Nº CATALOGUE /
KATALOGNUMMER / NR. CATALOGO / CATALOGO/

CONTENTS / CONTENU / INHALT /
CONTENUTO / CONTENIDO/

LOT # / Nº LOT / CHARGENUMMER /
NR. LOTTO / Nº. DE LOTE /

EXP / DAT: d'EXP / VERFALLSDATUM /
DATA DI SCADENZA / FECHA DE CADUC /

Jar Label