

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

Bulgarian (Български)

Инструкции за употреба можете да получите от 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 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 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 streck.com i produktets ressourcesektion, ved at ringe til +1 402-333-1982 eller ved at ringe til din lokale leverandør.

Estonian (Eesti keel)

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

Finnish (Suomi)

Käyttöohjeet löydät osoitteesta 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 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 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 streck.com, στην ενότητα Resources (Πόροι) του προϊόντος, είτε καλώντας στο 402-333-1982 είτε καλώντας τον τοπικό προμηθευτή σας.

Hebrew (עברית)

את הוראות השימוש ניתן להשיג בקישור streck.com, במדור Resources (משאבים) של המוצר, או להתקשר בטלפון למספר 1-402-333-1982. או להתקשר בטלפון אל הספק הממויני של.

Hungarian (Magyar)

A használatra vonatkozó utasításokat megtalálja a 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 streck.com oppure telefonare al numero 402-333-1982 o al fornitore di zona.

Latvian (Latviešu valodā)

Lietošanas instrukcijas pieejamas vietnes streck.com izstrādājumu resursu sadaļā, zvanot 402-333-1982 vai zvanot vietējam piegādātājam.

Lithuanian (Lietuvių)

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

Norwegian (Norsk)

Bruksanvisning kan fås på 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 instrukcję użytkowania, należy odwiedzić sekcję Resources (Zasoby) na podstronie produktu pod adresem streck.com lub skontaktować się telefonicznie, korzystając z numeru 402-333-1982 lub numeru lokalnego dostawcy.

Portuguese Brazil (Português Brasil)

As instruções de uso podem ser obtidas em streck.com na seção de Recursos do produto através do número de telefone 402-333-1982, ou contatando seu fornecedor local.

Portuguese Europe (Português UE)

As instruções de utilização podem ser obtidas em streck.com na seção 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 streck.com, în secțiunea Resurse a produsului, sau telefonic la numărul 402-333-1982 sau contactând telefonic furnizorul local.

Russian (Русский)

Инструкции по применению можно скачать по адресу streck.com в разделе Resources (Ресурсы) на странице продукта. Также инструкции можно заказать по номеру 402-333-1982 или у местного поставщика.

Serbian (Српски)

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

Slovak (Slovenčina)

Pokyny na používanie nájdete na stránke 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 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 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 streck.com internet adresinde ürünün Kaynaklar bölümüne bakabilir ya da 402-333-1982 telefon numarasını veya yerel tedarikçinizi arayabilirsiniz.

INSTRUCTIONS FOR USE

INTENDED USE

Sickle-Chex® is a positive and negative control for testing for the presence of sickling hemoglobin in solubility tests.

Sickle-Chex is compatible with the following sickle cell solubility kits: Streck *SICKLEDEX*®, Dade Behring Sickle-sol Solubility Test and Pacific Hemostasis SickleScreen Sickling Hemoglobin Screening Kit.

SUMMARY AND PRINCIPLES

Clinical laboratories are required to establish quality control programs for automated, semi-automated and manual procedures used for in vitro diagnostic testing of whole blood specimens.

Sickle-Chex is designed to be handled in the same manner as a patient specimen. There are several factors concerning the environment and technique that may affect the outcome of the test. When these are properly controlled, Sickle-Chex will produce the expected positive or negative result.

REAGENTS

Sickle-Chex is composed of stabilized human red blood cells in a preservative medium.

PRECAUTIONS

1. For In Vitro Diagnostic Use.
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 streck.com for specific FDA required blood tests.
3. The product should not be disposed in general waste, but should be disposed with infectious medical waste. Disposal by incineration is recommended.
4. The product is intended for use as supplied. Adulteration by dilution or addition of any materials to the product as supplied, invalidates any diagnostic use of the product.
5. SDS can be obtained at streck.com, by calling 800-843-0912, or by calling your local supplier.

