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Leuko-TIC®

1 : 20 • blue

Single Tests for Quick, Simple, Clean and Precise Counting of Leukocytes.

Product information for visual microscopic counting of white blood cells (WBCs). Leuko-TIC® »blue« corresponds to improved Türk's solution but without the distracting background of RBC membranes.

Intended Purpose

Leuko-TIC® is used for accurate dilution of the sample for microscopic counting of white blood cells. It is a ready-to-use solution that makes the sample evaluable for diagnostics and makes the shape and structure more recognizable by an authorized and qualified person.

Principle

Microscopic counting of white blood cells (WBCs) in a counting chamber after lysis of the red blood cells (RBCs) and fixing of WBC nuclei. The WBC nuclei stick out prominently against a clear background. Gentian violet staining gives WBC nuclei a light violet-blue color.

Leuko-TIC® for WBC counting is a quick, easy, clean, and precise analysis procedure. The Leuko-TIC® tubes are pre-filled with LeukoCount® solution. Use 20 µL blood as sample (dilution 1 : 20).

Reagents

Leuko-TIC® is ready to use with a shelf life at room temperature (+15 ... +25 °C) until the printed expiry date.

Remove individual tubes only for use. Store tubes in the dark (closed box) and upright in their package.

Do not use if reagent is not clear, blue and free of particles.

Risks and Safety

Please observe the necessary precautions for use of laboratory reagents and body fluids. Applications should be performed by expert personnel only. Follow the national and laboratory internal guidelines for work safety and infection control. Wear suitable protective clothing and disposable gloves while handling.

Use a capillary holder for volume capillaries.

It is important to ensure effective protection against infection according to laboratory guidelines.

SDS ID International
www.sds-id.com

For additional safety information please refer to the information on the label and the corresponding Safety Data Sheet (SDS).
Download by QR-Code or link: www.sds-id.com/100037-1

Contents / Main Components

004013-4380	Cont.	Acetat buffer pH = 3,0; Gentianaviolett 0,1 g/L, Detergent < 0,3 %.
004013-0007	**KIT**	**Leuko-TIC® 1 : 20 blue plus • Single test with capillaries**
004013-4380	1.	100× 380 µL Leuko-TIC® 1 : 20 blue Packed in styrofoam racks.
ETE020-0100	2.	100× 20 µL End-to-end volume capillaries
KFK-0100	3.	100× Chamber filling capillaries.
004013-0006	**SET**	**Leuko-TIC® 1 : 20 blue • Single test w/o capillaries**
004013-4380	1.	100× 380 µl Leuko-TIC® 1 : 20 blue Packed in styrofoam racks.
004013-6010	**SET**	**Leuko-TIC® 1 : 20 blue • Small package w/o capillaries**
004013-4380	1.	10× 380 µL Leuko-TIC® 1 : 20 blue Packed in aluminium foil sachet.

Replacement pack optional

TIC-CP20	**SET**	**TIC 20 µl Capillary Pack**
ETE020-0100	1.	100× 20 µL End-to-end volume capillaries
KFK-0100	2.	100× Chamber filling capillaries

Do not use other capillaries that are not intended for this TIC test kit.

Additional required or recommended materials and equipment:

099920-0001	Capillary Holder *
CC-NEUI	Counting Chamber Neubauer "improved" *
	Microskope for laboratory use

* Available from Bioanalytic GmbH.

Sample Material

Process fresh capillary blood immediately after collection. K_2- or K_3-EDTA blood can be processed within max. 24 hrs when stored closed at room temperature (+15 ... + 25 °C) or up to 48 hrs stored at +4 °C [4]. Do not freeze!

Never use NH4 heparin blood.

Blood from all mammalian species, including humans, can be used.

For synovial fluid use Leuko-TIC® SF.

Count fresh samples diluted with Leuko-TIC within 48 hrs. Resuspend cells before counting.

For sample collection, storage and labeling follow the standards of technology procedures and the corresponding instructions.

Reference Ranges

Capillary- / EDTA-blood	[10^9/L = 10^3/µL]
Neonates:	10.0 ... 30.0
Nurselings:	7.0 ... 17.0
Infants:	6.0 ... 15.0
Scholars:	5.0 ... 12.0
Adults:	4.0 ... 9.0

Procedure

Using capillary pipettes

Fill a 20 µL end-to-end volume capillary bubble-free with blood from end to end. We recommend using a capillary holder for this (see ordering Information). Discard the first drop of capillary blood. Remove blood on the outside with a lint-free tissue without sucking blood from the capillary. Place filled volume capillary into the opened vial, close and shake thoroughly until all blood is flushed from the capillary. Wait at least 30 seconds for complete lysis of RBCs. Leave capillary in the vial.

Shake the tube once more before loading the counting chamber.

Fill the chamber filling capillary about a quarter to half its length by capillary action and seal the upper end with your finger. Touch the tilted capillary (narrow angle) against the edge of the cover slip and load the counting chamber. Count cells immediately.

Using automatic micropipette

Only appropriately trained laboratory staff should use this method!

