NanoEntek

NESPI-ARH-002EN(V.0.3)

IVD

ADAM- rWBC HT Cell Counting System

For in vitro diagnostic use

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50 Tests – Catalog No. ADHK-050

For enumeration of residual leukocytes in leukoreduced blood products

Revised 10/2024

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1. INTENDED USE

The ADAM-rWBC HT 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.[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 ADAM-rWBC Kit is designed to provide an efficient, sensitive method for enumerating residual WBCs, while eliminating limitations associated with other methods.[6,7]

3. PRINCIPLES OF THE PROCEDURE

The ADAM-rWBC HT has an integral robotic sample loader. The internal sample loader accommodates the Magazine that can hold up to 5 Trays. As each Tray holds up to 10 r-Slides, the total capacity of the Magazine is 50 r-Slides.
The ability to load, test, and display multiple results provides a "walk-away" benefit for the end-user. The ADAM-rWBC HT automatically counts the number of residual white blood cells in leukoreduced blood products for transfusion.
It ensures that residual leukocytes are under the leucodepletion guideline range to minimize complication associated with the transfusion.
Automatic cell counting eliminates user bias or subjective interpretation that can be found when counting residual White Blood Cells using other methods.

4. REAGENTS

The ADAM-rWBC Kit consists of :

Contents	Cat. No.
r-Solution containing Propidium Iodide (0.04%, w/v), a nucleic acid dye (25 mL)	RDR-50
r-Slide (50 pcs)	RHS-50
Standard Bead Solution (PeakFlow flow cytometry reference beads, Abs 580nm, Em 620nm, 6-diameter) containing 0.1% sodium azide (7 mL)	ADST-001

Precautions

- For *in vitro* diagnostic use. Not for use in therapeutic procedures.
- Reagent should be handled with care to avoid microbial contamination.

⚠ WARNING

All biological specimens and materials coming in contact with them are considered biohazards. Handle as if capable of transmitting infection 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

The 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 which 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 shelf-life is one year.
   Do not use after the expiration date shown on the label. Opened r-Solution should be stored at 2 - 8 °C and used for up to 6 months, but not past the expiration date.
2. Store the r-Slides at 0 - 30 °C. Any unused slides should be sealed in the pouch.
   The expiration date is one year before the opening.
   Do not reuse the slide and after the expiration date shown on the label.

3. Store the Standard Bead Solution in the dark at 2 - 8 °C when not in use. Opened Standard Bead Solution should 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 Solution should not be exposed to light for a long time and is required to be placed on the bench during use.

5. INSTRUMENT

Also refer to the ADAM-rWBC HT Instruction Manual.

This ADAM-rWBC Kit is designed for use on the ADAM-rWBC HT white blood cell counter.

Below is a listing of the accessories:

Trays	5 ea
Barcode scanner	1 ea

Instrument Safety Precautions

1. Always ensure that the power supply input voltage matches the voltage available in your location.
2. To avoid the danger of electric shock, install the medical instrument per the environmental specifications described in “Technical Specifications”. If the medical instrument, the adaptor, or power inlet is exposed to water or other material, disconnect the power cord and contact an authorized service person.
3. Do not touch the main plug 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 instrument on a slant or a place prone to vibrations, which induces the risk of instrument malfunction or damage of the instrument.
6. Never insert any objects (especially metallic objects) into the air vents of the instrument as this could result in electrical shock, personal injury and instrument damage.
7. Always set the main switch on the power supply unit to OFF before connecting the power cord to the wall outlet.
8. To avoid a potential shock hazard, always connect the grounding terminal of the medical instrument and that of the wall outlet properly. The power cord should be connected to a grounded, 3-conductor power outlet.
9. Position the instrument so that there is sufficient length for the cable connection.

10. Before moving, set the main switch to “O” (OFF) and unplug the power cord.
11. If the medical instrument is broken or dropped, disconnect the power cord and contact an authorized service person. Do not disassemble the medical instrument.
12. Use authorized accessories only.
13. Use ADAM-rWBC HT only as instructed in this manual and as specified in any documentation associated with its components.

⚠WARNING

Cover: Do not remove the cover or dissemble a case. There are no adjustable components inside the instrument. If there is a malfunction, contact the NanoEntek technical service team.

