

IFU Revision History - Sickle Products

SICKLEDEX 12-Test IFU (#350512)

Lot Effective Date	Revision	Description of Changes
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
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
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

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

Lot Effective Date	Revision	Description of Changes
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
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