

# IFU Revision History - Sickle Products

## SICKLEDEX® 12-Test IFU (#350512)

| Lot Effective Date | Revision      | Description of Changes   |
|--------------------|---------------|--|
| 08/23/2021         | 18<br>2021-09 | <ul style="list-style-type: none"> <li>Changed #3 in Limitations section from 12% to 12g/dL.</li> <li>Removed from Expected Results section: "It should be noted that test time reads for some samples may not be evident at 6 minutes. It is recommended that the samples be observed for up to an hour to affirm a negative test."</li> <li>Added #10 to Limits section: It should be noted that test time reads for some non-patient samples (proficiency or control material) may not be evident at 6 minutes and may take up to 60 minutes to be resolved.</li> </ul> |
| 01/11/2021         | 17<br>2020-11 | <ul style="list-style-type: none"> <li>Added the following to the Blood Sample Collection section: 4. Blood samples stored at 1 °C to 10 °C for up to 45 days may be used for testing.</li> </ul>  |
| 09/14/2020         | 16<br>2020-07 | <ul style="list-style-type: none"> <li>Added comprehensive list of validated anticoagulants to the Blood Sample Collection section</li> <li>Added limit of detection to Limitations section</li> <li>Added optional inversion mixing procedure to Instructions for Use section</li> <li>Added caution to use the sample from the Streck Micro Pipette within 30 seconds of collection to avoid clotting</li> <li>Added Specificity and Sensitivity specifications to Limitations section</li> <li>Updated image in Expected Results section</li> </ul>                     |
| 05/29/2020         | 15<br>2020-04 | <ul style="list-style-type: none"> <li>Updated font to Open Sans</li> <li>Removed "www" from "streck.com" (Precautions, #3, Ordering Information, Glossary of Symbols, patents statement)</li> <li>Updated Page 2, Internet IFU Directions (updated with www removed from streck.com)</li> <li>Updated part number and date</li> <li>Added header/footer to translations</li> </ul>  |
| 05/06/2019         | 14<br>2019-03 | <ul style="list-style-type: none"> <li>Added "Rx Only"</li> <li>Removed the Glossary of Harmonized Symbols and replaced it with the Glossary of Symbols statement</li> <li>Added patent statement</li> <li>Updated brand artwork</li> </ul>  |
| 08/01/2016         | 13<br>2016-05 | <ul style="list-style-type: none"> <li>Updated hazard symbol with OSHA standard; updated manufacturing city from Omaha to La Vista</li> </ul>  |
| 07/06/2015         | 12<br>2015-06 | <ul style="list-style-type: none"> <li>Changed MSDS to SDS</li> </ul>  |
| 06/09/2014         | 11<br>2014-04 | <ul style="list-style-type: none"> <li>Instructions for Use - wording changes</li> </ul>   |
| 11/26/2012         | 10<br>2012-08 | <ul style="list-style-type: none"> <li>Ordering Information - revised statement</li> <li>Precautions - revised MSDS statement</li> </ul>   |
| 06/11/2012         | 9<br>2012-05  | <ul style="list-style-type: none"> <li>Indication of Product Deterioration - updated email address and phone number</li> <li>Instructions for Use - wording changes: from "transfer pipette" to "micropipette"; updated instructions for micropipette use</li> </ul>   |

## SICKLEDEX 50/100 Test IFU (#350430)

| Lot Effective Date | Revision      | Description of Changes  |
|--------------------|---------------|---|
| 08/23/2021         | 26<br>2021-08 | <ul style="list-style-type: none"> <li>Changed #3 in Limitations section from 12% to 12g/dL.</li> <li>Removed #4 from Expected Results section.</li> <li>Added #10 to Limits section: It should be noted that test time reads for some non-patient samples (proficiency or control material) may not be evident at 6 minutes and may take up to 60 minutes to be resolved.</li> </ul> |