6. SPECIMEN COLLECTION AND PREPARATION

Red blood cell or platelet samples must be collected and tested within 48 hours of leukoreduction.

ADAM-rWBC HT testing is not affected by hemolysis or lipemia.

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 temperate (18 - 25 °C) prior to testing.

7. PROCEDURE

Materials Required but Not Provided

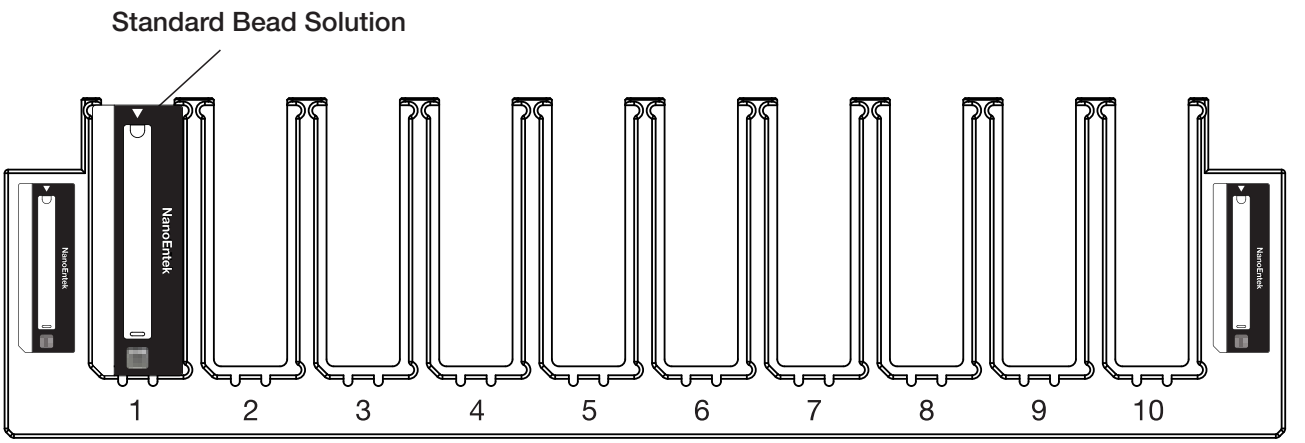
- Micropipette and tips
- Capped test tubes
- Test tube rack
- Timer
- Lint free wipes

ⓘ **NOTE:** *If tips must be wiped, use lint free material only, and discard after a single use. It is also not recommended to use materials that may generate or capture lint as a bench cover in the testing area.*

Calibration (Standard Bead)

For the calibration, Standard Bead Solution (with absolute particle count) is used to calibrate the automatic focus of ADAM-rWBC HT. It should be done as soon as the instrument is turned on. This calibration checks the position of the slide stage. The calibration should be done on a daily basis, at least once a day using the Bead. Figure 1 shows the position of the r-Slide for calibration test in the Tray.

Figure 1. Position of r-Slide in the Tray for calibration.



1. Click ‘Calibration’ button in the main software.
2. Let the beads come to room temperature for up to 10 minutes before use.
3. Scan the barcodes of the Standard Bead Solution and the r-Slide.
4. Place the scanned empty r-Slide in the Tray.
5. Mix the bead until the substance is distributed evenly.
6. Load 100 µL of the beads onto the r-Slide.
7. Insert the Tray into the Magazine of the ADAM-rWBC HT instrument.
8. Close the door and click ‘Next’ button followed by ‘Run’ button for calibration.

