SIEMENS
Hematek®

Hematek® Stain Pak – Modified Wright's Stain

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The information in this manual was correct at the time of printing. However, Siemens continues to improve products and reserves the right to change specifications, equipment, and maintenance procedures at any time without notice.

Hematek® Stain Pak

Contents

Hematek® Stain Pak - Modified Wright's Stain

Intended Use

The Hematek® Stain Pak is for *in vitro* diagnostic use in the differential staining of blood, bone marrow and body fluid smears on the Hematek Slide Stainer. Stained smears are evaluated for the identification and quantitation of cells in whole blood and other specimens to aid clinicians in the assessment of various clinical conditions.

Summary and Explanation

The Hematek Stain Pak is the reagent system for Hematek Slide Stainers. The reagent system consists of a modified polychrome methylene blue-eosin stain (similar to Wright's or Giemsa) and is based on the original stain proposed by Romanowsky.[1]

The Hematek Slide Stainer system has been evaluated and reported in the literature cited.[2-3]

Principle of the Procedure

When a thin blood film is processed with this system and examined microscopically, the nucleus and the cytoplasm of neutrophils, lymphocytes, monocytes, eosinophils, and basophils show a characteristic blue or red coloration. Cells are then manually differentiated and quantified.

Reagents

Reagents are provided in the Hematek Stain Pak and are not available separately. Each Hematek Stain Pak contains sufficient fluids to stain approximately 750 to 1000 glass slides depending on the user-defined settings for rotating speed of the pumps, which will determine stain usage.

Hematek Stain Pak – Modified Wright's Stain						
REF	SMN	Name	Product Number	Symbols	Content	Amount
06689653	10310965	Modified Wright's Stain	4481	① STN	Stain	1 x 250 mL
		Modified Wright's Buffer		② BUF	Buffer	1 x 420 mL
		Modified Wright's Rinse		③ RNS	Rinse	1 x 1060 mL

Components and Concentrations

Hematek Stain

- Methanol, > 99%
- Polychrome methylene blue-eosin stain

Hematek Buffer

- Phosphate buffer
- Surfactant

Hematek Rinse

- Methanol, 8%
- Surfactant

Warnings and Precautions

For *in vitro* diagnostic use.

For Professional Use.

Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare professional.

	H225, H301+H311+H331, H370 P210, P233, P260, P264, P280, P304+P340, P301+P310, P330, P361+P364, P403+P235, P501	**DANGER!** Highly flammable liquid and vapour. Toxic if swallowed, in contact with skin, or if inhaled. Causes damage to organs. Keep container tightly closed. Keep away from heat/sparks/open flames/hot surfaces. — No smoking. Do not breathe vapours. Wash hands thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection. IF INHALED: Remove person to fresh air and keep comfortable for breathing. IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. Rinse mouth. Take off immediately all contaminated clothing and wash it before reuse. Store in a well-ventilated place. Keep cool. Dispose of contents and container in accordance with all local, regional, and national regulations. **Contains:** methanol, (in Modified Wright Stain)
	H226, H302, H371 P210, P233, P260, P308+P311, P403+P235, P264, P330, P501	**WARNING!** Flammable liquid and vapour. Harmful if swallowed. May cause damage to organs. Keep away from heat/sparks/open flames/hot surfaces. — No smoking. Keep container tightly closed. Do not breathe dust/fume/gas/mist/vapours/spray. IF exposed or concerned: Call a POISON CENTER or doctor/physician. Store in a well-ventilated place. Keep cool. Wash hands thoroughly after handling. Rinse mouth. Dispose of contents and container in accordance with all local, regional, and national regulations. **Contains:** methanol, (in Wright's Rinse Solution)

Safety data sheets (MSDS/SDS) available on siemens-healthineers.com.

Dispose of hazardous or biologically contaminated materials according to the practices of your institution. Discard all materials in a safe and acceptable manner and in compliance with prevailing regulatory requirements.

