NanoEntek

NESPI-ARC-001EN(V.0.1)

CE UKCA IVD

ADAM-rWBC Cell Counting System

For enumeration of residual leukocytes in leukoreduced blood products

REF AD1K-050

IVD For *in vitro* diagnostic use only

Revised 05/2024

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Intended use

The ADAM-rWBC Kit is for in vitro quantitative use for enumeration of residual white blood cells (rWBCs) in leukoreduced blood products. The ADAM-rWBC Kit is designed for use with the ADAM-rWBC, ADAM-rWBC2 and ADAM-rWBC HT microscopic cell counter.

Summary and explanation of test

The presence of white blood cells (WBCs) in blood, platelet and plasma products is associated with an increased incidence of febrile transfusion reactions, transmission of cytomegalovirus, and alloimmunization to HLA antigens in transfusion recipients.[1-3] Leukoreduction, the collection of platelets via apheresis, or post-collection processing with special filters, can lower the WBC count to 5 x 10^6 per unit or below, thus minimizing complications associated with transfusions.[4,5] The kit is designed to provide an efficient, sensitive method for enumerating residual WBCs, while eliminating limitations associated with other methods.[6,7]

Principle of the assay

The ADAM-rWBC cell counting system utilizes sensitive fluorescence dye staining, LED excitation and CCD detection technologies to make the WBC analysis more accurate and reliable. To count WBCs using ADAM-rWBC, the sample to be tested is mixed with a Propidium Iodide (PI) stain and directly pipetted onto a disposable plastic slide. The slide is then loaded onto a precision stage. The ADAM-rWBC cell counting system automatically focuses on the slide, and cells that have been stained are recorded by a sensitive CCD camera. The image results are automatically processed, generating the cell count which is displayed on the front of the device.

Material provided

The ADAM-rWBC kit consists of:

Contents	Catalogue number	Q'ty
r-Solution	RDR-50	25 mL
r-Slide	RDS-50	50 EA
Standard Bead	ADST-001	7 mL

Warning and Precautions

- All biological specimens and materials coming in contact with them are considered biohazards. Handle as if capable of transmitting infection[8,9] and dispose of with proper precautions in accordance with federal, state, and local regulations. Never pipette by mouth. Wear suitable protective clothing and gloves.
- r-Solution reagent contains PI, a suspected mutagen, and a DNA stabilizer known to irritate skin and mucous membranes. Gloves and eye protection should be worn when handling. Avoid contact with eyes, skin, and clothing. Avoid breathing vapors and wash surfaces thoroughly after handling. If contact occurs, flush immediately with water. Consult a physician if contact with eyes occurs.
- Standard Bead Solution reagent contains sodium azide. Sodium azide is harmful if swallowed. Keep out of reach of children. Keep away from food, drink, and animal feed. Wear suitable protective clothing. If swallowed, seek medical advice immediately and show container or label. Contact with acids liberates very toxic gas. Azide compounds should be flushed with large volumes of water during disposal to avoid deposits in lead or copper plumbing where explosive conditions can develop.
- For *in vitro* diagnostic use. Not for use in therapeutic procedures.
- Care should be taken to avoid microbial contamination of the reagent.

Storage and Stability

- Store r-Solution at 2-8˚C when not in use. The expiration date is one year. Do not use after the expiration date shown on the label. Open r-Solution may be stored at 2-8˚C and used for up to 6 months, but not past the expiration date.
- Store r-Slides at 0-30˚C. Do not use after the expiration date shown on the label.
- Store the Standard Bead in the dark at 2-8˚C when not in use. Open Standard Beads may be stored at 2-8˚C for up to 6 months. Do not use after the expiration date shown on the label.
- The Standard Bead may be exposed the light for short periods of time, and may be stored on the bench during use.

Material	Catalogue number	Refrigerator temperature storage
r-Solution	RDR-50	2~8 ℃
Standard Bead	ADST-001	2~8 ℃
r-Slide	RDS-50	0~30 ℃

Device

The ADAM-rWBC Kit is designed for use on the ADAM-rWBC series microscopic cell counter.

For the details, please refer to the Instruction Manual of the ADAM-rWBC series.

