

IFU Revision History - Sickle Products

SICKLEDEX® 12-Test IFU (#350512)

Lot Effective Date	Revision	Description of Changes
08/23/2021	18 2021-09	<ul style="list-style-type: none"> Changed #3 in Limitations section from 12% to 12g/dL. 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." 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.
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
08/23/2021	26 2021-08	<ul style="list-style-type: none"> Changed #3 in Limitations section from 12% to 12g/dL. Removed #4 from Expected Results section. 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.

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

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
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
09/11/2023	16 2023-07	<ul style="list-style-type: none"> Added IVD symbol Increased size of CE Mark to 5mm Added "All product names..." statement under Glossary of Symbols section Removed Page 2, Internet IFU Directions

Sickle-Chex IFU (#350413) (continued)

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