



Thrombo-TIC®

1:100

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

Product information for quantitative visual microscopic counting of platelets (PLTs) with Thrombo-TIC®.

Intended Purpose

Thrombo-TIC® is used for accurate dilution of the sample for microscopic counting of platelets. 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 platelets (PLTs) in a counting chamber after lysis of red blood cells (RBCs) and disaggregation of platelets (separation and shape change). The platelets appear nearly round, frequently have one or more dendritic processes and are colourless with a darker rim. Their size is about 30% of red blood cells (RBCs).

Thrombo-TIC® allows quick, easy, clean and precise counting of PLTs. Vials are pre-filled ThromboCount® solution. Use 10µL blood as sample (dilution 1:100).

Reagent

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

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

Do not use if reagent is not clear, colorless and free of particles, or if any crystals have formed.

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.

It is important to ensure effective protection against infection according to laboratory guidelines. Use a capillary holder for volume capillaries.



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/100039-9

Contents/Main Components

004015-4990	Cont.	1% Oxalate buffer solution pH = 6.0
004015-0007	KIT	Thrombo-TIC® 1:100 pur plus • Single test with capillaries⁽¹⁾
004015-4990	1.	100x990µL Thrombo-TIC® 1:100 pur Packed in styrofoam racks.
ETE010-0100	2.	100x 10µL End-to-end volume capillaries
KFK-0100	3.	100x Chamber filling capillaries
004015-0006	SET	Thrombo-TIC® 1:100 pur • Single test w/o capillaries⁽¹⁾
004015-4990	1.	100x 990µL Thrombo-TIC® 1:100 pur Packed in styrofoam racks.
004015-6010	SET	Thrombo-TIC® 1:100 pur • Small package w/o capillaries⁽¹⁾
004015-4990	1.	10x 990µL Thrombo-TIC® 1:100 pur Verpackt im aluminiumfolierten Sachtet.

Replacement pack optional

TIC-CP20	SET	TIC 20µL Capillary Pack
ETE010-0100	1.	100x 10µL End-to-end volume capillaries
KFK-0100	2.	100x Chamber filling capillaries

Do not use other capillaries that are not intended for this TIC test kit. Different coatings may result in incorrect results.

Additional required or recommended materials and equipment

099920-0001 *	Capillary Holder *
CC-NEUI *	Counting Chamber Neubauer "improved" *
	Humidity chamber (moisturized filter paper in Petri Dish)
	Microscope for laboratory use
009101-0100 * 100 ml	Sodium citrate solution 0.11 mol/l (Anticoagulant) *

* Available from Bioanalytic GmbH

Sample Material

Dilute fresh capillary blood immediately with Thrombo-TIC®.

K₂- or K₃-EDTA blood can be processed within max. 24 hrs^{[5] [2]} when stored closed at room temperature (+15...+25°C). Do not freeze!

Citrate blood with sodium citrate 0,11 mol/L dilution 9:10 (= 9+1) can be used. Some hemagglutinins may (when cold and sample depending?) agglutinate PLTs. It is recommended to use fresh and still warm citrated blood. Heparin blood is not recommended.

Diluted samples

Count capillary blood diluted with Thrombo-TIC® within 3 hours.

Count EDTA samples diluted with Thrombo-TIC® within 4 hours.

Count other anticoagulants within 3 h if possible.

Resuspend the cells before chamber filling.

Sampling, storage and labeling must be performed according to the state of the art and the corresponding instructions.

Reference Ranges

	[10 ⁹ /µL]
.....	100 ... 440 ^[2]

For age-specific reference ranges, see literature^[5].

Procedure

Use the reagent at room temperature of 18...25°C.

Using capillary pipettes

Fill a 10µL end-to-end volume capillary bubble-free with blood from end to end. We recommend using a capillary holder for this. Discard the first drop of capillary blood. Remove blood adhering to 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 for at least 5 minutes for complete cell lysis. 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.

For sedimentation of the cells incubate the counting chamber in a humidity chamber for 10...20 minutes to allow sedimentation of the blood cells.

