

INSTRUCTIONS FOR USE

INTENDED USE

CD-Chex Select® is intended to be used as a quality control material for evaluating monoclonal antibody binding by flow cytometry. When these cells are stained with fluorescent antibodies and analyzed by flow cytometry they provide a reference for normal and abnormal peripheral blood leukocytes. CD-Chex Select is designed for use on BD Biosciences and Beckman Coulter® flow cytometry systems. **This product and the markers provided on the assay have not been cleared by the U.S. Food and Drug Administration for In Vitro Diagnostic use. This product and the values provided are For Research Use Only. Not for use in diagnostic procedures.**

SUMMARY/PRINCIPLES

Immunophenotyping by flow cytometry provides a rapid and accurate assessment of the frequency and type of leukocytes present in a whole blood sample. Quantitation of peripheral blood leukocyte subsets has been shown to be useful in research and clinical applications including the evaluation of autoimmune and oncologic disorders. CD-Chex Select is a positive procedure assayed control used to monitor reagent staining, erythrocyte lysis, sample preparation, and instrument performance. CD-Chex Select mimics whole blood samples by possessing surface antigens and intracellular antigens detectable with fluorescent monoclonal antibodies by flow cytometry.

Subsets of leukocytes can be distinguished on the basis of light scatter properties as well as the presence of cell surface antigens. CD-Chex Select is designed to represent normal and abnormal peripheral blood leukocytes where lymphocytes, monocytes, and granulocytes are distinguishable on the basis of light scatter properties.

REAGENTS

CD-Chex Select contains stabilized human blood in a preservative medium.

PRECAUTIONS

1. CD-Chex Select is For Research Use Only.
2. CAUTION: All blood products should be treated as potentially infectious. Source material from which this product was derived was found negative when tested in accordance with current FDA required tests. No known test methods can offer assurance that products derived from human blood will not transmit infectious agents. See the Instructions (IFU) tab under Resources on the product page at www.streck.com for specific FDA required blood tests.
3. This product should not be disposed in general waste, but should be disposed with infectious medical waste. Disposal by incineration is recommended.
4. This product is intended for use as supplied. Adulteration by dilution or addition of any materials to the product vial invalidates the use of the product.
5. CD-Chex Select should not be used as a calibrator.

STORAGE AND STABILITY

CD-Chex Select is stable through the expiration date when stored at 2 °C to 10 °C. After opening, CD-Chex Select is stable throughout the open-vial dating, as indicated on the assay sheet, when stored at 2 °C to 10 °C. DO NOT FREEZE.

INDICATIONS OF PRODUCT DETERIORATION

Inability to obtain expected values may indicate product deterioration. If the recovered values are not within the expected ranges:

1. Review control product package insert and the operating procedure of the instrument.
2. Check expiration date of the product on the vial. Discard outdated products.
3. Clumping of the cell suspension indicates instability or deterioration, in which case the reagent should not be used.
4. Assay an unopened vial of CD-Chex Select. If the values are still outside the expected range, contact Streck Technical Services at 800-843-0912 or technicalservices@streck.com.

INSTRUCTIONS FOR USE

1. Follow instrument manufacturer's instructions for instrument alignment and sample analysis.
2. Remove a vial of the control from refrigerator and warm to room temperature (18 °C to 30 °C) for 15 minutes before use.
3. Mixing Procedure (**mechanical mixing by vortex or rotator is not recommended**):
For a video demonstration, visit www.streck.com/mixing.
 - a. Holding the vial vertically between the palms of the hands, roll the vial back and forth for 20-30 seconds.



- b. Hold the vial by the ends between the thumb and finger, and mix by gently inverting the vial at least 8-10 times end-over-end until all cells are thoroughly suspended.



