

# **Instructions for Sperm Vitality Staining Solution (Eosin-Nigrosin Staining)**

### [Product Name]

Sperm Vitality Staining Solution (Eosin-Nigrosin Staining)

## [Package Specification]

20 tests/kit, 40 tests/kit

#### [Intended Use]

It is mainly used for sperm vitality staining.

### [Test Principle]

The dye can stain the sperm red through the damaged cell membranes of the sperm, while the sperm with intact structure will not be colored. After death of the sperm, the permeability of the membrane will be changed and the Eosin Y can penetrate and stain the sperm red, while the live sperm will not be stained, where the black background formed by nigrosin makes the staining difference between dead and live sperm easier to be observed.

### [Main Component]

	No.	Main component	Specification		Main inquadiant
			20 tests/kit	40 tests/kit	Main ingredient
	1	Eosin-Nigrosin Solution	1.0 mL×1	1.0mL×2	Eosin Y and Nigrosin

### [Storage Conditions and Expiration Date]

Transported in ice bags, and can be stored protected from light at 2-8°C for 12 months; it can be used for 30 days after the vial is opened and stored at 2-8°C.

### [Applicable Instruments]

None.

#### [Sample Requirements]

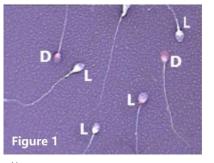
- 1. Subjects are required to abstain from sexual intercourse for 2-7 days and all semen specimens should be retained by masturbation or by intercourse using a special semen collection sleeve.
  - 2. Fresh semen specimens will be tested after liquefaction.

### [Test Method]

- 1. Add 10 µl of fresh semen and 50 µl of eosin-nigrosin reagent to a test tube and mix them gently.
- 2. Leave it at room temperature for 30 seconds.
- 3. Transfer about 5  $\mu$ l of the staining solution-sperm mixture onto the edge of the slide before smearing.
  - 4. Dry the slide prepared by pushing in the air.
- 5. Test the slide immediately after drying, or seal the slide with anhydrous sealing solution for long-term storage.
- 6. Observe the results under the General Optical Microscope with the objective 100× oil lens. The head of dead sperm (D) will be stained red or dark pink, and the head of live sperm (L) will be white or light pink (as in Figure 1).
  - 7. At least 200 sperm should be observed, and then count and calculate the percentage of live sperm.

## [Reference Value]

Normal reference value: Survival rate ≥ 58%





### [Test Result Explanation]

Poor preservation of sperm specimens prior to the test can lead to unexpected inactivation of the sperm, resulting in falsely reduced results. Such as, a specimen container that has a sperm-killing effect is used, improper storage temperature, and prolonged retention of sperm outside the body.

### [Method Limitations]

None

# [Product Performance Index]

Staining effect: The head of dead sperm is red or dark red, and the head of live sperm is white or light pink.



- 1. Since all samples from the subject should be considered as potential sources of infection, samples and reagents after testing must be disposed of as medical waste to avoid contamination of the environment.
- 2. Nigrosin contained in the kit are chemically hazardous and should be avoided in contact with the skin and eyes.
- 3. This product is an In vitro diagnostic medical device and the test results are for clinical reference only. The clinical management of the patient should be considered in conjunction with his or her symptoms, signs, medical history, other laboratory tests and treatment response.
  - 4. The user of the product must have the professional qualifications required for inspection personnel.
  - 5. The product should be used before the expiration date to ensure its effectiveness.

### [Symbol Explanation]

Symbol	Symbol Note	Symbol	Symbol Note
<b>W</b>	Manufacturer	IVD	In vitro diagnostic medical device
M	Date of manufacture	LOT	Batch code
EC REP	Authorized representative in the European Community	REF	Catalogue Number
CE	CE mark	><	Use-by Date
[]i	Consult instructions for use	1	Temperature Limit
$\triangle$	Caution	Σ	Contains sufficient for <n> tests</n>

#### [References]

Laboratory Manual for the Examination and Processing of Human Semen (Fifth Edition), World Health Organization, People's Medical Publishing House, 2010



## [Essential Information]



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# [Revision History]

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