Below is a listing of the accessories:

Accessories	Model/version	Validation Information
Power cord for ADAM-rWBC	KKP series	UL, FCC
AC/DC Adaptor for ADAM-rWBC2	KPL-060F-VI	UL, FCC, CE

Device safety precautions

1) Always ensure that the power supply input voltage matched the voltage available in your location.
2) Do not install the device in heavy humidity such as a greenhouse or an incubator to avoid a danger of electric shock. If water or other material enters the device, the adaptor, or power inlet, disconnect the power cord and contact a service person.
3) Do not touch the adaptor or power cord with wet hands.
4) This device is air-cooled so its surfaces become hot during operation. When installing it, leave a space of more than 10 cm (4 inches) around it.
5) Do not install the device on a slant or a place prone to vibrations, which induces the risk of device malfunction or damage of the device.
6) Never insert any objects (especially metallic objects) into the air vents of the device as this could result in electrical shock, personal injury and device damage.
7) Always set the main switch on the power supply unit to (OFF) or disconnect adaptor before connecting the power cord to the wall outlet.
8) Always ensure that the grounding terminal of the device and that of the wall outlet are properly connected. The power cord should be connected to a grounded, 3-conductor power outlet.
9) To avoid potential shock hazard, make sure that the power cord is properly grounded.
10) Do not position the device so that it is difficult to disconnect the device.
11) Be sure to lock the stage, set the main switch to (OFF), and unplug the power cord or adaptor before moving.
12) If the device is broken or dropped, disconnect the cord and contact an authorized service person. Do not disassemble the device.
13) Use only authorized accessories.
14) Use this device only as specified in the instruction manual and as specified in any documentation associated with its components. Any use of the device in an unspecified manner is strongly discouraged and may result in damage or injury.

Device warnings

1. Battery inside device

Risk of explosion if battery is replaced by an incorrect type. This battery is not replaceable by a user. Contact a qualified representative.

2. Cover

Do not remove the cover or dissemble a case. There are no adjustable components inside the device. If a malfunction is found, contact a service representative.

Specimen collection and handling

Red Blood Cell, platelet and plasma samples must be collected and tested within 48 hours of leukoreduction. ADAM-rWBC testing is not affected by the use of lipemic or hemolyzed samples.

1. Stained sample stability

Stained samples (RBC, Platelet and Plasma) may be stored for up to one hour at room temperature prior to use.

2. Stored sample stability

- RBC sample taken from the leukoreduced products may be stored for up to 48 hours at refrigerated temperature (2~8°C) prior to testing.
- Platelet sample taken from the leukoreduced products may be stored for up to 48 hours at room temperature (18~25°C) prior to testing.
- Plasma sample taken from the leukoreduced products may be stored for up to 24 hours at refrigerated temperature (2~8°C) prior to testing.

Procedure

Materials required but not provided

- Micropipette and tips
- Test tubes that come capped
- Timer
- Lint free wipes

Note: If tips must be wiped, use lint free material only, and discard after a single use. It is also not recommended that any materials that may generate or capture lint be used as bench cover in the area where testing is being performed.

Warning: Dispense 100 µL of sample into the r-Slide to ensure correct filling. The device will not detect low or high volume samples.

Warning: Completely insert r-Slides face up, in the direction of the arrow on the slide, all the way into the ADAM-rWBC device. The device will not detect if slides are inserted incorrectly. See below for proper insertion. Additional pictures are located in the Instruction Manual.

Warning: The red blood cell and platelet sample must be diluted with the r-Solution at a ratio of dilution ratio is 1:4 (i.e. 100 µL sample + 400 µL r-Solution). The plasma sample must be diluted with the r-Solution at a ratio of dilution ratio is 1:1 (i.e. 100 µL sample + 100 µL r-Solution). The device will not detect incorrectly diluted samples.

Calibration

Calibration of the ADAM-rWBC series device uses Standard Bead Solution to provide absolute particle numbers, and is used to calibrate the Automatic Focus which is carried out at when the device is started. This calibration checks the position of the slide stage.

The ADAM-rWBC series must be calibrated after each start up and at least once each day of use.

1) Let beads equilibrate to room temperature before use (~10 minutes).
2) Mix by rocking gently, including upside down.
3) Load 100 µL of the beads into the r-Slide. Let settle for 40-60 seconds.
4) Insert bead loaded r-slide into ADAM-rWBC series main device and press ▶ to start. The bead counting result will be shown on screen of ADAM-rWBC series. The result should be within the range on the label of the standard solution bead bottle. If calibration results are not within the range of the value on the label, contact NanoEntek.

