

## INSTRUCTIONS FOR USE

### INTENDED USE

CD-Chex CD117<sup>®</sup> Plus is intended to be used as a quality control material for evaluating CD117, CD25 and CD71 monoclonal antibody binding by flow cytometry. When these cells are stained with fluorescent antibodies and analyzed by flow cytometry, they provide a reference value for the abnormal cells found in certain types of hematopoietic neoplasms. CD-Chex CD117 Plus is designed for use on BD Biosciences and Beckman Coulter<sup>®</sup> 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/BACKGROUND

CD-Chex CD117 Plus is designed to represent abnormal peripheral blood leukocytes similar to a hematolymphoid neoplastic patient sample<sup>1,2,3</sup>. CD-Chex CD117 Plus possesses surface CD117, CD25 and CD71 that are detectable with fluorescent monoclonal antibodies by flow cytometry. Abnormal leukocytes are distinguishable from normal leukocytes on the basis of light scatter properties and a low level of CD45 expression. CD-Chex CD117 Plus is a positive procedural assayed control used to monitor reagent staining, erythrocyte lysis, sample preparation, and instrument performance.

### REAGENTS

CD-Chex CD117 Plus contains stabilized human blood and cells of human origin in a preservative medium.

### PRECAUTIONS

1. CD-Chex CD117 Plus 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](http://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 CD117 Plus should not be used as a calibrator.

### STORAGE AND STABILITY

CD-Chex CD117 Plus is stable through the expiration date when stored at 2 °C to 10 °C. After opening, CD-Chex CD117 Plus 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

If CD-Chex CD117 Plus values are not within the expected range on the assay sheet:

1. Review control product package insert, assay and operating procedures of the instrument.
2. Check expiration date of the product 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 CD117 Plus. If the values are still outside the expected range, contact Streck Technical Services at 800-843-0912 or [technicalservices@streck.com](mailto:technicalservices@streck.com).

## INSTRUCTIONS FOR USE

1. Follow instrument manufacturer's instructions for instrument compensation 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](http://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: A negative staining control is recommended due to the heterogeneous expression of CD117, CD25 and CD71.*
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 by gating the abnormal cells and/or a total leukocyte "Live"<sup>4</sup> gate from a CD45/SSC or FSC/SSC plot. See Figure 1.

### LIMITATIONS

1. For optimum results, CD117 should be evaluated using a mAb conjugated to fluorochromes other than PerCP-Cy5.5.
2. CD117 evaluated with mAb 95C3 when using lyse other than ammonium chloride will result in sub-optimal recovery.
3. CD25 recovery is reduced when using the Beckman Coulter<sup>®</sup> mAb B1.49.9 conjugated to FITC.

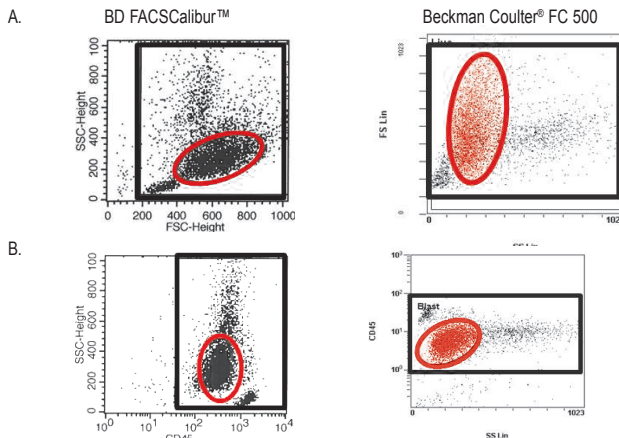
### EXPECTED RESULTS

The mean values provided are derived from replicate analyses on properly compensated flow cytometers. 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.

Use of alternate gating strategies not specified in these instructions may result in values outside the published range. It is recommended that an individual laboratory establish its own control means and ranges 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.

### GATING

The most common gating strategy used in neoplastic cell assessment is to gate on the abnormal cells and then determine the CD marker percent positivity using a negative staining control<sup>1-4</sup>. Abnormal cells are generally located with either a FSC/SSC plot or a CD45/SSC plot; although other gating strategies can be employed<sup>1-4</sup>. A less frequently employed method is to gate all of the leukocytes in a "Live"<sup>4</sup> gate, then determine the CD marker percent positivity of the white blood cells.