- c. Aliquot immediately after mixing.
 - d. Subsequent analyses during this test period may be performed by inverting the vial 5 times prior to sampling.
Note: Vials stored for an extended period of time may require extra mixing.
4. Return control reagent to refrigeration after sampling to ensure maximum open-vial stability.
 5. Add recommended monoclonal antibodies according to manufacturer's instructions to each tube and mix gently.
Note: For optimal results, antibody titration may be necessary.
 6. Incubate according to antibody manufacturer's instructions.
 7. Add recommended amount of RBC lysing agent and follow manufacturer's instructions.
 8. Analyze by flow cytometry using your laboratory's established protocol.

INTRACELLULAR MARKER INSTRUCTIONS FOR USE

Follow steps 1-3 above. CD-Chex Select is a stabilized blood material. Therefore, the fixation step (Reagent 1 or Reagent A) used prior to permeabilization in commercially available intracellular staining kits is not required. Use of the fixation reagent will result in sub-optimal recovery.

LIMITATIONS

1. For optimum results, CD26 should be evaluated using a mAb conjugated to fluorochromes other than FITC.
2. IgM antibodies are not recommended for TCR α/β.

EXPECTED RESULTS

The mean values provided are derived from replicate analyses on properly compensated flow cytometers.^{1,2} The assay values are obtained using reagents recommended by each instrument manufacturer. The expected ranges listed represent estimates of variation due to different laboratories' reagents, instrument performance, maintenance, and operator technique.

It is recommended that an individual laboratory establish its own control means and ranges for each parameter and sample analyzed that reflect the laboratory's specific conditions and protocols. These established control means should fall within the published expected ranges. Data collected from interlaboratory quality control programs can be used as a cumulative approach when calculating ranges.

REFERENCES

1. Clinical and Laboratory Standards Institute, H43-A2, Clinical flow cytometric analysis of neoplastic hematology cells. Approved Guideline - Second Edition.
2. Clinical and Laboratory Standards Institute, H42-A2, Enumeration of immunologically defined cell populations by flow cytometry. Approved Guideline - Second Edition.

QUALITY CONTROL

Streck offers STATS®, an interlaboratory quality control program, to all customers at no charge. For more information, contact the STATS Department at 800-898-9563 or statsdata@streck.com. Additional information can be found at www.streck.com.

ORDERING INFORMATION

Please call our Customer Service Department at 800-228-6090 for assistance. Additional information can be found online at www.streck.com.

GLOSSARY OF HARMONIZED SYMBOLS

Batch Code	Biological Risk	Catalog Number	Use By	Manufacturer	Consult Instructions For Use	Temperature Limitation

Glossary of symbols may contain symbols not used in the labeling of this product.

The brand and product names of the instruments are trademarks of their respective holders.

See www.streck.com/patents for patents that may be applicable to this product.



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Instructions for use can be obtained at www.streck.com in the product's Resources section, by calling 402-333-1982, or by calling your local supplier.

Bulgarian (Български)

Инструкциите за употреба можете да получите от www.streck.com в секцията с източници на информация за продукта, като се обадите на 402-333-1982 или като се обадите на своя местен доставчик.

Croatian (Hrvatski)

Upute za upotrebu možete dobiti posjetom internetne stranice www.streck.com u razdjelku Resursi, pozivom na broj 402-333-1982 ili pozivom svog lokalnog dobavljača.

Czech (Čeština)

Pokyny k použití lze získat na adrese www.streck.com v části „Resources“ (Zdroje) daného produktu, telefonicky na čísle 402 333 1982, nebo telefonicky od místního dodavatele.

Danish (Danske)

Brugsvejledning kan fås på www.streck.com i produktets ressourceafdeling, ved at ringe til +1 402-333-1982 eller ved at ringe til din lokale leverandør.

Estonian (Eesti keel)

Kasutusjuhendeid on võimalik leida internetiaadressilt www.streck.com tootja ressurside (Resources) jaotisest või helistades 402-333-1982 või võttes ühendust kohaliku endasimüüjaga.

Finnish (Suomi)

Käyttöohjeet löydät osoitteesta www.streck.com tuotteen resurssija käsittelevästä osiosta, soittamalla numeroon +1 402-333-1982 tai ottamalla yhteyttä paikalliseen toimittajaasi.

