Retic-Chex® Linearity for BC

streck.com/IFU IVD STRECK

To Verify Performance Limits of Beckman Coulter® Hematology Analyzers

350403-29
2023-09

Rx Only

Open-vial stability **5 days**

2024-09-01

Beckman Coulter® UniCel® DxH™ 600/800/900/690T		Parameter	$\bar{\chi}$	+/-
Level 1	LOT - 41410771	Retic %	1.00	1.00
Level 2	LOT - 41410772	Retic %	5.55	1.00
Level 3	LOT - 41410773	Retic %	10.62	2.00
Level 4	LOT - 41410774	Retic %	15.73	3.00
Level 5	LOT - 41410775	Retic %	28.02	5.00

Approximate RBC	10^{12}/L	3.14

The Approximate RBC value is used to calculate the absolute reticulocyte number. It should not be used to monitor the RBC parameter.

$\bar{\chi}$ **Mean**

+/- **Expected Range**

The brand and product names of the instruments are trademarks of their respective holders.

Streck
7002 S. 109 Street, La Vista, NE 68128 USA

INSTRUCTIONS FOR USE

INTENDED USE
Retic-Chex® Linearity for BC is an assayed linearity control kit, which can be used to assess the instrument's accuracy and to verify patient reportable ranges of automated hematology instrumentation capable of enumerating reticulocytes.

SUMMARY AND PRINCIPLES
Regulatory agencies mandate that laboratories substantiate their test methods throughout the reportable range for patient test results. Circumstances which may call for verification include installation, major preventative maintenance, unusual trends in control performance, or whenever recommended by the instrument manufacturer. Retic-Chex Linearity for BC contains retic concentrations which span typical patient reportable ranges; allowing the user to comply with these guidelines.

REAGENTS
Retic-Chex Linearity for BC 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. SDS can be obtained at streck.com, by calling 800-843-0912, or by calling your local supplier.

STORAGE AND STABILITY
Retic-Chex Linearity for BC is stable through the expiration date when stored at 2 °C to 10 °C. After opening, Retic-Chex Linearity for BC is stable throughout the open-vial dating, as indicated on the assay sheet, when stored at 2 °C to 10 °C. **DO NOT FREEZE.**

INDICATION OF PRODUCT DETERIORATION
Inability to obtain assay values may indicate product deterioration. To determine the source of potential problems:
1. Check the expiration date and discard outdated product. Overheating or freezing during the shipping or storage may cause discoloration of the product. Gross hemolysis (darkly colored supernatant) may indicate product deterioration. However, moderately colored supernatant is normal and should not be mistaken for product deterioration.
2. Review the operating procedures for your instrument.
3. If problems persist, contact Streck Technical Services at 800-843-0912 or technicalservices@streck.com.

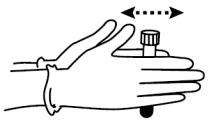
INSTRUCTIONS FOR USE

Preparation
1. Perform routine maintenance, quality control procedures, calibration and precision checks according to your laboratory protocol. If acceptable, proceed with running Retic-Chex Linearity for BC.
2. Remove vials of control from the refrigerator and warm to room temperature (18 °C to 30 °C) for 15 minutes before use.

Mixing and Handling
1. To mix: **(Do NOT mix mechanically or vortex.)**

For a video demonstration, visit www.streck.com/mixing.

a. Hold the vial vertically and roll each vial between the palms of the hands for 15-20 seconds.



b. Continue to mix by holding the vial by the ends between the thumb and finger, rapidly inverting the vial 20 times end-over-end using a very quick turning motion of the wrist.

c. Analyze immediately after mixing. Subsequent analyses during this test period may be performed by inverting the vial 5 times prior to instrument analysis.

d. Steps a-c must be repeated upon removing the sample from the refrigerator for the entire open-vial time period regardless of the method of analysis (open tube, cap piercing, auto sample or manual sample).

2. Retic-Chex Linearity for BC samples should be prepared for reticulocyte analysis in the same manner as patient samples.

Analysis Protocol for Retic-Chex Linearity for BC
1. Perform a background count and, if acceptable, proceed. The user should follow the instrument manufacturer's instructions for performing automated reticulocyte counts.
2. Analyze all levels in order of lowest concentration to highest concentration in Patient Mode.
3. Run each vial four times, mixing before each aspiration.
4. After sampling, return to refrigeration for maximum open-vial stability. If run in the open mode, wipe the threads of both the vial and cap before replacing cap and returning to refrigeration.
5. Key data into the product-specific *STATS*® Data Input Form located at streck.com and email the completed form to statsdata@streck.com, or login to your *STATS*-Link® account to submit your data. Instruments with assay-specific values should verify that the mean values recovered are within the expected ranges.

EXPECTED RESULTS
Values recovered should fall within the suggested tolerance limits on the accompanying assay. However, lab to lab variation in instrument performance, instrument calibration and operator technique may yield differences in results obtained. Therefore, each laboratory must establish its own acceptance criteria.
1. If your mean values are outside of your laboratory's established acceptance limits, rerun product.
2. If the mean values remain outside your established limits, contact your instrument service representative. **DO NOT ADJUST YOUR INSTRUMENT.**

QUALITY CONTROL PROGRAM
Streck offers *STATS*®, an interlaboratory quality control program, to all customers at no charge. For more information, contact the *STATS* Department at 800-898-9563 or statsdata@streck.com. Additional information can be found at streck.com.

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

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GLOSSARY OF HARMONIZED 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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