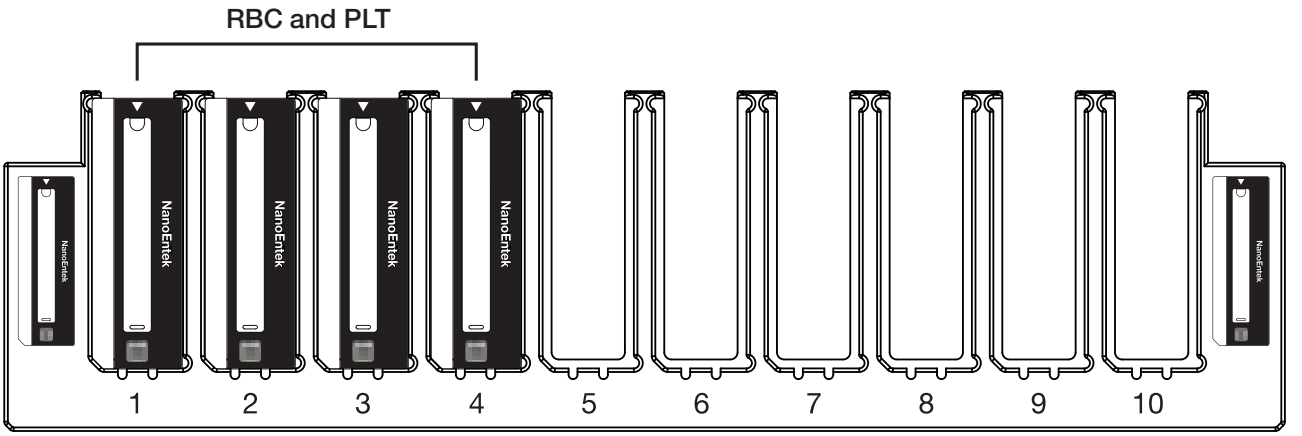
ⓘ **NOTE:** *Please refer to the ADAM-rWBC HT instruction manual for detailed information.*

The instrument is ready to use only if the calibration result is within range as indicated on the individual Standard Bead Solution provided.

Quality Control (Control Material)

The package insert will include instructions to test external quality control (RBC Low level and High level; PLT low level and High level) at initial operation and after long-term non-use, using ‘Control’ mode. The quality control material can run together in a single Tray. Figure 2 shows an example of the r-Slides for quality control material inserted in the Tray. The slides do not have to be in this order as long as they are inserted in the slot 1 through 4.

Figure 2. Position of the r-Slides in the Tray for quality control material.



1. Click ‘Control’ button in the main software.
2. Let the quality control materials come to room temperature for up to 15 minutes before use.
3. Scan the barcode of the r-Solution.
4. Sequentially scan the barcodes of each pair of control material and r-Slide. Scan the control material tube first and then the empty r-Slide.
5. Place the scanned empty r-Slide in the Tray.
6. Gently invert the control material until mixed thoroughly.
7. Insert 400 µL of r-Solution and 100 µL of quality control material into a clean test tube.
8. Mix the tube well.
9. Load 100 µL of the mixed sample onto the r-Slide.
10. Insert the Tray into the Magazine of the ADAM-rWBC HT instrument.
11. Close the door and click ‘Next’ button followed by ‘Run’ button for measurement.

ⓘ **NOTE:** *Please refer to the ADAM-rWBC HT instruction manual for detailed information.*

The instrument is ready to use only if the quality control material result is within range as indicated on the data sheet provided with quality control material.

