

IFU Revision History - Sickle Products

SICKLEDEX® 12-Test IFU (#350512)

| Lot Effective Date | Revision | Description of Changes |
|--------------------|---------------|--|
| 01/11/2021 | 17 2020-11 | <ul style="list-style-type: none"> 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. |
| 09/14/2020 | 16 2020-07 | <ul style="list-style-type: none"> Added comprehensive list of validated anticoagulants to the Blood Sample Collection section Added limit of detection to Limitations section Added optional inversion mixing procedure to Instructions for Use section Added caution to use the sample from the Streck Micro Pipette within 30 seconds of collection to avoid clotting Added Specificity and Sensitivity specifications to Limitations section Updated image in Expected Results section |
| 05/29/2020 | 15 2020-04 | <ul style="list-style-type: none"> Updated font to Open Sans Removed "www" from "streck.com" (Precautions, #3, Ordering Information, Glossary of Symbols, patents statement) Updated Page 2, Internet IFU Directions (updated with www removed from streck.com) Updated part number and date Added header/footer to translations |
| 05/06/2019 | 14 2019-03 | <ul style="list-style-type: none"> Added "Rx Only" Removed the Glossary of Harmonized Symbols and replaced it with the Glossary of Symbols statement Added patent statement Updated brand artwork |
| 08/01/2016 | 13 2016-05 | <ul style="list-style-type: none"> Updated hazard symbol with OSHA standard; updated manufacturing city from Omaha to La Vista |
| 07/06/2015 | 12 2015-06 | <ul style="list-style-type: none"> Changed MSDS to SDS |
| 06/09/2014 | 11 2014-04 | <ul style="list-style-type: none"> Instructions for Use - wording changes |
| 11/26/2012 | 10 2012-08 | <ul style="list-style-type: none"> Ordering Information - revised statement Precautions - revised MSDS statement |
| 06/11/2012 | 9 2012-05 | <ul style="list-style-type: none"> Indication of Product Deterioration - updated email address and phone number Instructions for Use - wording changes: from "transfer pipette" to "micropipette"; updated instructions for micropipette use |

SICKLEDEX 50/100 Test IFU (#350430)

| Lot Effective Date | Revision | Description of Changes |
|--------------------|---------------|--|
| 01/11/2021 | 25 2020-11 | <ul style="list-style-type: none"> 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. |
| 09/14/2020 | 24 2020-07 | <ul style="list-style-type: none"> Added comprehensive list of validated anticoagulants to the Blood Sample Collection section Added limit of detection to Limitations section Added optional inversion mixing procedure to Instructions for Use section Added caution to use the sample from the Streck Micro Pipette within 30 seconds of collection to avoid clotting Added Specificity and Sensitivity specifications to Limitations section Updated image in Expected Results section |

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

| Lot Effective Date | Revision | Description of Changes |
|--------------------|---------------|---|
| 05/29/2020 | 23 2020-04 | <ul style="list-style-type: none"> ■ Updated font to Open Sans ■ Removed "www" from "streck.com" (Precautions, #3, Ordering Information, Glossary of Symbols, patents statement) ■ Updated Page 2, Internet IFU Directions (updated with www removed from streck.com) ■ Updated part number and date ■ Added header/footer to translations |
| 05/06/2019 | 22 2019-03 | <ul style="list-style-type: none"> ■ Added "Rx Only" ■ Updated Internet IFU Directions (page 2) with Portuguese for Brazil (Brasil) and Europe (UE) ■ Added patent statement ■ Updated brand artwork |
| 02/12/2018 | 21 2017-12 | <ul style="list-style-type: none"> ■ Removed the Glossary of Harmonized Symbols and replaced it with the Glossary of Symbols statement ■ Updated brand artwork |
| 08/01/2016 | 20 2016-04 | <ul style="list-style-type: none"> ■ Updated hazard symbol with OSHA standard; updated manufacturing city from Omaha to La Vista |
| 07/06/2015 | 19 2015-06 | <ul style="list-style-type: none"> ■ Changed MSDS to SDS |
| 06/09/2014 | 18 2014-04 | <ul style="list-style-type: none"> ■ Instructions for Use - wording changes |
| 10/01/2012 | 17 2012-07 | <ul style="list-style-type: none"> ■ Kit Contents - wording changes ■ Expected Results - wording changes ■ Precautions - revised MSDS statement ■ Indication of Product Deterioration - updated email address and phone number |
| 04/16/2012 | 16 2012-03 | <ul style="list-style-type: none"> ■ Directions for Use of 20µL Plastic Micropipette - Added section ■ Minor wording changes |

Sickle-Chex® IFU (#350413)

| Lot Effective Date | Revision | Description of Changes |
|--------------------|---------------|---|
| 06/19/2020 | 15 2020-04 | <ul style="list-style-type: none"> ■ Updated font to Open Sans ■ Removed trademarking from competitor products ■ Removed "The brand and product names of the instruments are trademarks of their respective holders." ■ Removed "www" from "streck.com" (Precautions, #2 and #5, Instructions for Use #2, Ordering Information, Glossary of Symbols) ■ Added patent statement ■ Updated Page 2, Internet IFU Directions (updated with www removed from streck.com) ■ Added header/footer to translations |
| 02/04/2019 | 14 2018-12 | <ul style="list-style-type: none"> ■ Storage and Stability - added closed-vial storage conditions ■ Added "Rx Only" ■ Updated brand artwork |
| 02/07/2018 | 13 2017-12 | <ul style="list-style-type: none"> ■ Precautions - added SDS statement ■ Removed the Glossary of Harmonized Symbols and replaced it with the Glossary of Symbols statement ■ Updated brand artwork |
| 07/25/2016 | 12 2016-04 | <ul style="list-style-type: none"> ■ Clarified mixing instructions; updated manufacturing city from Omaha to La Vista |

Sickle-Chex IFU (#350413) (continued)

| Lot Effective Date | Revision | Description of Changes |
|--------------------|---------------|--|
| 06/30/2014 | 11 2014-03 | <ul style="list-style-type: none">■ Intended Use - Removed discontinued sickle solubility kits - Chembio Diagnostic System Sickle-STAT and Columbia Calibre Sickle Cell Reagent■ Indication of Product Deterioration - Updated Streck contact information |
| 02/15/2010 | 10 2009-09 | <ul style="list-style-type: none">■ Change "Instructional Information" to "Instructions for Use"■ Glossary of Symbols - Updated |