INSTRUCTIONS FOR USE

STROMATOL®

STROMATOLYTIC AGENT FOR BLOOD PLATELET COUNTS

1 – INTRODUCTION AND INTENDED USE

For ***in Vitro*** diagnostic use only

Platelets (or thrombocytes), cells produced by the bone marrow and released into the blood, are essential for blood clotting. Their count is a test that checks the amount in a blood sample.

When a blood vessel or tissue suffer an injury, it is common to experience it starts to bleed. Platelets are used to stop bleeding because they have different roles as: adhere to injury, aggregate with each other and release chemicals that stimulate the aggregation of the same.

These three mechanisms create a cap on the lesion, through a process which on the whole is called primary hemostasis. At the same time, the activated platelets promote the cascade of the coagulation process, that is, the series of steps that involves the sequential activation of special proteins (coagulation factors). This process, called secondary hemostasis, form of the fibrin bands that strengthen the cap, form a network and they tighten close to form a stable clot which remains on the wound until the wound has healed. When the clot is no longer needed, other factors destroy it by dissolution.

Because coagulation work in the right way, all primary and secondary hemostasis components must be present, activated at the right time and properly functioning. When platelets are insufficient or do not function normally, you can form a clot unstable and the patient may risk hemorrhage. Platelets survive in blood for 8-10 days and the bone marrow must continually produce new ones to replace those worn out and / or lost through bleeding. The platelet count may be useful to diagnose various disorders that have to do with the excess or the shortage of platelets. It can be performed manually with a microscope or with an automatic device.

Stromatol® is a reagent that brings some advantages on the platelet count, manual or automatic, by facilitating the execution of the examination. Stromatol® is recommended for automated counts because he eliminates the platelet aggregates that usually invalidate the results of the automatic counters.

2 - PRINCIPLE OF THE METHOD

The stromatolytic agent acts lysing the red blood cells, and by staining in an elective way the platelets. In this way the platelets are well visible to microspcope.

3 - MATERIALS PROVIDED – PACKAGING

Product	Type	REF	Pack
Stromatol®	Stromatolytic agent: aqueous solution with Lactic acid, **Nikethamide, Quinine,** Sodium chloride, supravital stain.	3212001	1 dark glass bottle containing 50 mL of Stromatol® (50-60 tests) Warning H302; H319; H315; H317 P280; P261; P333+P313; P337+P313; P264; P362+P364 (Quinine, Nikethamide)  Secondary packaging: cardboard box.

4 - MATERIALS REQUIRED BUT NOT PROVIDED

Red Cell Diluting Pipette, watch glass or similar, Thoma's chambre

5 - PRECAUTIONS AND WARNINGS

- Normal precautions exercised in handling laboratory reagents should be followed. Dispose of waste observing all local, state, provincial or national regulations. Refer to Material Safety Data Sheet for any updated risk, hazard or safety information.
- The kit is for professional use and for in vitro diagnosis only.
- Do not use after expiration date. The quality of the reagent cannot be guaranteed beyond their shelf-life date or if the reagents are stored under inappropriate conditions.
- All operations linked to the use of the test must be performed in accordance with Good Laboratory Practices.
- All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- Stromatol® is a reagent for *in vitro* diagnostic, for professional use only; it is to be used by adequately trained and qualified laboratory personnel.
- Repeated openings of bottle do not affect the performances and do not cause contamination of the reagent.
- Do not use if the reagent present signs of deterioration, turbidity, precipitates, atypical colour.
- This product is classified as dangerous according to current European legislation (view above table and consulting the MSDS).
- The Certificates of Analysis and the Safety Data Sheet of the product are available on the website www.masciabrunelli.it.
- The information provided in this document has been defined to the best of our knowledge and ability and represents a guideline for the proper use of the product but without obligation or liability. In all cases existing local laws, regulations and standard procedures must be observed for the examination of samples collected from human and animal organic districts, for environmental samples and for products intended for human or animal consumption. Our information does not relieve our customers from their responsibility for checking the suitability of our product for the intended purpose.
- Notify Mascia Brunelli Spa and the Relevant Authorities of any serious incidents occurring in connection with the in vitro diagnostic device.

6 - STORAGE CONDITIONS AND SHELF LIFE

Store as packaged at temperature between *10* and 30ºC. The reagent is stable through the expiration date printed on the bottle. Any crystalline deposits caused by temperature drops can be eliminated without harm by bringing the STROMATOL® to +40°C for 2 to 3 hours. STROMATOL® is deteriorated by exposure to light and must therefore be kept in coloured or opaque bottles.

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7 – Specimens Collection

It is advisable to keep the blood for examination in silicon glass or in plastic test-tubes, using E.D.T.A. dipotassium salt 4 mM as anticoagulant (in practice it is sufficient to add one drop of 40% E.D.T.A. for 5 mL of blood in the test-tube).
In this way the following tests can be made on the same sample: red corpuscle count, white corpuscle count, haemoglobin content, blood group and leucocyte formula.

8 - Test Procedure

1. Fully compressing the rubber bulb, fill the dropper with STROMATOL®.
2. Pour the contents of the dropper into a watch-glass or similar container.
3. Fill a red cell pipette up to mark "1" with the sample of blood.
4. Then completely fill with STROMATOL® up to the mark "101"
5. Shake thoroughly to mix the blood and STROMATOL®.
6. Leave to stand for 4 - 5 minutes (with automatic equipment it take 10 - 15 minutes).
7. Shake again and put into a Thoma's chamber.
8. On completion of sedimentation, count the platelets in the chamber.

9 - Reading and Interpretation

The interpretation of the results is facilitated by the complete elimination of red cells and of the background staining that highlights the platelets electively.

Result x 100 (coeff. Of dilution) x 10 (chamber volume) = N° of platelets per mm³.

10 – Expected Values

Platelet Normal values: 150000-400000/mm^3 (unit IS: 150-400 x 109/L)

11 - Limitations of the Method and Notes

- The light can alter STROMATOL®. Then it must keep it in its container dark glass, tightly closed.
- Some drugs are incompatible with STROMATOL®: be careful if you use drugs based on iodine, iodide, benzoate, salicylate.
- STROMATOL®, is harmful by ingestion, skin contact and inhalation. (It must be used only for analysis with proper precautions). Refer to the Material Safety Data Sheet.
- As with all diagnostic tests, a final diagnosis cannot rely on the outcome of a single test and must be supported by other clinical parameters.

12 - References

1. Hematology: Principles and Procedures, Sixth Edition, Brown AB, Lea & Febiger, Philadelphia 1993 p101

TABLE OF APPLICABLE SYMBOLS

IVD	In Vitro Diagnostic Medical Device		Temperature limitation	LOT	Batch code (EXXX)		Manufacturer		Keep dry	NON STERILE	Non-sterile
	Consult Instructions for use		Use by (year/month)	REF	Catalogue number		Do not reuse		Fragile, handle with care		Keep away from heat

REVISION HISTORY

Version	Description of changes	Date
Instructions for Use (IFU) - Revision 3	Updated layout and content in compliance with IVDR 2017/746	2022/03
Instructions for Use (IFU) - Revision 4	Removal obsolete classifications	2023/03

Note: minor typographical, grammatical, and formatting changes are not included in the revision history.

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