French (Français)

Les instructions sont disponibles à l'adresse www.streck.com dans la section Ressources du produit, en composant le 402-333-1982, ou en appelant votre fournisseur local.

German (Deutsch)

Gebrauchsanweisungen erhalten Sie unter www.streck.com im Produktressourcen-Abschnitt, unter der Telefonnummer +1 402-333-1982 oder durch einen Anruf bei Ihrem örtlichen Lieferanten.

Greek (Ελληνικά)

Οδηγίες χρήσης μπορούν να ληφθούν από τη διεύθυνση www.streck.com, στην ενότητα Resources (Πόροι) του προϊόντος, είτε καλώντας στο 402-333-1982 είτε καλώντας τον τοπικό προμηθευτή σας.

Hebrew (ת.י.ר.ב.ט.)

או, בצומה לש (סיבאשמ) Resources רודמב , www.streck.com ורשיקב גישהל תיני שומישה תוארוה תא ד.לש ימוקמה קפסה לא ופלטב רשקהלה, 1-402-333-1982 רפסמל ופלטב רשקהלה

Hungarian (Magyar)

A használatra vonatkozó utasításokat megtalálja a www.streck.com webhelyen a termék Resources (Forrásanyagok) című szakaszában, illetve kérheti a 402-333-1982 telefonszámon vagy a helyi beszállítótól.

Italian (Italiano)

Per le Istruzioni per l'uso, consultare la sezione Risorse del prodotto sul sito www.streck.com oppure telefonare al numero 402-333-1982 o al fornitore di zona.

Latvian (Latviešu valodā)

Lietošanas instrukcijas pieejamas vietnes www.streck.com izstrādājumu resursu sadaļā, zvanot 402-33-1982 vai zvanot vietējam piegādātājam.

Lithuanian (Lietuvių)

Naudojimo instrukcijas rasite www.streck.com, produkto skiltyje „Resources“ (ištekliai). Be to, jų galite paprašyti paskambinę 402-333-1982 arba susisiekti su savo vietiniu tiekėju.

Norwegian (Norsk)

Bruksanvisning kan fås på www.streck.com i produktets Resources [ressurs]-avsnitt, ved å ringe +402-333-1982 eller ved å ringe til den lokale forhandler.

Polish (Polski)

Aby uzyskać instrukcje użytkowania, należy odwiedzić sekcję Resources (Zasoby) na podstronie produktu pod adresem www.streck.com lub skontaktować się telefonicznie, korzystając z numeru 402-333-1982 lub numeru lokalnego dostawcy.

Portuguese (Português)

As instruções de utilização podem ser obtidas em www.streck.com na secção de Recursos do produto através do número de telefone 402-333-1982, ou contactando o seu fornecedor local.

Romanian (Română)

Instrucțiunile de utilizare sunt disponibile pe pagina www.streck.com, în secțiunea Resurse a produsului, sau telefonic la numărul 402-333-1982 sau contactând telefonic furnizorul local.

Serbian (Српски)

Упутство за коришћење можете наћи на интернет сајту www.streck.com под разделком Ресурси, позивом на 402-333-1982 или позивом свог локалног добављача.

Slovak (Slovenčina)

Pokyny na používanie nájdete na stránke www.streck.com na podstránke produktu v časti Resources (zdroje) alebo zavolajte na číslo 402-333-1982, prípadne kontaktujte vášho miestneho dodávateľa.

Spanish (Español)

Para obtener las instrucciones de uso, visite www.streck.com, en la sección de recursos del producto, o llame al número telefónico +1 402 333 1982 o al proveedor de su localidad.

Swedish (Svenska)

Bruksanvisning finns på www.streck.com i sektionen "Resources" för produkten, genom att ringa till +1-402-333-1982 eller genom att ringa närmaste leverantör.

Turkish (Türkçe)

Kullanım talimatlarınıza ulaşmak için www.streck.com internet adresinde ürünün Kaynaklar bölümüne bakabilir ya da 402-333-1982 telefon numarasını veya yerel tedarikçinizi arayabilirsiniz.