



Instruction for Use of Specimen Preservation Reagent

[Product Name]

Generic name: Specimen Preservation Reagent

[Packaging Specification]

1.5 mL/tube, 100 tubes/kit; 3 mL/tube, 100 tubes/kit; 5 mL/tube, 100 tubes/kit; 6 mL/tube, 100 tubes/kit; 10 mL/tube, 50 tubes/kit; 500 mL/bottle, 1 bottle/kit.

[Intended Application]

This kit is used for tissue and cytopathological analysis specimen preservation.

[Testing Principle]

Guanidine salt is the main component of the Specimen Preservation Reagent which can lyse and denature virus and microorganisms in the specimen and at the same time inhibit or denature the RNASE in the specimen, thereby preserving the RNA in the specimen.

[Main Components]

The main components of this kit are guanidine isothiocyanate and Proclin-300.

[Storage Conditions and Validity Date]

Store at room temperature with a period of validity of 18 months.

See the product label for the manufacture date and expiry date of the kit.

[Applicable Instrument]

DA3000 automatic nucleic acid extraction instrument, Chemagic Magnetic Separation Module I, or other automatic nucleic acid extraction system of the same type and with the same function.

[Specimen Requirements]

1. Applicable specimen types

Swab specimen, serum or plasma, virus culture medium, tissue, and saliva specimen. Specimen collection, storage, and transportation should comply with related operation regulations.

2. Specimens collection

1) Swab specimen: After sampling, immerse the swab head into the tube containing 1.5mL of specimen preservation solution, mix completely to elute the swab specimen, then ready for RNA extraction.

2) Serum or plasma: Mix 1x volume of serum or plasma with 4x volumes of the specimen preservation solution, then ready for RNA extraction.

3) Virus culture medium: Mix 1x volume of virus culture medium with 4 volumes of the specimen preservation solution, then ready for RNA extraction.

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4) Tissue specimen: Cut the tissue into small pieces not more than 0.5cm in each edge, and immerse it into 5x volumes of the specimen preservation solution under room temperature.

5) Saliva specimen: Mix 0.5-1.5x volume of saliva with 1x volume of specimen preservation solution, then ready for RNA extraction.

3. Storage

The specimen immersed in the preservation solution can store at 37°C for 3 days; 25°C for one week; 4°C for one month; under -20°C for long term preservation. Avoid repeated freezing and thawing.

4. Transportation

Specimens should be added to the specimen preservation solution and be sent to the laboratory as soon as possible after collection. If the specimens need to be transported over long distances, it is recommended to use dry ice or other refrigeration methods for storage.

Note: Disposable specimen collectors supplied by Guangzhou Yunda Health Technology Co., Ltd. (YSXB No. 20200811) and Guangzhou DaTe Bioengineering Technology Co.,Ltd. (YSXB No. 20200848) are recommended.

[Test Method]

For specific operation steps, please follow the corresponding nucleic acid extraction or purification kit instructions.

[Limitations of Product]

The efficiency of specimen extraction depends on whether the operator follows the instruction strictly. If cross contamination is not well controlled during specimen extraction and purification, false positive results may occur.

[Performance Indicators]

Preservation efficiency: Using the specimen preservation solution as the diluent, the high, medium, and low concentration novel coronavirus pseudovirus particle reference P1, P2, P3 and the negative reference product N as specimens to conduct the testing. The results shall conform to the following:

Specimen	Positive rate	Verification standard
P1	3/3	Ct value \leq 30
P2	3/3	Ct value \leq 34
P3	3/3	Positive rate is 100%
N	0/3	No positive result

[Precautions]

1. Please read the instructions carefully before experiment.
2. In order to avoid any potential biological risk in the specimen, the detected specimen shall be deemed as having infectious substances, avoid contacting with skin and mucos; conducting the specimen treatment in biosafety cabinet which can prevent aerial fog from outflow, the test tube and pipettor used in specimen preparation area shall throw into

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the container with sanitizer, and can be discarded after being sterilized with wastes; the specimen operation and treatment shall both conform to the requirements of relevant laws and regulations: *General biosafety standard for microbiological and biomedical laboratories* and *Regulations on the management of medical waste* issued by Ministry of Health.

3. The reagent should be used within the validity period.

4. Laboratory management shall be strictly in accordance with management standard of PCR gene amplification laboratory, the experimenter shall undergo professional training, experimental process shall perform under strict partitions (reagent preparation area, specimen preparation area, amplification and product analyzing area), consumables after used shall be disposable after sterilization, each stage of experimental operation shall use exclusive instrument and equipment, articles of each area and each stage shall not be cross-used.

5. Use autoclaved disposable centrifuge tubes and tips or purchase RNase-free centrifuge tubes and tips.

6. After the RNA extraction of specimen is completed, it is recommended to proceed to the next experiment immediately; otherwise, please store at -20°C for use (within 24h).

7. After the experiment, 10% hypochlorite or 75% alcohol should be used to disinfect the worktable and pipette, followed by exposing them in ultraviolet light for 20-30 minutes.

[References]

1. Fang Qiaoyun, Yang Jianying, Ju Xiongfei et al. The laboratory detection of a new human influenza A (H1N1). *Chinese Journal of Disease Control & Prevention*, 2010, 14(12): 1213-1215.

2. Mackay IM et al. Molecular assays for detection of human metapneumovirus. *Journal of Clinical Microbiology*, 2003, 41(1):100-105.

3. Greenberger S et al. Transcription-controlled gene therapy against tumor angiogenesis. *J Clin Invest*, 2004, 113(7), 1017-1024.

4. Clinical management of severe acute respiratory infection when novel coronavirus (nCoV) infection is suspected-Interim guidance. 2020.

[Basic Information]

Registrant/manufacturer name: Daan Gene Co., Ltd.

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



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[Index of CE Symbols]

	For in vitro diagnostic use only		Do not reuse
	Expiry date		See instruction for use
	Warning, please refer to the instructions in the annex		Manufacturer
	Temperature scope within which the product is reserved		Batch number
	Catalog #		Tests per kit
	European union authorized representative		Biological risks
	Keep away from sunlight		
	The product meets the basic requirements of European in vitro diagnostic medical devices directive 98/79/EC		



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