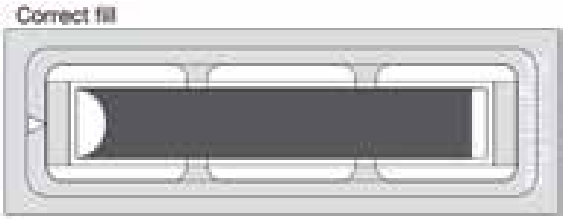
Quality control

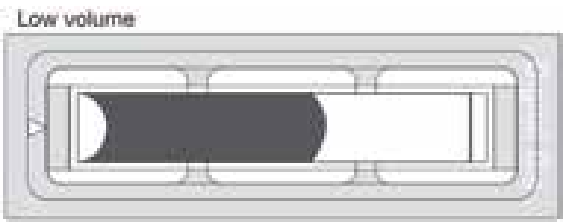
Quality Control material should be run daily with use

- Red blood cell controls should be run with red blood cell samples.
- Platelet controls should be run with platelet samples.

Sample preparation and testing

1) Leave the ADAM-rWBC Kit at room temperature for 10 minutes before use.
2) Carefully dispense 100 uL of well-mixed RBC or platelet or plasma sample into a clean test tube.
3) Add reagent into the tube. For RBC or platelet, the reagent should be add 400 µL. For Plasma, the reagent should be add 100 µL.
4) Mix the tube well.
   - RBC or platelet : 100 µL sample + 400 µL reagent
   - Plasma: 100 µL sample + 100 µL reagent
5) Load 100 µL mixed sample/reagent onto a r-Slide.





6) Wait 4~7 minutes for sample settling.
7) Insert r-Slide into ADAM device and press ▶ to start.
8) The result calculated as WBC per µL will be displayed automatically.

Device setup

This section provides guidelines for device setup. If you have additional questions about device setup or procedures, refer to the ADAM-rWBC series Instruction Manual or contact your local NanoEntek representative. Addresses and telephone numbers are listed at the end of this package insert. In the United States call the NanoEntek Customer Support Center at +1-781-472-2558.

1) Press ▲ on the main device to eject the r-Slide holder.
2) Insert the r-Slide loaded with the sample onto the slide holder. Be careful not to create bubbles.
3) Press ▶ on the main device.
4) After calculating the cell number, the r-Slide will be ejected automatically. Then the slide can be removed.

Results

The calculated number of WBCs per µL will be displayed automatically.

Performance characteristics

Stain-to-Stain

The precision of ADAM-rWBC was assessed at four concentration cell levels (Low, Mid1, Mid2, and High). Each concentration was tested in three run/one day, and over two days. Each of samples was tested in triplicate.

Stain-to-Stain Precision									
WBC/μL	RBC			Platelet			Plasma		
target	Mean	SD	CV%	Mean	SD	CV%	Mean	SD	CV%
Low	0.13	0.12	N/A	0.05	0.122	N/A	0.34	0.21	N/A
Mid1	2.87	0.40	13.80	2.23	0.35	15.80	2.82	0.49	17.30
Mid2	11.34	1.12	9.89	10.45	1.05	10.06	11.37	0.91	8.02
Mid3	103.21	4.31	4.19	102.71	3.50	3.50	107.18	3.90	3.64

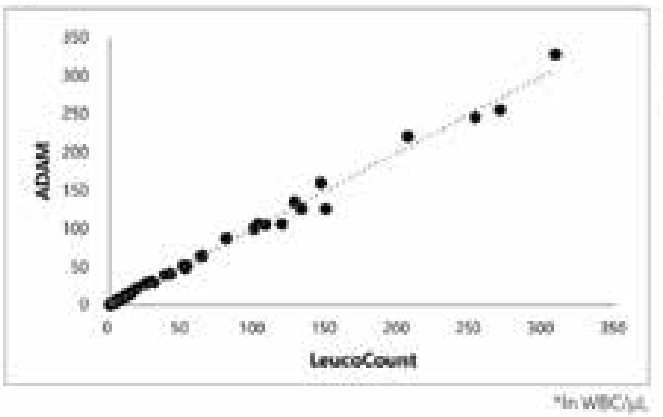
Linearity

The ADAM-rWBC has a linear range of 1 -100 WBCs/μL for RBC, platelet and plasma products.

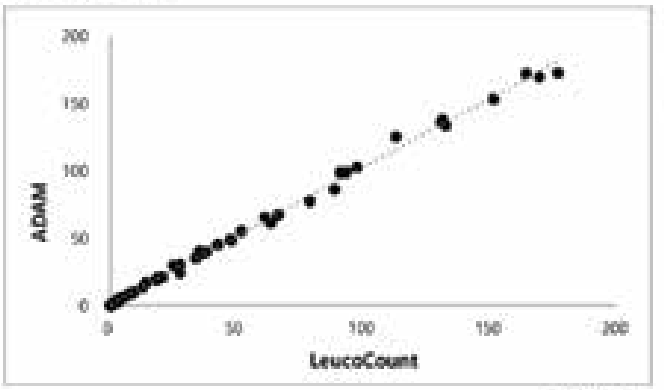
Accuracy

Accuracy was assessed on RBC, platelet and plasma products (each n=80).