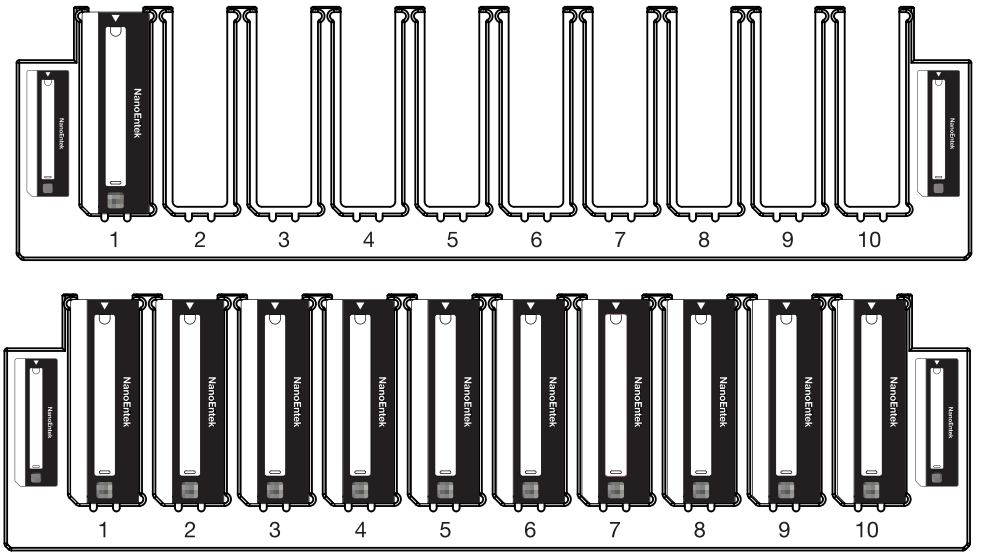
Sample Preparation and Testing

1. Click 'Sample' button the main software.
2. Enter the ‘Folder Name’, if necessary.
3. Select sample type. For each test, select only one sample type (RBC or PLT).
4. Place the Tray(s) to be used on a flat table (Fig. 3).
5. Sequentially scan the barcodes of each pair of blood sample and r-Slide. Scan the blood sample first, and then the empty r-Slide.
6. Enter ‘Optional ID’ and ‘Volume’, if necessary.
7. Place the scanned empty r-Slide in the Tray.
8. Repeat step from 5 to 7 until all of the r-Slides for testing are well positioned.

ⓘ **NOTE:** *Please refer to the ADAM-rWBC HT instruction manual for detailed information.*

Figure 3. An example of empty Tray.

Figure 4. Position of r-Slide in the Tray for sample test.

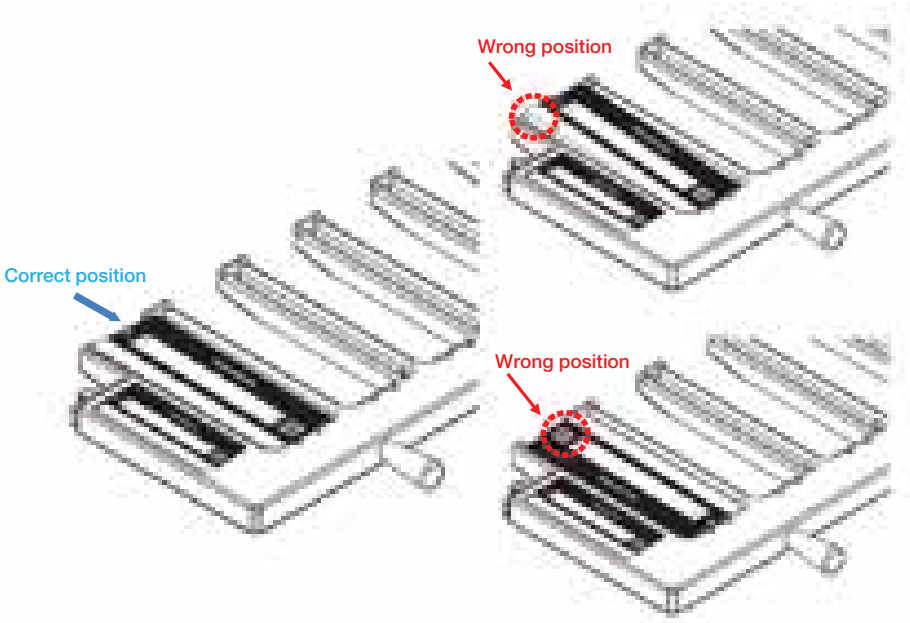


※ *Up to 50 samples (in the 5 Trays) can be performed at once.*

⚠WARNING

The r-Slide(s) should be inserted in the same direction as the example attached in the Tray.

Figure 5. Position of r-Slide in the Tray.



※ *The barcode must be located at the bottom of the Tray.*

Due to stained sample stability, there should be no delay between any of the following steps: sample processing, r-Slide loading, Tray insertion into the Magazine and starting of the counting process.

7. Add 400 µL of r-Solution to each test tube using a pipette.
8. Carefully add 100 µL of well-mixed RBC or platelet sample into a test tube (400 µL of r-Solution + 100 µL of sample).

⚠ WARNING

[Mix ratio error]
Please mix the sample & reagent with the correct ratio. The ADAM-rWBC HT does not provide the mixing ratio.

