INSTRUCTIONS FOR USE

HEMOFAST

MODIFIED WRIGHT'S SOLUTION QUICK DIFFERENTIAL STAINING OF BLOOD SMEARS

1 – INTRODUCTION AND INTENDED USE

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

Wright's stain, original or modified, is the most widely used alternative to Leishman's stain for blood smears.
The composition of HEMOFAST is a modification of Wright's stain, studied and tried in many Laboratories in order to provide a quick and reliable method of staining slides.
HEMOFAST is a buffered staining solution, prepared from substances of the highest purity.
The methyl alcohol contained in it, being neutral and free from acetone, makes the solution fix by itself, so that there is no need for prior fixing of the smeared slides.
Hemofast is a modified Wright solution quick differential staining of blood smears.

2 - PRINCIPLE OF THE METHOD

Wright's stain is a mostly water insoluble salt formed from the coprecipitation of two water insoluble dyes. Eosin Y (an anionic dye) and methylene blue and its oxidation series (cationic dyes), also called thiazine dyes. When present in a buffered solution, these dyes will bind in specific ways to cationic and anionic sites on the protein molecules that make up cells on the prepared blood smear used for hematological examination.

3 - MATERIALS PROVIDED – PACKAGING

Product	Type	REF	Pack
HEMOFAST	Modified Wright's solution quick differential staining of blood smears.	3213001	1 dark glass bottle containing 200 mL of HEMOFAST (3000 stains) Danger H225; H301+H311+H331; H370 P233; P210; P280; P243; P264; P270; P271; P260; P370+P378; P303+P361+P353; P301+P310; P330; P302+P352; P361+P364; P309+P311; P304+P340; P404; P403+P235; P501; P403+P233 (Methanol) Secondary packaging: cardboard box.

4 - MATERIALS REQUIRED BUT NOT PROVIDED

Glass smears; distilled water pH 6-7

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.
- Hemofast 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.
- HEMOFAST must therefore be kept in its container, which must be hermetically sealed.
- This product is classified as dangerous according to current European legislation (view above table and consulting the MSDS).
- HEMOFAST is poisonous (it must be used only for analysis) and flammable (it must be used at room temperature, away from sources of heat).
- 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. HEMOFAST is flammable and must therefore be kept from heat sources.

7 – SPECIMENS COLLECTION

Prepare a very thin blood smear and dry it quickly in the air by shaking it.

8 - TEST PROCEDURE

1. Immerse the slide in HEMOFAST for 30-60 seconds (Before immersion the slide must be perfectly dry).

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2. Immerse the slide in distilled water for about 10 - 20 seconds (dilution of stain).
3. In order to obtain a more marked staining of leucocytes, keep the slide immersed in distilled water for more than a minute.
4. Rinse the slide well in distilled water, dry it at room temperature and read it under the microscope.

9 - READING AND INTERPRETATION

The colours of the blood cells and the cellular components vary slightly with the variation of the pH of the distilled water in which the slide is dipped after staining.
The staining results given below are therefore an indication, since more intense or less intense shades of colour may be obtained.

ERYTHROCYTES	pink

LEUCOCYTES	Nucleus	Cytoplasm	Granules
GRANULOCYTES OR POLYMORPHONUCLEATES			
NEUTROPHILS	violet	pale pink	pink – violet
EOSINOPHILS	violet	light blue	red- eosin
BASOPHILS	violet	light blue	dark blue
LYMPHOCYTES	purple	mid-blue	deep violet
MONOCYTES	violet	grey	pink-violet

THROMBOCYTES OR PLATELETS	Chromomere: red-eosin Hyalomere: light-blue

11 - LIMITATIONS OF THE METHOD AND NOTES

- The blood smears must be very thin.
- Different staining and dilution times produce different shades of colour.
- If under the microscope the slide appears to be too stained, it is advisable to dip it into distilled water again, so as to further dilute the colour; allow to dry and then read it.
- It is not advisable to use tap water instead of distilled, since, apart from the content of various interfering substances, water with a high calcium content causes precipitation of the eosin as insoluble calcium salt.
- To avoid contamination of HEMOFAST, it must not be kept in metal containers.
- 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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