R&D 3K Retic

HEMATOLOGY CONTROLS

CONTROL

ASSAY VALUES AND EXPECTED RANGES

QCP Data Months: **DEC, JAN** **2025-02-05**

	LEVEL 1 LOT E1224 -1		LEVEL 2 LOT E1224 -2	
	Mean	*Range*	*Mean*	*Range*
CELL-DYN 3200 CELL-DYN Ruby™ Retic %	1.30	± 0.80	5.85	± 1.50

NOTE: Flags may occur with control materials and should be disregarded.

INTENDED USE

R&D 3K Retic is a bi-level control for use in monitoring the performance of Abbott CELL-DYN® hematology instruments. Refer to the assay table for specific instrument models.

SUMMARY AND PRINCIPLE

It is an established laboratory practice to use a stable control to monitor the performance of diagnostic tests. This control is composed of stable materials that provide a means of monitoring the performance of reticulocyte counting methods. It is sampled in the same manner as a patient specimen.

REAGENTS

R&D 3K Retic is an *in vitro* diagnostic reagent composed of human erythrocytes and a reticulocyte surrogate suspended in a plasma-like fluid with preservatives.

PRECAUTION

R&D 3K Retic is intended for ***in vitro*** **diagnostic use** only by trained personnel.

WARNING:

POTENTIALLY BIOHAZARDOUS MATERIAL. For *in vitro* diagnostic use. Each human donor/unit used in the preparation of this product has been tested by a FDA licensed method/test and found to be negative or non-reactive for the presence of HBsAg, Anti-HCV, NAT testing for HIV-1, HCV (RNA) and HIV-1/2. Each unit is also negative by a serological test for Syphilis (RPR or STS). Because no test method can offer complete assurance that infectious agents are absent, this material should be handled as potentially infectious. When handling or disposing of vials follow precautions for patient specimens as specified in the OSHA Bloodborne Pathogen Rule (29 CFR Part 1910.1030) or other equivalent biosafety procedures.

STABILITY AND STORAGE

Store R&D 3K Retic upright at 2 - 8°C (35 - 46°F) when not in use**. Protect vials/ tubes from overheating and freezing.** Unopened vials/tubes are stable until the expiration date. Opened vials/tubes are stable for at least 16 days provided they are handled properly. A stained sample is stable for 15 minutes after the minimum incubation time.

INDICATIONS OF DETERIORATION

After mixing, product should be similar in appearance to fresh whole blood. In unmixed vials/tubes, the supernatant may appear cloudy and reddish; this is normal and does not indicate deterioration. Other discoloration, very dark red supernatant or unacceptable results may indicate deterioration. **Do not use the product if deterioration is suspected.**

INSTRUCTIONS FOR USE

1. Remove vials/tubes from the refrigerator and allow to warm to room temperature (15 - 30°C or 59 - 86°F) for 15 minutes before mixing.

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2. To mix, hold a vial/tube horizontally between the palms of the hands. **Do not pre-mix on a mechanical mixer**.
   a. Roll the vial/tube back and forth for 20 - 30 seconds; occasionally invert the vial/tube. Mix vigorously, but do not shake.
   b. Continue to mix in this manner until the red cells are completely suspended. Vials/tubes stored for a long time may require extra mixing.
   c. Gently invert the vial/tube 8 - 10 times immediately before sampling.
3. Prepare a stained sample of R&D 3K Retic as described in the CELL-DYN Reticulocyte Reagent insert except limit the staining time to between 15 and 30 minutes. Analyze the sample as instructed in the Quality Control section of the Operator's Manual for your instrument.
4. After sampling R&D 3K Retic, carefully wipe the tube rim and cap with lint-free tissue. Replace the cap tightly and return vials to refrigerator within 30 minutes.

EXPECTED RESULTS

Verify that the lot number on the tube matches the lot number on the table of assay values. Assay values are determined on well-maintained, properly calibrated instruments using the instrument manufacturer's recommended reagents. Reagent differences, maintenance, operating technique, and calibration may contribute to inter-laboratory variation.

PERFORMANCE CHARACTERISTICS

Assigned values are presented as a Mean and Range. The Mean is derived from replicate testing on instruments operated and maintained according to the manufacturer's instructions. The Range is an estimate of variation between laboratories and also takes into account inherent imprecision of the method and expected biological variability of the control material.

Assay values on a new lot of control should be confirmed before the new lot is put into routine use. Test the new lot when the instrument is in good working order and quality control results on the old lot are acceptable. The laboratory's recovered mean should be within the assay range.

For greater control sensitivity each laboratory should establish its own mean and acceptable range and periodically reevaluate the mean. The laboratory range may include values outside of the assay range. The user may establish assay values not listed on the Assay Sheet, if the control is suitable for the method.

LIMITATIONS

R&D 3K Retic is not suitable for manual microscopic counting methods. The performance of this product is assured only if it is properly stored and used as described in this insert. Incomplete mixing of a tube prior to use invalidates both the sample withdrawn and any remaining material in the tube.

INSTRUMENT DATA ALERTS

If the instrument detects an atypical condition during specimen processing, it will display a data alert message. There are six data alerts that do not suppress results.

These three alerts invalidate whole blood results **but do not** invalidate R&D 3K Retic results:

- Fragile RBCs
- Noise error
- Histogram shifted left

These three alerts invalidate **both** whole blood results and R&D 3K Retic results:

- Setup error
- Sample degradation
- High RBC peak

Refer to the CELL-DYN System Operator's Manual for troubleshooting assistance.

TECHNICAL ASSISTANCE AND CUSTOMER SERVICE

For assistance in resolving control recovery problems, please call Technical Service at (800) 523-3395. For additional information on R&D Systems, Inc. hematology controls and calibrators, or to place an order, call Customer Service at (800) 428-4246.

QUALITY CONTROL PROGRAM

For information on CBC-Monitor, our Inter-Laboratory Quality Control Program, call (800) 523-3395 ext. 4435.

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EC REP

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