Instructions for Modified Papanicolaou Staining Solution

[Product Name]

Modified Papanicolaou Staining Solution

[Package Specification]

50mL×3; 500mL×3

[Intended Use]

It is mainly used for sperm smear staining and is suitable for morphological staining analysis.

[Test Principle]

Hematoxylin is an alkaline dye that can combine with deoxyribonucleic acid, the main chemical component in the nucleus, to produce a blue-purple color. Eosin and Brilliant Green are acidic dyes that can bind to protein components with opposite charges in the cytoplasm to show varying degrees of red and blue-green. Multicolor staining of cells using different properties of dyes can stain the acrosome region, body and tail of sperm in different colors, thus making it easier to detect abnormal cells and observe the percentage of sperm with normal morphology.

[Main Component]

No.	Main component	Specification		Main ingredient
		50mL×3	500mL×3	
1	Liquid A	50mL×1	500mL×1	Contains hematoxylin
2	Liquid B	50mL×1	500mL×1	Contains hydrochloric alcohol
3	Liquid C	50mL×1	500mL×1	Contains Brilliant green, Eosin

[Storage Conditions and Expiration Date]

Transported in ice bags, and can be stored at 4℃~30℃ for 12 months.It is valid for 3 months after being opened and stored at room temperature (4℃~30℃).

[Applicable Instruments]

Suitable for Full Automatic Staining Machine (models RS-160, RS-161, RS-162) manufactured by Zhuhai Cariad Medical Technology Co., Ltd.

[Sample Requirements]

1. Collect semen from 2-7 days of abstinence by masturbation in a sampling cup, with attention to complete collection.
2. Semen samples should be transported to the test laboratory within 1 hour, and the temperature must be maintained at 20-37°C.
3. Semen samples should be placed in a 37°C water bath or at room temperature for 1 hour to allow for complete liquefaction before being tested.

[Test Method]

95% ethanol should be prepared before the test.

1. Specimen preparation

1) Prepare the film immediately after complete liquefaction of the fresh specimen. If the liquefaction of the specimen is delayed or the viscosity is too high, a liquefying agent may be added to promote complete liquefaction, and the film may be produced after complete liquefaction.

2) Low-density, high-viscosity, debris-filled semen specimens require sperm washing followed by film preparation, and the method is as follows:

① Add 0.2~0.5 mL of semen and 10mL of saline to a test tube.

② Centrifuge at 800 g for 10min and remove the vast majority of the supernatant.

③ Gently flick the test tube to suspend the centrifuged sperm mass in the remaining saline, count the sperm density, and adjust the sperm density appropriately with saline (no more than 80×10^6/ mL).

2. Operation method

2.1 Manual method

1) Add a small drop of semen (5~10 μL) on a clean slide, and dry naturally in air.
2) Immerse the smear in 95% ethanol for 3 minutes and rinse with running water.
3) Add drops of Liquid A to cover the smear, stain for 3 minutes, and rinse with running water.
4) Add drops of Liquid B to cover the smear, fractionate for 5 s, and rinse with running water.
5) Add drops of Liquid C to cover the smear, stain for 3 minutes, and rinse with running water.
6) Observe at least 200 sperms after drying under a General Optical Microscope with the objective 100× oil lens and classify and count the morphology of sperms.

2.2 Staining machine method

Applicable to the Full Automatic Staining Machine of Cariad, but the parameter set for different instruments will be adjusted, welcome to request the parameters for the machine.

[Positive Judgment Value or Reference Interval]

Reference interval: Percentage of sperm with normal morphology > 4% in normal population.

[Test Result Explanation]

1. When the percentage of sperm with normal morphology is less than 4%, the chance of fertilization is reduced.
2. Excessive sperm slide thickness and poor sperm liquidation can affect the sperm staining effect.

[Method Limitations]

It is only used for sperm smear staining.

[Product Performance Index]

Staining effect: The acrosome region of the sperm shows a light blue color, the non-acrosome region of the head shows a dark blue or dark blue-purple color, and the tail of the sperm body shows a red or blue-green color.

Caution

1. The thickness of the slides should be appropriate, and either dry fixation or wet fixation is acceptable.
2. The amount of liquid injected to cover the slides should be appropriate, but not too small to avoid evaporation leading to the precipitation of the dye.
3. 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.
4. This kit is an in vitro diagnostic medical device and the test results are for clinical reference only. The clinical diagnosis of the patient should be considered in conjunction with his or her symptoms, signs, medical history, other laboratory tests and treatment response.
5. The methanol contained in the device is chemically dangerous and the operator should follow the operation instructions and should not touch or inhale them.
6. The user of the product must have the professional qualifications required for inspection personnel.
7. The product should be used before the expiration date to ensure its effectiveness.

[Symbol Explanation]

Symbol	Symbol Note	Symbol	Symbol Note
	Manufacturer	IVD	In vitro diagnostic medical device
	Date of manufacture	LOT	Batch code
EC REP	Authorized representative in the European Community	REF	Catalogue Number

Symbol	Symbol Note	Symbol	Symbol Note
CE	CE mark		Us e-by Date
	Consult instructions for use		Temperature Limit
	Caution		Contains sufficient for <n> tests

[References]

Laboratory Manual for the Examination and Processing of Human Semen (Fifth Edition), World Health Organization, People's Medical Publishing House, Beijing, 2011

[Essential Information]

Manufacturer: Zhuhai Cariad Medical Technology Co., Ltd.

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CE mark

CE

EC REP

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