

# ADAM- rWBC Cell Counting System

*For in vitro diagnostic use*

## 50 Tests – Catalog No. AD1K-050

For enumeration of residual leukocytes in leukoreduced blood products

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## **1. INTENDED USE**

The ADAM-rWBC system is designed for counting residual white blood cells (rWBCs) in leukoreduced blood products.

## **2. SUMMARY AND EXPLANATION**

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

## **3. PRINCIPLES OF THE PROCEDURE**

The ADAM-rWBC 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 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.

## **4. REAGENTS**

The ADAM-rWBC kit consists of:

- 25 mL r-Solution(RDR-50) containing Propidium Iodide (0.04%, w/v), a nucleic acid dye
- 50 pieces r-Slide (RDS-50)
- 7 mL Standard Bead (ADST-001) (PeakFlow flow cytometry reference beads, Abs 580nm, Em 620nm, 6-diameter) Solution containing 0.1% sodium azide.

## Precautions

- For *in vitro* diagnostic use. Not for use in therapeutic procedures.
- Care should be taken to avoid microbial contamination of the reagent.

## WARNING

All biological specimens and materials coming in contact with them are considered biohazards. Handle as if capable of transmitting infection<sup>8, 9</sup> and dispose of with proper precautions in accordance with federal, state, and local regulations. Never pipette by mouth. Wear suitable protective clothing and gloves.

## WARNING

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.

## WARNING

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.

## Storage and Handling

1. 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.

2. Store r-Slides at 0 - 30°C. Do not use after the expiration date shown on the label.
3. 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.
4. The Standard Bead may be exposed to light for short periods of time, and may be stored on the bench during use.

## 5. DEVICE

**Also refer to the ADAM-rWBC series Instruction Manual.**

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

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 matches 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 machine 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**

**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.

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

## **6. SPECIMEN COLLECTION AND PREPARATION**

Red Blood Cell or platelet 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.

### **Stained Sample Stability**

Stained samples may be stored for up to one hour at room temperature prior to use.

### **Stored Sample Stability**

**RBC products:** Leukoreduced RBC products may be stored for up to 48 hours at a refrigerated temperature (1 - 8 °C) prior to testing.

**Platelet (PLT) products:** Leukoreduced PLT products may be stored for up to 24 hours at a refrigerated temperature (1 - 8 °C), or up to 48 hours at a room temperature (18 - 25 °C) prior to testing.

## **7. 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 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 blood sample must be diluted with the r-Solution at a ratio of dilution ratio is 1:5 (i.e. 100 $\mu$ L sample + 400 $\mu$ L 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  $\mu$ L 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.

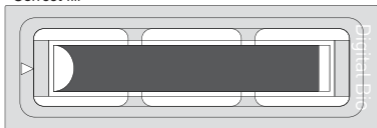
## Quality Control

Quality Control material should be run daily with use. Red blood cell controls should be run with red blood cell samples and platelet controls run with platelet samples.

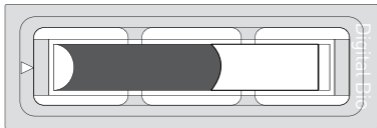
## Sample Preparation and Testing


1. Leave the ADAM-rWBC Kit at room temperature for 10 minutes before use.
2. Carefully dispense 100  $\mu\text{L}$  of well-mixed RBC or platelet sample into a clean test tube.
3. Add 400  $\mu\text{L}$  of reagent into the tube.
4. Mix the tube well (100  $\mu\text{L}$  sample + 400  $\mu\text{L}$  reagent).
5. Load 100  $\mu\text{L}$  mixed sample/reagent onto a r-Slide.

Correct fill





Low volume



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  $\mu\text{L}$  will be displayed automatically.

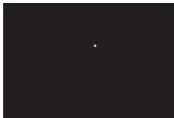
## Device Setup

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.

Examples of external video monitor (option) displays

1~2 WBC/ $\mu$ L



5~20 WBC/ $\mu$ L



80~100 WBC/ $\mu$ L



## 8. RESULTS

The calculated number of WBCs per  $\mu$ L will be displayed automatically.

## 9. PERFORMANCE CHARACTERISTICS

### Stain-to-Stain Precision

Stain-to-stain precision was assessed at three sites. Each site tested two RBC products and two platelet products. Each concentration was tested in duplicate in two shifts/day, and over two days. Each of the four products was tested in different two day periods.

The CV% is not an appropriate statistic for values close to zero and is therefore not included for WBC values < 1.