**FIGURE 1. Gating methods used to obtain CD117, CD25 and CD71 reference values.**

In CD-Chex CD117 Plus, the abnormal cells (RED OVALS) are CD45<sup>dim</sup>/FSC<sup>heterogeneous</sup>/SSC<sup>intermediate</sup>. These cells are positioned in the monocyte region of a FSC/SSC plot (A) or in the blast region of a CD45/SSC plot (B). In CD-Chex CD117 Plus, the "Live"<sup>4</sup> gates (BLACK RECTANGLES) are the total leukocytes, which include all of the cells, normal and abnormal, excluding debris.

### REFERENCES

1. Gorczyca, W. *Flow Cytometry in Neoplastic Hematology, Morphologic-Immunophenotypic Correlation-Second Edition*, Informa Healthcare, New York, NY USA, 2010.
2. Cheria, S., Wood, B. *Flow Cytometry in Evaluation of Hematopoietic Neoplasms; A Case-Based Approach*. CAP Press, Northfield, IL USA, 2012.
3. Nguyen, D., Diamond, L.W., Braylan, R.C. *Flow Cytometry in Hematopathology, A Visual Approach to Data Analysis and Interpretation-Second Edition*, Humana Press, Totowa, NJ USA, 2007.
4. Clinical and Laboratory Standards Institute H43-A2 *Clinical Flow Cytometric Analysis of Neoplastic Hematolymphoid Cells; Approved Guideline - Second Edition*. Clinical and Laboratory Standards Institute, Wayne, PA USA, 2009.

### ADDITIONAL RESOURCES

van Dongen, J.J., Lhermitte, L., Böttcher, S., Almeida, J., van der Velden, V.H., Flores-Montero, J., Rawstron, A., Asnafi, V., Lécrovisse, Q., Lucio, P., Mejstrikova, E., Szczepański, T., Kalina, T., de Tute, R., Brüggemann, M., Sedek, L., Cullen, M., Langerak, A.W., Mendonça, A., Macintyre, E., Martin-Ayuso, M., Hrusak, O., Vidrales, M.B., Orfao, A. EuroFlow Consortium. EuroFlow Antibody Panels for Standardized n-Dimensional Flow Cytometric Immunophenotyping of Normal, Reactive and Malignant Leukocytes. *Leukemia*. 2012 Sep; 26(9):1908-75.

Wood, B.L., Arroz, M., Barnett, D., DiGiuseppe, J., Greig, B., Kussick, S.J., Oldaker, T., Shenkin, M., Stone, E., Wallace, P. 2006 Bethesda International Consensus Recommendations on the Immunophenotypic Analysis of Hematolymphoid Neoplasia by Flow Cytometry: Optimal Reagents and Reporting for the Flow Cytometric Diagnosis of Hematopoietic Neoplasia. *Cytometry B Clin Cytom*. 2007; 72 Suppl 1:S14-22.

### QUALITY CONTROL PROGRAM

Streck offers STATS<sup>®</sup>, 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](mailto:statsdata@streck.com). Additional information can be found at [www.streck.com](http://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](http://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.						

See [www.streck.com/patents](http://www.streck.com/patents) for patents that may be applicable to this product.

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



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Instructions for use can be obtained at [www.streck.com](http://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](http://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](http://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](http://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](http://www.streck.com) i produktets ressourcektion, 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](http://www.streck.com) tootja ressursside (Resources) jaotisesest või helistades 402-333-1982 või võttes ühendust kohaliku endasimüüjaga.

## Finnish (Suomi)

Käyttöohjeet löydät osoitteesta [www.streck.com](http://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](http://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](http://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](http://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.ע.)

או, רצומה של (סיבאשמ) Resources רודמב, [www.streck.com](http://www.streck.com) ורשיקב גישהל תיני שומישה תוארוה תא דלש ימוקמה קפסה לא ופלטב רשקתהל ו, 1-402-333-1982 רפסמל ופלטב רשקתהל

## Hungarian (Magyar)

A használatra vonatkozó utasításokat megtalálja a [www.streck.com](http://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](http://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](http://www.streck.com) izstrādājumu resursu sadaļā, zvanot 402-33-1982 vai zvanot vietējam piegādātājam.

## Lithuanian (Lietuvių)

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

## Norwegian (Norsk)

Bruksanvisning kan fås på [www.streck.com](http://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](http://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](http://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](http://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](http://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](http://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](http://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](http://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 talimatlarına ulaşmak için [www.streck.com](http://www.streck.com) internet adresinde ürünün Kaynaklar bölümüne bakabilir ya da 402-333-1982 telefon numarasını veya yerel tedarikçinizi arayabilirsiniz.