BIOGNOST®

FEULGEN KIT

CE IVD *In vitro* diagnostic medical device Classified acc. to Regulation (EU) 2017/746 - **Class A** device

Five-reagent DNA staining kit acc. to Feulgen

INSTRUCTIONS FOR USE

BASIC UDI number	385889212HPC30708STARVF	
EMDN code	W01030708	
REF **Catalog number**	**Volume**	**UDI-DI number**
FE-100T	100 tests	03858890004915
FE-K-100	6x100 mL	03858888822071

Intended use and test principle

The Feulgen reaction, first described by Robert Feulgen, is one of the broadest and most commonly used cytochemical methods for semiquantitative DNA determination in histological and cytological samples. The reaction is based on first treating the sample with an acid, which breaks down part of the DNA structure and releases aldehyde groups. These groups then react with the BioSchiff reagent, producing a magenta (red violet) color. Therefore, structures containing DNA, such as the nuclei, are clearly visible, and the color intensity corresponds to the amount of DNA present. For the purpose of diagnosing and further steps in the treatment of malignant tumors, it is extremely important to determine the exact amount and condition of the nuclear DNA. The key parameter to accurately measure the nuclear DNA is the repeatability of the Feulgen reaction. If the instructions for use are followed precisely, the aforementioned repeatability is easily and reliably achieved with the reagents of the BioGnost Feulgen kit. The kit additionally contains a counterstain for the cytoplasm, which enables easier and clearer detection of stained DNA. The use of a counterstain is not necessary in the staining protocol, but it certainly gives a better contrast to the stained DNA on the slide.

Product description

- **FEULGEN KIT** – Semi-quantitative DNA determination kit

The kit contains:	**100 tests (FE-100T)**	**6 x 100 mL (FE-K-100)**	**Storage temperature**:
HCL reagent, Feulgen	30 mL (HCLF-OT-30)	100 mL (HCLF-OT-100)	15-25°C
BioSchiff reagent	30 mL (BS-OT-30)	100 mL (BS-OT-100)	**2-8°C**
Sodium metabisulfite, Feulgen solution	2x30 mL (NMF-OT-30)	2x100 mL (NMF-OT-100)	15-25°C
Sodium thiosulphate, 2% solution	30 mL (NT2-OT-30)	100 mL (NT2-OT-100)	15-25°C
Fast Green F.C.F. contrast reagent	30 mL (FGKR-OT-30)	100 mL (FGKR-OT-100)	15-25°C

Additional reagents and materials that can be used in the method

- Fixatives such as BioGnost's neutral buffered formaldehyde solutions: Formaldehyde NB 4%, Formaldehyde NB 10%
- Dehydration/rehydration agents such as BioGnost's alcohol solutions: Histanol 70, Histanol 80, Histanol 95, and Histanol 100
- Clearing agents, such as BioClear xylene or BioClear New, an aliphatic hydrocarbon-based xylene substitute
- Infiltration and embedding agents such as BioGnost's granulated paraffins BioWax 52/54, BioWax 56/58, BioWax Plus 56/58, BioWax Blue
- Microscopic slide covering agents and cover glass mountants such as BioGnost's BioMount, BioMount High, BioMount M, BioMount New, BioMount New Low, BioMount DPX, BioMount DPX High, BioMount DPX Low, BioMount DPX New, BioMount C, BioMount Aqua
- VitroGnost slides and coverslips for use in histopathology and cytology

Preparation of histological sections for staining

- Fix (Formaldehyde NB 4%, Formaldehyde NB 10%) and process the tissue sample
- Embed the tissue in a paraffin block (BioWax 52/54, BioWax 56/58, BioWax Plus 56/58, BioWax Blue)
- Cut the paraffin block into 4-6 micron thin slices and mount on a VitroGnost microscope slide

NOTE

Apply the reagent so that it completely covers the section.