Stain-to-Stain Precision Red Blood Cell products						
WBC/ µL target	Site #	Mean	Intra- assay SD	Intra- assay CV%	Total SD	Total CV%
<b>Unit 1</b>						
0-1	1	<1	0.27	NA	0.43	NA
	2	<1	0.62	NA	0.62	NA
	3	<1	0.19	NA	0.19	NA
5-10	1	6	0.93	15.17	1.05	17.20
	2	6	1.85	28.97	1.85	28.97
	3	7	0.54	8.22	0.62	9.39
20-30	1	26	2.11	7.98	2.11	7.98
	2	20	0.76	3.76	0.89	4.38
	3	25	2.12	8.36	2.15	8.49
50-60	1	49	2.77	5.64	2.77	5.64
	2	47	1.83	3.93	3.47	7.42
	3	54	2.35	4.34	2.39	4.41
80-100	1	82	1.87	2.28	1.91	2.33
	2	73	2.41	3.30	6.35	8.69
	3	91	4.23	4.64	4.27	4.68
<b>Unit 2</b>						
0-1	1	1	0.47	43.83	0.47	44.15
	2	1	0.53	38.31	0.96	69.91
	3	<1	0.60	NA	0.60	NA
5-10	1	8	0.62	7.54	0.89	10.84
	2	10	1.00	10.19	1.32	13.49
	3	6	0.59	10.54	0.98	17.57
20-30	1	27	1.92	7.00	2.34	8.53
	2	24	2.16	8.99	2.33	9.70
	3	27	3.58	13.50	3.60	13.59
50-60	1	54	3.24	6.03	3.26	6.07
	2	64	4.59	7.21	4.59	7.21
	3	55	3.60	6.57	3.67	6.71
80-100	1	90	7.17	7.97	7.37	8.19
	2	84	4.85	5.74	5.14	6.09
	3	89	4.66	5.24	4.66	5.24

Stain-to-Stain Precision Platelet products						
WBC/ μL target	Site #	Mean	Intra- assay SD	Intra- assay CV%	Total SD	Total CV%
<b>Unit 1</b>						
0-1	1	1	0.81	60.05	0.81	60.05
	2	<1	0.18	NA	0.217	NA
	3	<1	0.55	NA	0.61	NA
5-10	1	8	0.57	7.21	0.85	10.77
	2	5	0.59	11.19	1.08	20.66
	3	6	0.84	13.54	0.92	14.84
20-30	1	26	1.70	6.64	1.79	7.00
	2	15	0.79	5.27	2.08	13.89
	3	28	2.62	9.35	2.65	9.47
50-60	1	52	2.83	5.47	2.84	5.48
	2	32	2.57	7.94	2.57	7.94
	3	61	3.07	5.04	3.07	5.04
80-100	1	92	3.82	4.15	5.89	6.39
	2	53	0.89	1.69	2.27	4.30
	3	98	2.77	2.82	3.39	3.45
<b>Unit 2</b>						
0-1	1	<1	NA	NA	NA	NA
	2	<1	0.42	NA	0.42	NA
	3	<1	0.22	NA	0.44	NA
5-10	1	8	0.82	10.98	0.83	11.02
	2	9	0.87	9.54	0.87	9.54
	3	6	0.82	12.78	1.17	18.37
20-30	1	25	1.55	6.26	2.49	10.07
	2	26	1.57	6.09	1.64	6.34
	3	29	1.31	4.47	2.02	6.88
50-60	1	55	1.65	2.99	2.74	4.96
	2	49	1.01	2.07	1.68	3.42
	3	61	2.02	3.33	3.99	6.58
80-100	1	90	1.55	1.73	3.93	4.38
	2	84	1.79	2.13	3.03	3.61
	3	100	2.74	2.73	3.69	3.67

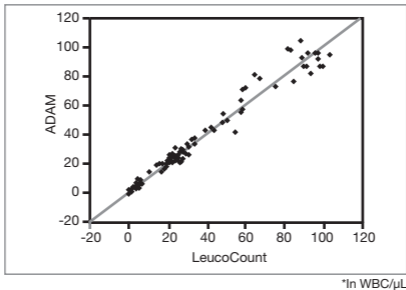
### Linearity

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

### Accuracy

Accuracy was assessed at three sites, where the n=151 for both RBCs and platelets.

### RBC products

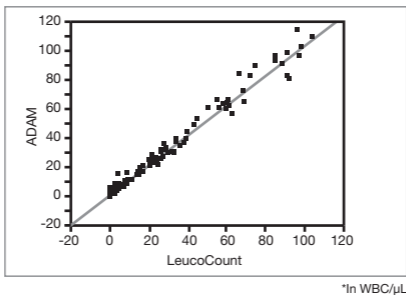


Slope = 1.009

Intercept = 0.299

$r^2 = 0.989$

### Platelet products



Slope = 1.027

Intercept = 1.066

$r^2 = 0.989$

## 10. 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, Rebullia 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
	Catalogue number/Reference number
 <small><a href="http://www.nanocentek.com/eifu.php">www.nanocentek.com/eifu.php</a></small>	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 number/Batch number
	Use by YYYY-MM-DD or YYYY-MM
	Manufacturer
	Authorized representative in the European Community
	CE marking
	<i>In vitro</i> diagnostic medical device
	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 sale by or on order of a physician.

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