RBC products



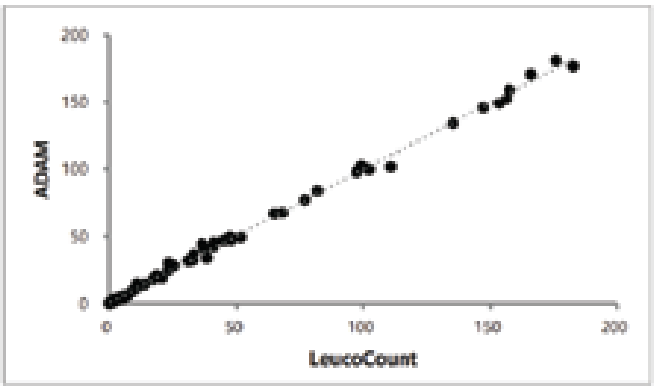
Platelet products



Slope = 1.024
Intercept = 0.453
r^2 = 0.998

*In WBC/μL

Plasma products



Slope = 0.993
Intercept = 0.7068
r^2 = 0.998

*In WBC/μL

Limitations

It is important to follow these Directions for Use and the ADAM-rWBC series Instruction Manual.

Our Kit is made specifically for ADAM-rWBC series device, use provided reagents and materials. Do not use reagents or slides beyond the expiration date. Do not use previously used r-Slides.

References

1) Wenz B, Gurtlinger K, O'Toole A, Dugan E.Preparation of granulocyte-poor red blood cells by micro aggregate filtration. A simplified method to minimize febrile transfusion reactions. *Vox Sang.* 1980;39:282-287.
2) de Graan-Hentzen YCE, Gratama JW, Mudde GC, et al. Prevention of primary cytomegalovirus infection in patients with hematologic malignancies by intensive white cell depletion of blood products. *Transfusion*. 1989;29:757-760.
3) Snieciski I, O'Donnell M, Nowicki B, Hill L.Prevention of refractoriness and HLA-alloimmunization using filtered blood products. *Blood*. 1988;71:1402-1407.
4) Venglen-Tyler V, ed. Leukoreduction of RBC and platelet units. *American Association of Blood Banks*. 1996; 722-725.
5) Dumont IJ, Dzik WH, Rebulla P, Brandwein H.Practical guidelines for process validation and process control of white cell-reduced blood components: report of the Biomedical Excellence for Safer Transfusion (BEST) Working Party of the International Society of Blood Transfusion (ISBT). *Transfusion*. 1996;36:11-20.
6) Rubella P, Porretti L, Bertolini F, et al. White cell-reduced red cells prepared by filtration: a critical evaluation of current filters and methods for counting residual white blood cells. *Transfusion.* 1993;33:128-133.
7) Vachula M, Simpson SJ, Martinson JA, et al. A flow cytometric method for counting very low levels of white cells in blood and blood components. *Transfusion*. 1993;33:262-267.
8) Center for Biologics Evaluation and Research. *Recommendations and Licensure Requirements for Leukocyte-Reduced Blood Products*. Rockville, MD: Food and Drug Administration; 1996. NCCLS document.
9) *Protection of Laboratory Workers from Infectious Disease Transmitted by Blood, Body Fluids, and Tissue: Tentative Guideline*. Villanova, PA: National Committee for Clinical Laboratory Standards; 1991. NCCLS document M29-T2.

Glossary of Symbols

	Caution, warning, Consult accompanying documents
REF	Catalogue number/Reference number
 www.nanoentek.com/eifu.php	Consult Instructions for Use An electronic instructions for use (eIFU) indicator (website address) may accompany the symbol when used to indicate an instruction to consult an eIFU.
LOT	Lot number/Batch number
	Use by YYYY-MM-DD or YYYY-MM
	Manufacturer
CE	CE marking
IVD	*In vitro* diagnostic medical device
UK CA	UK Conformity Assessment
	Temperature limitation
	Contains sufficient for <n> tests
	Do not reuse
	Do not use if package is damaged
Rx Only	For prescription use only CAUTION: Federal (U.S.) law restricts this device to saleby or on order of a physician.
US Corporation	US Corporation
EC REP	Authorized representative in the European Community
UK Representative	Authorized representative in United Kingdom
CH REP	Authorized representative in Switzerland
BRH	Authorized representative in Brazil

Revised on 2024.05