STORAGE AND STABILITY

Sickle-Chex is stable through the expiration date when stored at 2 °C to 10 °C. Open-vial stability is 100 days. After opening, Sickle-Chex is stable throughout the open-vial dating when stored at 2 °C to 10 °C, not to exceed the expiration date stated on the product vial.

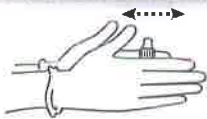
INDICATION OF PRODUCT DETERIORATION

Inability to obtain expected values may indicate product deterioration. Discoloration of the product may be caused by overheating or freezing during shipping or storage. Darkly colored supernatant may be indicative of product deterioration, however, moderately colored supernatant is normal and should not be confused with product deterioration. It is normal to observe a gradual darkening in the appearance of Sickle-Chex over the life of the product. This darkening is not an indication of product deterioration. If the recovered test results are not as expected:

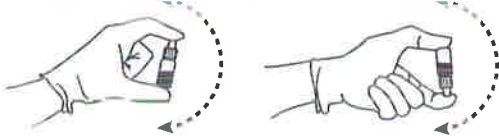
1. Review control product package insert and the reagent test kit instructions.
2. Check expiration date of the product on the vial. Discard outdated products.
3. Repeat the run to confirm erroneous results, if the same result is obtained, contact Streck Technical Services at 800-843-0912 or technicalservices@streck.com.

INSTRUCTIONS FOR USE

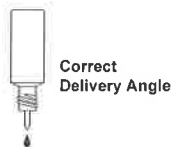
1. Remove the vial of the control from the refrigerator and warm to room temperature (18 °C to 30 °C) for 15 minutes before use.
2. To mix (**do NOT mix mechanically or vortex**):
For a video demonstration, visit streck.com/mixing



- a. Hold the vial vertically and roll each vial between the palms of the hands for 20-30 seconds.
- b. Continue to mix by holding the vial by the ends between the thumb and finger and rapidly inverting the vial 20 times end-over-end using a turning motion of the wrist.



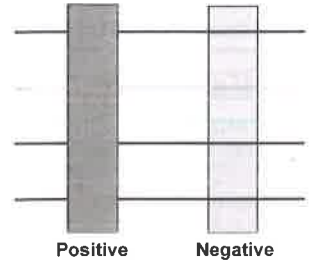
- c. Visually inspect the bottom of the vial to ensure all cells are resuspended and sample immediately after mixing. Subsequent analyses during this test period may be performed by inverting the vial 5-10 times prior to sampling.
 - d. Steps a-c must be repeated upon removing the sample from the refrigerator for the entire open-vial time period.
3. Refer to the reagent test kit instructions for analyzing control and patient materials.
 4. **Test kits that require a 20µl sample should use 1 drop of Sickle-Chex control. Test kits that require a 50µl sample should use 3 drops of Sickle-Chex control. For accurate delivery volume, the control vial MUST be inverted and held vertically directly over the test tube.**



5. After sampling, return to refrigeration for maximum open-vial stability. Wipe the threads of both vial and cap before replacing cap and returning to refrigeration.

EXPECTED RESULTS

The results of the Sickle-Chex control are read macroscopically. Incubate the control for the proper incubation time as indicated by the reagent test kit. The control results can be determined by holding the vial in front of the ruled lines as in the example shown or by using the viewing device included with the solubility test kit.



The positive test for sickling hemoglobin will result in a cloudy, turbid suspension and the ruled lines will not be visible through the vial. A negative control solution will appear virtually transparent and the ruled lines will be visible through the vial. Sickle-Chex controls are designed to verify the activity of the reagent. Negative patient results may not clear as quickly or as completely as the control.

REFERENCES

CONTROL - = negative control

CONTROL + = positive control

ORDERING INFORMATION

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

Rx Only

GLOSSARY OF SYMBOLS

See the Instructions (IFU) tab under Resources on the product page at streck.com.

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



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