Reagent Preparation and Use

Reagents are ready to use and require no preparation.

Storage and Stability

Hematek Stain Pak reagents are stable until the expiration date printed on the product label when stored at room temperature between 15 °C and 30 °C.

Due to the design of the package, the product is protected from air exposure even after installation on the system; therefore the on-system shelf life (on-board stability) is considered to be equivalent to the expiration date printed on the product label.

Do not refrigerate.

Do not open Hematek Stain Pak until inserted into the Hematek Slide Stainer.

Procedure

The Hematek Stain Pak must be used in the Hematek Slide Stainer according to instrument instructions. Refer to the Hematek Instruction Manual Maintenance/Instrument Setup section to install the Hematek Stain Pak.

Installation instructions

Refer to the Hematek Instruction Manual Installation section for instructions on instrument setup.

Operating instructions

Refer to the Hematek Instruction Manual section on Operating the system.

Materials Required but not provided

The materials required but not provided to perform staining are standard glass slides and a Hematek Slide Stainer.

Limitations

Hematek Stain Paks produce high quality stained blood films. However, there may be personal preferences in shades and intensities of staining not satisfied by the system. To adjust staining intensity to suit personal preferences, refer to the Hematek Instruction Manual, pump volume adjustment section.

Results

The Hematek Stain Pak when used with the Hematek Slide Stainer will produce a consistent stain quality to facilitate accurate and reliable interpretation.

Technical Assistance

According to EU regulation 2017/746, any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the EU Member State in which the user and/or patient is established.

For customer support, please contact your local technical support provider or distributor.

siemens-healthineers.com

Bibliography

1. Romanowsky DL. On the Question of Parasitology and Therapy of Malaria. *St. Petersburg Medical Weekly* **16**:297-302 (1891)
2. White WL, Erickson MM, Stevens SC. Practical Automation for the Clinical Laboratory. St. Louis, MO, CV Mosby Co., pp 476-487 (1972)
3. Moss ED. Automated Slide Staining in Haematology. *Can. J. Med. Tech.* **30 (5)**: 169 (1968)

Definition of Symbols

The following symbols may appear on the product labeling:

Symbol	Symbol Title	Source	Symbol	Symbol Title	Source
	Manufacturer	5.1.1[a]		Authorized representative in the European Community	5.1.2 [a]
	Use-by date	5.1.4 [a]		Authorized representative in Switzerland	Proprietary
	Catalog number	5.1.6 [a]		Batch code	5.1.5 [a]
	Consult Instructions for Use	5.4.3 [a]		Contains sufficient for <n> tests	5.5.5 [a]
	Internet URL address to access the electronic instructions for use	Proprietary		Version of Instructions for Use	Proprietary
	*In vitro* diagnostic medical device	5.5.1 [a]		Revision	Proprietary
	Prescription device (US only)	FDA[c]		Unique Device Identifier	5.7.10[b]
	CE Marking with Notified Body	EU IVDR[d]		CE Marking	EU IVDR[d]
	Temperature limit	5.3.7[a]		Keep away from sunlight	5.3.2[a]

	Upper limit of temperature	5.3.6[a]		Lower limit of temperature	5.3.5[a]
	Do not re-use	5.4.2[a]		Do not freeze	Proprietary
	Recycle	1135[e]		This way up	0623[e]
	Biological risks	5.4.1[a]		Caution	5.4.4[a]
YYYY-MM-DD	Date format (year-month-day)	N/A	YYYY-MM	Date format (year-month)	N/A
	Target	Proprietary		Interval	Proprietary

a International Standard Organization (ISO). ISO 15223-1 Medical Devices- Symbols to be used with medical device labels, labelling and information to be supplied.
b ISO 15223-1:2020-04
c Federal Register. Vol. 81, No 115. Wednesday, June 15, 2016. Rules and Regulations: 38911.
d IVDR REGULATION (EU) 2017/746
e International Standard Organization (ISO). ISO 7000 Graphical symbols for use on equipment.