9. Load 100 uL of mixed sample/reagent onto the r-Slide.

   Note: *Reverse pipetting is recommended.*

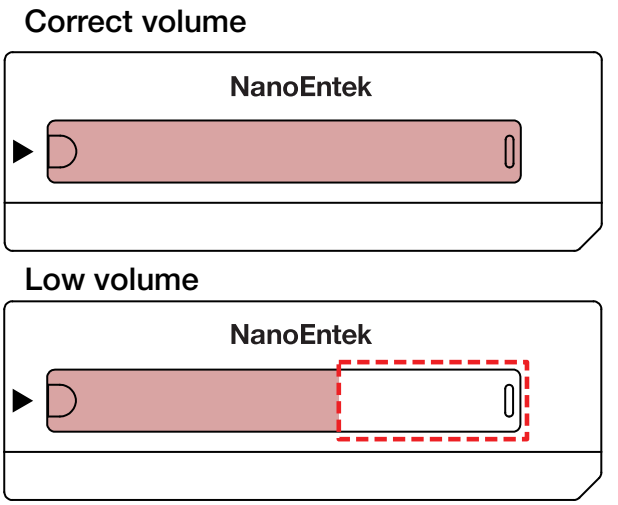
⚠ WARNING

Avoid bubbles which may negatively affect the result.

⚠ WARNING

[Sample loading error]
Make sure to load the correct volume (100 µL) of the sample onto the r-Slide. The ADAM-rWBC HT will not detect low or high sample volume.

Figure 6. Example of correct volume and low volume loaded onto the r-Slide.



10. Insert the first Tray at the bottom of the ADAM r-WBC HT Magazine.
11. Click 'Next' in the main software.
12. After finishing Tray(s) insertion, make sure that the software displays the correct number and placement of inserted Tray(s) with blue color.
13. Close the door.
14. Click ‘Run’ button to start.

8. RESULTS

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

[Error message – Bad Sample]

Figure 7. In case of bad sample after test.

In case this error message appears in the results, discard the error sample, prepare a new stained sample and retest. If the error occurs repeatedly, please obtain a new whole sample and start again.

9. PERFORMANCE CHARACTERISTICS

All testing was conducted at the NanoEntek laboratory.

Linearity

Linearity was assessed using 2 clinical samples (RBCs and platelets) at 7 concentrations. Results were observed to be linear within the 1 – 100 cells/μL range.

Method Comparison- Accuracy

Method comparison was conducted comparing the ADAM-rWBC HT to the ADAM-rWBC. 300 CPDA-1 RBC and 300 CPDA-1 Platelet clinical samples per three (3) operator/ instrument were tested (N=900 total for each sample type).

Figure 8. RBC.

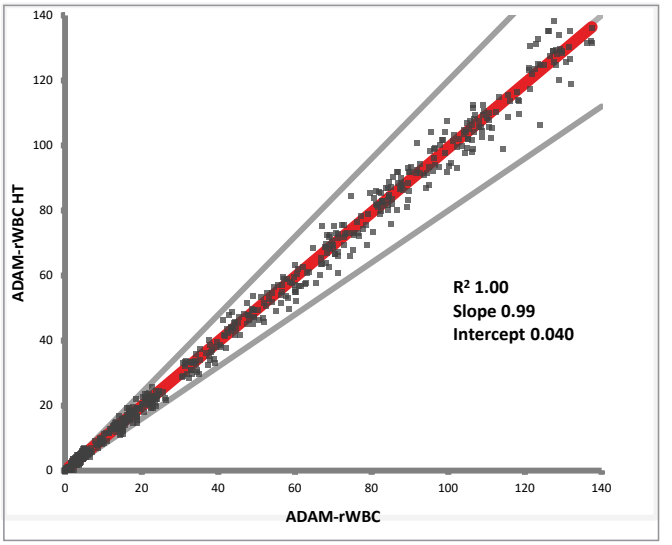


Figure 9. Platelet.

