

LeukoReduced RBC

HEMATOLOGY CONTROLS

CONTROL

LOT LKR0717



2017-09-05

ASSAY VALUES AND EXPECTED RANGES

Method:	Parameter:	LOW		HIGH	
		LOT	LKR0717L	LOT	LKR0717H
		Mean	Range	Mean	Range
Flow Cytometer	WBC/uL	2.4	0.4 – 4.4	20.0	15.0 – 25.0
Nageotte Chamber	WBC/uL	2.0	0.5 – 3.5	19.0	13.3 – 24.7
ADAM rWBC	WBC/uL	2.5	0.5 – 4.5	20.0	14.0 – 26.0

INTENDED USE

LeukoReduced RBC is used as a complete process control to monitor leukoreduced red blood cell products, including the dilution and staining process, method setup and WBC enumeration.

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 methods that measure residual leukocytes in blood products. It is sampled in the same manner as blood products used for transfusion purposes.

REAGENTS

LeukoReduced RBC is an *in vitro* diagnostic reagent composed of mammalian erythrocytes and human leukocytes suspended in a plasma-like fluid with preservatives.



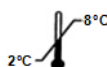
PRECAUTION

LeukoReduced RBC 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 LeukoReduced RBC upright at 2 - 8° C (35 - 46° F) when not in use. **Protect tubes from overheating and freezing.** Unopened tubes are stable through the expiration date. Opened tubes are stable for 30 days or 21 thermal cycles (uses), whichever comes first, provided they are handled properly.

INDICATIONS OF DETERIORATION

After mixing, product should be similar in appearance to fresh whole blood. In unmixed tubes, the supernatant may appear pink; 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

- Remove tubes from the refrigerator and allow to warm to room temperature (15 to 30°C or 59 to 86°F) for 15 minutes before mixing.
- To mix, hold a tube horizontally between the palms of the hands. Do not pre-mix on a mechanical mixer.
 - Roll the tube back and forth for 20 - 30 seconds; occasionally invert the tube. Mix vigorously, but do not shake. Tubes stored for a long time may require extra mixing.
 - Continue to mix in this manner until the red cells are completely suspended. Tubes stored for a long time may require extra mixing. Confirm that cell button on bottom of tube is suspended.
 - Gently invert the tube 8 - 10 times immediately before sampling.
- After sampling:
 - After sampling, clean residual material from the cap and tube rim with a lint-free tissue. Replace the cap tightly.
 - Return tubes to refrigerator within 30 minutes of use.

LeukoReduced RBC

HEMATOLOGY CONTROLS

CONTROL

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 by the specific method. 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. 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

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.

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

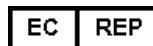
For information on CBC-Monitor, our Inter-Laboratory Quality Control Program, call (800) 523-3395 ext. 4435.

All brands and products are trademarks or registered trademarks of their respective companies.



R & D Systems, Inc.
614 McKinley Place NE
Minneapolis, MN USA 55413

AIS094-005 Rev. 07/14



EUROCELL Diagnostics
19 Rue Louis Delourmel
35230 NOYAL CHATILLON/
SEICHE
France



LeukoReduced PLT

HEMATOLOGY CONTROLS

CONTROL

LOT LKP0717

 **2017-09-05**

ASSAY VALUES AND EXPECTED RANGES

Method:	Parameter:	LOW		HIGH	
		LOT	LKP0717L	LOT	LKP0717H
		Mean	Range	Mean	Range
Flow Cytometer	WBC/uL	2.0	0.5 – 3.5	19.9	14.9 – 24.9
Nageotte Chamber	WBC/uL	2.0	0.5 – 3.5	19.3	13.9 – 24.7
ADAM rWBC	WBC/uL	2.6	0.6 – 4.6	21.0	15.7 – 26.3

INTENDED USE

LeukoReduced PLT is used as a complete process control to monitor leukoreduced platelet products, including the dilution and staining process, method setup and WBC enumeration.

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 methods that measure residual leukocytes in blood products. It is sampled in the same manner as blood products used for transfusion purposes.

REAGENTS

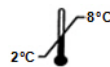
LeukoReduced PLT is an *in vitro* diagnostic reagent composed of human leukocytes and mammalian platelets suspended in a plasma-like fluid with preservatives.

 **PRECAUTION**

LeukoReduced PLT 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 LeukoReduced PLT upright at 2 - 8° C (35 - 46° F) when not in use. **Protect tubes from overheating and freezing.** Unopened tubes are stable through the expiration date. Opened tubes are stable for 30 days or 21 thermal cycles (uses), whichever comes first, provided they are handled properly.

INDICATIONS OF DETERIORATION

Product should be colorless and slightly cloudy. Discoloration of the product or unacceptable results may indicate deterioration. **Do not use the product if deterioration is suspected.**



INSTRUCTIONS FOR USE

1. Remove tubes from the refrigerator and allow to warm to room temperature (15 to 30°C or 59 to 86°F) for 15 minutes before mixing.
2. To mix, hold a tube horizontally between the palms of the hands. Do not pre-mix on a mechanical mixer.
 - a) Roll the tube back and forth for 20 - 30 seconds; occasionally invert the tube. Mix vigorously, but do not shake. Tubes stored for a long time may require extra mixing. Confirm that cell button on bottom of tube is suspended.
 - b) Gently invert the tube 8 - 10 times immediately before sampling.
3. After sampling:
 - a) After sampling, clean residual material from the cap and tube rim with a lint-free tissue. Replace the cap tightly.
 - b) Return tubes to refrigerator within 30 minutes of use.

LeukoReduced PLT

HEMATOLOGY CONTROLS

CONTROL

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 by the specific method. 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. 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

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.

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

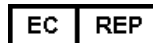
For information on CBC-Monitor, our Inter-Laboratory Quality Control Program, call (800) 523-3395 ext. 4435.

All brands and products are trademarks or registered trademarks of their respective companies.



R & D Systems, Inc.
614 McKinley Place NE
Minneapolis, MN USA 55413

AIS095-006 Rev. 07/14



EUROCELL Diagnostics
19 Rue Louis Delourmel
35230 NOYAL CHATILLON/
SEICHE
France