It is necessary to close the vial containing the BioSchiff reagent well in order to avoid SO_2 evaporation and to preserve the quality of the reagent. Store the reagent immediately after use at +2 to +8 °C in its original packaging.

Sample staining procedure

a) using kit for 100 tests (FE-100T)

1.	Deparaffinize in xylene (BioClear) or xylene substitute (BioClear New)	3 exchanges, 2 min each
2.	Rehydrate in 100% alcohol (Histanol 100)	2 exchanges, 5 and 3 min
3.	Rehydrate in 95% alcohol (Histanol 95)	2 min
4.	Rehydration in distilled/demineralized water	2 min
5.	Add HCl reagent, Feulgen (≥5 drops)	40 min
6.	Rinse twice in distilled/demineralized water	
7.	Apply BioSchiff reagent (≥5 drops) *for more intensive staining, extend incubation up to 60 min	10 min
8.	Without rinsing, drain the slide and remove excess reagent from the slide using filter paper	
9.	Apply Sodium metabisulfite, Feulgen solution (≥5 drops)	2 exchanges, 2 min each
10.	Without rinsing, drain the slide and remove excess reagent from the slide using filter paper	
11.	Apply Sodium thiosulphate solution, 2% solution (≥5 drops)	3 min
12.	Rinse under tap water	2 min
13.*	Apply Fast Green F.C.F. contrast reagent (≥5 drops)	10-15 sec
14.*	Rinse under tap water	1 min
15.	Dehydrate in 95% alcohol (Histanol 95)	2 exchanges of 10-15 dips
16.	Dehydrate in 100% alcohol (Histanol 100)	3 exchanges of 10-15 dips
17.	Clear in xylene (BioClear) or xylene substitute (BioClear New)	2 exchanges, 2 min each

* Steps 13 and 14 involve the application of a counterstain; if the samples do not need to be counterstained, these steps should be skipped.

Immediately after clearing, apply an appropriate BioMount covering/mounting medium. If BioClear xylene was used, use one of BioGnost's xylene-based mountants (BioMount, BioMount High, BioMount M, BioMount DPX, BioMount C, or universal BioMount New). If BioClear New xylene substitute was used, the appropriate mountant is BioMount New. Cover the section with a VitroGnost cover glass.

b) using five-reagent kit, 100 mL (FE-K-100)

Pour the reagents into glass staining jars (type Coplin, Hellendahl or Schifferdecker) and return them to the original bottles after staining. Close well. If necessary, filter the reagents.

1.	Deparaffinize in xylene (BioClear) or xylene substitute (BioClear New)	3 changes, 2 minutes each
2.	Rehydrate in 100% alcohol (Histanol 100)	2 exchanges, 5 and 3 min
3.	Rehydrate in 95% alcohol (Histanol 95)	2 min
4.	Rehydration in distilled/demineralized water	2 min
5.	Immerse into HCl reagent, Feulgen	40 min
6.	Rinse twice in distilled/demineralized water	
7.	Immerse into BioSchiff reagent *for more intense staining, extend incubation up to 60 min	10 min
	Note: when staining, cover the jar containing BioSchiff reagent, in order to reduce sulfite evaporation	
8.	Without rinsing, drain the slide and remove excess reagent from the slide using filter paper	
9.	Immerse into Sodium metabisulfite, Feulgen solution	2 exchanges, 2 min each
	Note: when treating, cover the container to reduce sulfite evaporation	
10.	Without rinsing, drain the slide and remove excess reagent from the slide using filter paper	
11.	Immerse into Sodium thiosulfate, 2% solution	3 min
12.	Rinse under tap water	2 min
13.*	Immerse into Fast Green F.C.F. contrast reagent	10 -15 sec
14.*	Rinse under tap water	1 min
15.	Dehydrate in 95% alcohol (Histanol 95)	2 exchanges of 10-15 dips
16.	Dehydrate in 100% alcohol (Histanol 100)	3 exchanges of 10-15 dips
17.	Clear in xylene (BioClear) or xylene substitute (BioClear New)	2 exchanges, 2 min each

* Steps 13 and 14 involve the application of a counterstain; if the samples do not need to be counterstained, these steps should be skipped.