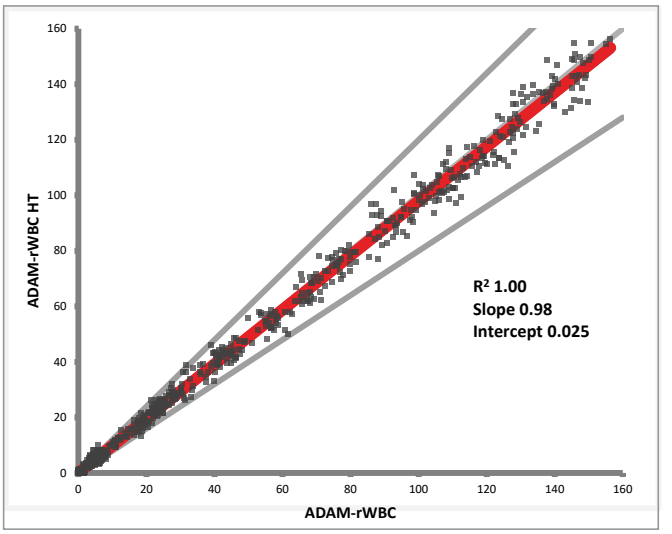


Table 1. Method Comparison Bias.

ADAM-rWBC HT compared to ADAM-rWBC					
Bias	N	Parameter	Estimate	95% CI	SE
RBC					
WBC (<5 cells/uL)	379	Mean difference	0.016	-0.0440 to 0.0754	0.0304
WBC (≥5 cells/uL)	521	Mean relative difference	-1.94%	-2.626% to -1.256%	0.349%
Platelet					
WBC (<5 cells/uL)	318	Mean difference	0.1008	0.03183 to 0.16986	0.03508
WBC (≥5 cells/uL)	582	Mean relative difference	1.89%	1.102% to 2.677%	0.401%

Precision

For the study, three operators & instruments have operated using 5 target concentrations as follows:

- 0-1, 5-10, 20-30, 50-60 and 80-100 cells/μL
- It was conducted in 2 days and the operator conducted 50 replicates (testing) per sample twice each day.

Table 2. RBC

Sample	Mean value	N	Repeatability		Between Day		Between Run		Between instrument		Reproducibility	
			SD	% CV	SD	% CV	SD	% CV	SD	% CV	SD	% CV
0-1	<1	600	0.20	NA	0.00	NA	0.00	NA	0.26	NA	0.33	NA
5-10	7.94	600	0.94	11.81%	0.12	1.50%	0.00	0.00%	0.48	6.00%	1.06	13.34%
20-30	21.39	600	1.68	7.87%	0.00	0.00%	0.00	0.00%	0.57	2.70%	1.78	8.31%
50-60	52.15	600	2.65	5.09%	0.00	0.00%	0.00	0.00%	2.11	4.00%	3.39	6.50%
80-100	97.02	600	4.21	4.34%	0.59	0.60%	0.00	0.00%	2.69%	2.80%	5.03	5.19%

Table 3. Platelet

Sample	Mean value	N	Repeatability		Between Day		Between Run		Between instrument		Reproducibility	
			SD	% CV	SD	% CV	SD	% CV	SD	% CV	SD	% CV
0-1	<1	600	0.22	NA	0.05	NA	0.00	NA	0.05	NA	0.24	NA
5-10	8.14	600	0.81	9.95%	0.00	0.00%	0.00	0.00%	0.15	1.90%	0.82	10.12%
20-30	21.02	600	1.41	6.71%	0.00	0.00%	0.00	0.00%	0.67	3.20%	1.56	7.43%
50-60	54.35	600	2.36	4.35%	0.00	0.00%	0.00	0.00%	1.89	3.50%	3.02	5.56%
80-100	100.08	600	3.80	3.80%	0.73	0.70%	0.00	0.00%	1.45%	1.40%	4.14	4.13%

Interfering Substances

ADAM-rWBC HT testing is not affected by the use of lipemic or hemolyzed samples.

10. LIMITATIONS

It is important to follow these Directions for Use and the ADAM-rWBC HT Instruction manual. Our kit is made specifically for use with the ADAM-rWBC HT instrument - only use provided reagents and materials. Do not use reagents or slides beyond the expiration date. Do not use previously used r-Slides.

REFERENCES

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2. de Graan-Hentzen YC, 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.
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5. Dumont LJ, 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.

Glossary of Symbols

	Caution, warning, Consult accompanying documents
REF	Catalogue number/Reference number
	Consult Instructions for Use
LOT	Lot number/Batch number
	Use by YYYY-MM-DD or YYYY-MM
	Manufacturer
EC REP	Authorized representative in the European Community
CE	CE marking
IVD	*In vitro* 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 saleby or on order of a physician.
US Corporation	US Corporation