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Leuko-TIC® SF

Counting of WBC in Synovial Fluid

Product information for counting of white blood cells (WBC) in synovial fluid.
According to the expected values two methods are possible:

- Dilution 1 : 100 (10 µL sample material).
- Dilution 1 : 21 (50 µL sample material).

Intended Purpose

Leuko-TIC® SF is used for accurate dilution of the sample for microscopic counting of white blood cells in synovial fluid. 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 (WBC) in the counting chamber after lysis of the Red Blood Cells (RBC). Leuko-TIC® SF (SF = Synovial Fluid) contains no acetic acid.

Synovial fluids

Synovial fluids often contain substances that form precipitates with acetic acid, such as hyaluronic acid.
By the precipitates, the cells are clumped and the required even dispersion for counting in the counting chamber significantly disrupted.
Therefore, Leuko-TIC® for the counting of WBC in blood can not, or only limited used after testing for absence of precipitate forming substances.

Reagents

Leuko-TIC® SF are ready for use and have a shelf life at room temperature (+15 ... +25 °C) up to the imprinted expiry date.
Remove tube only for use. Store tubes on a dark place (closed box) and upright in the 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. Wear protective clothing and disposable gloves during work. Use a capillary holder for volume capillaries.

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For additional and general safety information please see details on the label and the corresponding Safety Data Sheet (SDS).
Download by QR code or link: www.sds-id.com/100113-6

Contents / Main Components

004008-...	Cont.	1 % Ammonia/Oxalic acid buffer pH = 6.0
004008-6100	**KIT**	**Leuko-TIC® SF 1 : 100 plus • Single test with capillaries**
004008-4990	1.	100×990 µL Leuko-TIC® SF 1 : 100 Packed in styrofoam racks.
ETE010-0100	2.	1× 100 pcs End-to-end volume capillaries 10 µL
KFK-0100	3.	1× 100 pcs Chamber filling capillaries.
004008-6010	**SET**	**Leuko-TIC® SF 1 : 100 • Small package w/o capillaries**
004008-4990	1.	10× 990 µL Leuko-TIC® SF 1 : 100 Packed in aluminium foil sachet.

Replacement pack optional

TIC-CP10	**SET**	**TIC 10 µL Capillary Pack, containing:**
ETE010-0100	1.	1× 100 pcs End-to-end volume capillaries 10 µL
KFK-0100	2.	1× 100 pcs Chamber filling capillaries.

Do not use other capillaries which are not approved for this TIC test kit.

Additionally required or recommended materials

099920-0001	Capillary holder *
CC-NEUI / CC-NEUIB	Neubauer "improved" counting chamber *
	Microscope for use in biomedical laboratory.

* Available from Bioanalytic GmbH.

Sample Material

Collect Synovial fluid with K_3-EDTA- tubes and processed as fresh as possible.
About the shelf life of synovial fluid for WBC count we have no literature references.

Reference Ranges

At present there are no reliable published data available. Therefore, the following table must be examined.

Synovial fluid	[10^3/µL]
Not inflamed:	0.3 ... 1.0
Inflamed:	3.0 ... 50.0
Infectious:	> 50.0

Procedure

Using capillary pipettes 10 µL (Dilution 1 : 100):

Fill a 10 µL end-to-end volume capillary bubble-free with synovial fluid from end to end. We recommend using a capillary holder for this (see ordering Information). Remove outside adhesive synovial fluid with a lint free tissue - don't change the synovial fluid volume. Give the filled volume capillary into the opened tube, close and shake very well until all specimen has been removed out of the capillary. Wait at least 30 seconds for complete lysis of RBC. Leave capillary in the vial. Count WBC within 6 hrs.
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. 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 cells immediately.
Use an automatic pipette 10 µL for dilution 1 : 100 or 50 µL for dilution 1 : 21.

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Examination / Calculation

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

With Leuko-TIC® the WBC of blood appear under the microscope as blue stained nuclei without cell membrane and without cytoplasm. But with Leuko-TIC® SF the cells appear as whole cells.

Hemocytometer Neubauer / Neubauer "improved".

Dilution 1 : 100

Count the WBC of all 9 large squares of each 1 mm^2 surface. If the Neubauer „improved“ counting chamber is used count cells up to the center line.

Total count of the 9 large squares × 0.11111 = WBCs $\times 10^9$/L SF
Total count of the 9 large squares × 111.11 = WBCs / µL SF

For lower quality counting (overview) or very high values it is also possible to count the WBC only of the 4 large corner squares of each 1 mm^2 surface.

Total count of the 4 large corner squares × 0.25 = WBCs $\times 10^9$/L SF
Total count of the 4 large corner squares × 250 = WBCs / µL SF

Dilution 1 : 21

Count the WBC of the 4 large corner squares of each 1 mm^2 surface, consisting of 4 × 4 squares. If the Neubauer „improved“ counting chamber is used count cells up to the center line.

Total count of the 4 large corner squares × 0.052 = WBCs $\times 10^9$/L SF
Total count of the 4 large corner squares × 52 = WBCs / µL SF

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.

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

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: 4061609-0002-NQ.
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 / Information service

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 for further developments will be considered.

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.