Instead of end-to-end and chamber filling capillaries use an adequate automatic micropipette (only when working with EDTA blood). Proceed as outlined above for the capillaries. Flush pipette tip sufficiently with the reagent solution. Shake the tube once more before loading the counting chamber. Count immediately.

Analysis / Calculation

For microscopic counting, use phase-contrast optics or bright field (lowered condenser) at 100× magnification.

Neubauer "improved" counting chamber

Count the WBCs in the 4 large corner squares (each 1 mm^2; subdivided into 4 × 4 subsquares). When using the Neubauer „improved" counting chamber, count cells up to the center line.

Total count from the 4 large corner squares × 0.05 = WBCs × 10^9/L blood

Total count from the 4 large corner squares × 50 = WBCs / µl blood

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Diagnosis

Diagnoses are to be made only by authorized and qualified persons. This method is to be used as a supplement in human diagnostics. For a final diagnosis, further tests are to be performed according to recognized, valid methods.

Capability Characteristics

The method is an absolute (counting) method. It is traceable to the dilution and volume of the counting chamber.

Leuko-TIC® clearly outperforms the (now outdated) method using Türk's solution and dilution with blood mixing pipettes.

Limitations

Strongly increased or decreased cell values can complicate a correct cell counting. In these cases a suitable diluting should be chosen, which has to be considered in the calculation.

Analysis of samples that contain significant amounts of nucleated erythrocytes (erythroblasts) should correct for these.

Exclusively use Leuko-TIC® SF (Synovial Fluid) to count WBCs in synovial fluid. Instructions can be downloaded.

Precision Leuko-TIC®

Intra-assay n = 25	Mean [10^3/µl]	SD [10^3/µl]	CV [%]
Sample 1	6.75	0.424	6.27
Sample 2	9.91	0.618	6.23

Precision Türk's Solution and blood mixing pipette

Intra-assay n = 25	Mean [10^3/µl]	SD [10^3/µl]	CV [%]
Sample 1	6.88	0.794	11.54
Sample 2	10.1	1.073	10.62

Quality Controls and Proficiency Test

Exceptions to the quality assurance obligation

Unit-use reagents are portioned for single determination and are consumed with single determination. Such unit-use reagents are usually exempt from the requirements of internal and external quality control. This is subject to the condition that the reagent is used exactly in accordance with the manufacturer's instructions.

Please observe the national quality assurance guidelines.

Quality controls

A suitable control material can be used to check precision and accuracy. All common control blood samples (or interlaboratory samples) can be used that

- are suitable or designated for visual microscopic counting of leukocytes.

Pay attention to the corresponding data of the control blood manufacturer.

Control bloods intended only for automatic counting devices may not be suitable.

Specific features

Control blood cells mostly contain stabilized cells with denatured cell membranes or they contain replacement cells (e.g. nucleated avian erythrocytes instead of mammalian leukocytes). This may cause the microscopic appearance to differ from that of fresh human or mammalian blood.

Note:

Resuspend control blood very carefully before each opening. Please note the information for the control blood. Use a cell-friendly mixing device (e.g. roller mixer).

Notes

Special product information for counting very low WBC values is available via download.

This product information exclusively relates to the product described in this leaflet. In particular, this product information cannot be applied to similar reagents from other manufacturers.

Instruction for Use

For professional use only.

To avoid errors, the use of qualified personnel is carried out. Double determinations are always advisable. National guidelines for work safety and quality assurance must be followed.

The used equipment must comply with the state of technology and the laboratory requirements.

All samples and used tubes/vials must be marked clearly identifiable to exclude any confusion.

Classifications

EU: EDMA: 13 01 09 90 00; IVD Class A (in vitro diagnostic medical device). Basis UDI: 4061609-0004-NW.
AU: Class 1; IVD.
CA: HC: Class I; exempt; for in-vitro diagnostic use.
US: FDA: JCG; Class I; exempt; for in-vitro diagnostic use.

Support / Infoservice

For methodological and technical support, please contact us by E-Mail at support@bioanalytic.de.

Periodically check for updates of this product information on our website.

Feedback

Information from users can be reported to support@bioanalytic.de.

Suggestions will be considered for further development.

If a serious incident has occurred during or as a result of use, please report it to the manufacturer and/or its authorized representative and to your national authority.

Waste Management

Please observe your national laws and regulations.

Used and expired solutions must be disposed of in accordance with your local regulations.

Inside the EU, national regulations apply that are based on the current, amended version of Council directive 67/548/EEG on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.

Decontaminated packaging can disposed of as household waste or recycled, unless otherwise specified.

Literature & Footnotes

Legends for the graphic symbols and tags used follow relevant norms or are available on our internet pages.

[1] DIN 58932
[2] Wintrobe, Clinical Hematology, S. 1795 (1974), Lea & Febiger Philadelphia.
[3] Rick, Klinische Chemie und Mikroskopie, 24 (1977), Springer Verlag Berlin.
[4] L. Thomas: Labor und Diagnose, 4. Auflage (1992), Die Medizinische Verlagsgesellschaft Marburg, p. 620. ISBN: 3-921320-21-6.
[5] Richtlinie der Bundesärztekammer (RiLiBÄK)