**SICKLEDEX 50/100 Test IFU (#350430) (continued)****Lot Effective Date Revision Description of Changes**

|            |               |  |
|------------|---------------|--|
| 01/11/2021 | 25<br>2020-11 | <ul style="list-style-type: none"> <li>Added the following to the Blood Sample Collection section: 4. Blood samples stored at 1 °C to 10 °C for up to 45 days may be used for testing.</li> </ul>  |
| 09/14/2020 | 24<br>2020-07 | <ul style="list-style-type: none"> <li>Added comprehensive list of validated anticoagulants to the Blood Sample Collection section</li> <li>Added limit of detection to Limitations section</li> <li>Added optional inversion mixing procedure to Instructions for Use section</li> <li>Added caution to use the sample from the Streck Micro Pipette within 30 seconds of collection to avoid clotting</li> <li>Added Specificity and Sensitivity specifications to Limitations section</li> <li>Updated image in Expected Results section</li> </ul> |
| 05/29/2020 | 23<br>2020-04 | <ul style="list-style-type: none"> <li>Updated font to Open Sans</li> <li>Removed "www" from "streck.com" (Precautions, #3, Ordering Information, Glossary of Symbols, patents statement)</li> <li>Updated Page 2, Internet IFU Directions (updated with www removed from streck.com)</li> <li>Updated part number and date</li> <li>Added header/footer to translations</li> </ul>  |
| 05/06/2019 | 22<br>2019-03 | <ul style="list-style-type: none"> <li>Added "Rx Only"</li> <li>Updated Internet IFU Directions (page 2) with Portuguese for Brazil (Brasil) and Europe (UE)</li> <li>Added patent statement</li> <li>Updated brand artwork</li> </ul>   |
| 02/12/2018 | 21<br>2017-12 | <ul style="list-style-type: none"> <li>Removed the Glossary of Harmonized Symbols and replaced it with the Glossary of Symbols statement</li> <li>Updated brand artwork</li> </ul>   |
| 08/01/2016 | 20<br>2016-04 | <ul style="list-style-type: none"> <li>Updated hazard symbol with OSHA standard; updated manufacturing city from Omaha to La Vista</li> </ul>  |
| 07/06/2015 | 19<br>2015-06 | <ul style="list-style-type: none"> <li>Changed MSDS to SDS</li> </ul>  |
| 06/09/2014 | 18<br>2014-04 | <ul style="list-style-type: none"> <li>Instructions for Use - wording changes</li> </ul>   |
| 10/01/2012 | 17<br>2012-07 | <ul style="list-style-type: none"> <li>Kit Contents - wording changes</li> <li>Expected Results - wording changes</li> <li>Precautions - revised MSDS statement</li> <li>Indication of Product Deterioration - updated email address and phone number</li> </ul>   |
| 04/16/2012 | 16<br>2012-03 | <ul style="list-style-type: none"> <li>Directions for Use of 20µL Plastic Micropipette - Added section</li> <li>Minor wording changes</li> </ul>   |

**Sickle-Chex® IFU (#350413)**

| <b>Lot Effective Date</b> | <b>Revision</b> | <b>Description of Changes</b>   |
|---------------------------|-----------------|---|
| 06/19/2020                | 15<br>2020-04   | <ul style="list-style-type: none"> <li>Updated font to Open Sans</li> <li>Removed trademarking from competitor products</li> <li>Removed "The brand and product names of the instruments are trademarks of their respective holders."</li> <li>Removed "www" from "streck.com" (Precautions, #2 and #5, Instructions for Use #2, Ordering Information, Glossary of Symbols)</li> <li>Added patent statement</li> <li>Updated Page 2, Internet IFU Directions (updated with www removed from streck.com)</li> <li>Added header/footer to translations</li> </ul> |
| 02/04/2019                | 14<br>2018-12   | <ul style="list-style-type: none"> <li>Storage and Stability - added closed-vial storage conditions</li> <li>Added "Rx Only"</li> <li>Updated brand artwork</li> </ul>  |

**Sickle-Chex IFU (#350413) (continued)**

| Lot Effective Date | Revision      | Description of Changes   |
|--------------------|---------------|--|
| 02/07/2018         | 13<br>2017-12 | <ul style="list-style-type: none"><li>■ Precautions - added SDS statement</li><li>■ Removed the Glossary of Harmonized Symbols and replaced it with the Glossary of Symbols statement</li><li>■ Updated brand artwork</li></ul>  |
| 07/25/2016         | 12<br>2016-04 | <ul style="list-style-type: none"><li>■ Clarified mixing instructions; updated manufacturing city from Omaha to La Vista</li></ul>   |
| 06/30/2014         | 11<br>2014-03 | <ul style="list-style-type: none"><li>■ Intended Use - Removed discontinued sickle solubility kits - Chembio Diagnostic System Sickle-STAT and Columbia Calibre Sickle Cell Reagent</li><li>■ Indication of Product Deterioration - Updated Streck contact information</li></ul> |
| 02/15/2010         | 10<br>2009-09 | <ul style="list-style-type: none"><li>■ Change "Instructional Information" to "Instructions for Use"</li><li>■ Glossary of Symbols - Updated</li></ul>   |