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 anticoagulated blood). Proceed as outlined above for the capillaries. Flush pipette tip sufficiently with the reagent solution.

Shake the vial once more before loading the counting chamber.

Analysis / Calculation

For microscopic counting, use phase-contrast optics or bright field (lowered condenser) at 400× magnification.

Counting chamber Neubauer ("improved"):

Count PLTs in all 25 group squares (composed of 16 smallest squares each). This is the entire central area of 1 mm². In the border squares, count cells up to the center line.

Capillary and EDTA blood

$$\text{Sum} \times 1'000 = \text{platelets (PLT)}/\mu\text{L blood}$$

Citrated blood (Dilution 9: 10)

$$\text{Sum} \times 1'111 = \text{platelets (PLT)}/\mu\text{L blood}$$

Counting chamber Neubauer (conventional):

Count PLTs in all 16 group squares (composed of 25 smallest squares each). This is the entire central area of 1 mm². In the border squares, count cells up to the outer line.

Capillary and EDTA blood

$$\text{Sum} \times 1'000 = \text{platelets (PLT)}/\mu\text{L blood}$$

Citrated blood (Dilution 9: 10)

$$\text{Sum} \times 1'111 = \text{platelets (PLT)}/\mu\text{L blood}$$

Thrombocytopenia

In cases of thrombocytopenia, the following options are recommended:

- Count the entire Neubauer grid (= 9 mm²). This is 9× the normal area, so the conversion factor changes.
 $\text{Calculating factor for capillary and EDTA blood} = 1000/9 = 111$
 $\text{Calculating factor for citrated blood (9:10)} = 1111/9 = 123$
- Change the dilution. Instead of 10 μL, draw a larger blood volume with an automatic pipette. Rinse pipette tip repeatedly with Thrombo-TIC® solution:
 - Recommended dilution for values < 80000:
20 μL blood (dilution 990 + 20 = 1010. 20: 1010 = 1: 50.5).
 $\text{Calculating factor for capillary and EDTA blood} = 505$
 $\text{Calculating factor for citrated blood (9:10)} = 561$
 - Recommended dilution for values < 40000:
50 μL blood (dilution 990 + 50 = 1040. 50: 1040 = 1: 20.8).
 $\text{Calculating factor for capillary and EDTA blood} = 208$
 $\text{Calculating factor for citrated blood (9:10)} = 231$

Thrombocytosis & PRP

- For cases of thrombocytosis with results of > ~400 × 10³/μl it is possible to count only 5 of the 25 group squares or alternatively, 4 horizontal lines.
 $\text{Calculating factor for capillary and EDTA blood} = 5000$
 $\text{Calculating factor for citrated blood (9:10)} = 5555$
- With results > ~1000 × 10³/μl, e.g. for PLT counts from platelet rich plasma (PRP), a higher dilution is required (e.g. 1: 250 or 1: 550). Please download/request special instructions.

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.

Thrombo-TIC® clearly outperforms the (now outdated) method using solutions and diluting with blood mixing pipettes.

Limitations

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

Precision Thrombo-TIC®

Intra-assay n = 25	Mean [10 ³ /μl]	SD [10 ³ /μl]	CV [%]
Sample 1	218	12.2	5.58
Sample 2	394	20.9	5.30

Precision Thrombo-Solution and blood mixing pipette

Intra-assay n = 25	Mean [10 ³ /μl]	SD [10 ³ /μl]	CV [%]
Sample 1	202	21.3	10.6
Sample 2	367	37.8	10.3

The above results were obtained with EDTA blood.

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: 4061609-0005-NZ.

AU: HC: 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 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 be 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] WHO-Bericht Lab/88.3
 - [5] L. Thomas: Labor und Diagnose, 4. Auflage (1992), Die Medizinische Verlagsgesellschaft Marburg. ISBN: 3-921320-21-6.
- *1) Alternatively we recommend Thrombo-TIC® fix-20 for dilution of 1:20. Therefore only 1/5 of the squares have to be counted, however the value of counts is identical.
- *2) The data of the optimum storage temperature in the literature are different.