Immediately after clearing, apply an appropriate BioMount covering/mounting medium. If BioClear xylene was used, use one of BioGnost's xylene-based mountants (BioMount, BioMount High, BioMount M, BioMount DPX, BioMount C, or universal BioMount New). If BioClear New xylene substitute was used, the appropriate mountant is BioMount New. Cover the section with a VitroGnost cover glass.

Result

Core – red purple (magenta) color

Cytoplasm and background – no staining unless Fast Green F.C.F. contrast reagent was used, stained green if counterstain was used

Limitations

This product is intended for professional laboratory use for diagnostic purposes only. Deviations from the staining procedure described in this Instruction for use may cause differences in staining results.

Sample preparation and diagnostics

Use only appropriate instruments for collecting and preparing the samples. Process the samples using modern technology and mark them clearly. It is necessary to follow the manufacturer's instructions for use. To avoid errors, staining and diagnosis may only be performed by qualified personnel. Use a microscope that complies with medical diagnostic laboratory standards. To avoid a false result, it is recommended to use a positive and negative control.

If a serious incident occurs during use or as a result of its use, please report it to the manufacturer or authorized representative and competent authority.

Safety at work and environmental protection

Handle the product in accordance with occupational health and environmental protection guidelines. Used and expired solutions must be disposed of as special waste following national guidelines. Reagents used in this procedure can pose a danger to human health. The examined tissue samples are potentially infectious, therefore it is necessary to implement human health protection measures in accordance with good laboratory practice guidelines. It is mandatory to read and act according to the information and warning signs printed on the product label, instructions for use and in the safety data sheet, which is available on request.

Storage, stability, and shelf life

Components of Feulgen kit are kept under different storage conditions. Upon receipt, store the components in a dry place and well-closed original packaging at temperature indicated on the label. The product can be transported at room or ambient temperature. Do not freeze and avoid exposing to direct sunlight. After first opening, the product can be used until the specified expiry date, if stored properly. The expiration date is printed on the product label.

References

1. Kasten, F. H. (2003): Robert Feulgen and his histochemical reaction for DNA, Biotechnic & Histochemistry, 78 (1); p. 45-49.
2. Millett, J. A. et al. (1982): Feulgen-hydrolysis profiles in cells exfoliated from the cervix uteri: a potential aid in the diagnosis of malignancy, J. Clin. Pathol. 35 (3): p. 345-349.
3. Pearse, A.G.E. (1972): Histochemistry: Theoretical and Applied, 3rd ed., London, Churchil Livingstone.
4. Schulte, E. et Wittekind, D. (1989): Standardization of the Feulgen-Schiff technique, Histochemistry and Cell Biology, 91 (4): p. 321-331.

Warnings and precautions regarding the materials contained in the product:

EUH031	Contact with acids liberates toxic gas.
H314	Causes severe skin burns and eye damage.
H335	May cause respiratory irritation.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P305+P351+P338	IF IN EYES: rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.
P308+P313	IF exposed or concerned: Get medical advice/attention.

FE-IFU_ENV10, 07.04.2026, IŠP

	Manufacturer	LOT	Batch code	°C	Temperature limit	IVD	*In vitro* diagnostic medical device	UDI	Unique device identifier
	Date of manufacture	REF	Catalogue number		Consult instructions for use	Σ	Contains sufficient for <n>tests		
	Use-by date		Fragile, handle with care		Caution	CE	European conformity		

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Version	Description / reason for change	Date
10	Revised in accordance with Regulation (EU) 2017/746 – IVDR; change in storage temperature of BioSchiff reagent to 2-8 °C	07/04/2026