

Sample Release Reagent INSTRUCTION FOR USE

[Product Name]

Sample Release Reagent

[Packing Specifications]

Specification: 100 tests/kit

[Applications]

It is used for the pretreatment of the samples so that the determinand is released from the state of being combined with other substances to use in vitro diagnostic reagents or instruments to test the determinand.

[Mechanism]

Sample release reagents use protein denaturants and biochemical reagents to quickly destroy protein structures and release nucleic acids. The sample release reagent is suitable for lysis of the virus samples and release of the nucleic acid. The released DNA or RNA is directly used as a PCR template for amplification without heating or nucleic acid extraction.

[Kit Component]

This kit consists of the following components.

NO.	Reagent name	Specification & quantity		Main components
1	Nucleic acid release reagent	1 mL/tube	1 tube	Surfactant
2	RNA protectant	50 µL/tube	1 tube	RNase inhibitor

[Storage & Expiration Date]

Storage: Store at -20±5°C Expiration: 12 months

[Applicable Reagents]

Shenzhen Uni-medica Technology Co. Ltd Real Time PCR Kit for Novel Coronavirus 2019-nCoV.

[Sample requirements]

- Sample type: Swab samples, oropharyngeal/ nasopharyngeal (non-deactivated viral transport medium or physiological saline matrix)
 - Recommend to use Shenzhen Uni-medica Technology Co. Ltd Classic Disposable Virus Sampling Tube

- physiological saline matrix: throw the swab sample into 1ml physiological saline matrix (0.9 %NaCl solution)
 - Sample collection: Collect in accordance with conventional sampling procedures or standards.
- NOTE: The inactivated sampling tube cannot be used for sampling

[Sample Delivery and Storage]

The samples should be sent for inspection as soon as possible after collection. If the sample cannot be tested immediately, it should be stored at 18-25°C for no more than 4 hours, 2-8°C for no more than 24 hours, and -20±5°C for no more than 7 days.

[Operational Approach]

- Sample release reagent preparation
Take the nucleic acid release reagent out of the kit and thaw at room temperature, vortex and centrifuge at 6000rpm for a few seconds. Mix the following components sufficient for the number of tests (N) and vortex the mixture. All volumes include 10% overage for pipette error.
Note: prepare the sample release reagent **right** before each use.

Components	Volume for each sample	Volume for N samples
		(in case any loss 10% more are prepared here)
Nucleic acid release reagent	10 µL	11 × N µL
RNA protectant	0.5 µL	0.55 × N µL

- Sample Deactivation
All samples are considered as potential infectious, deactivate at 56°C for 30 minutes before use according to relative national standards.
- Oropharyngeal Swab/Nasopharyngeal Swab (**non-deactivated viral transport medium or physiological saline matrix**)
Vortex the sample for 10~15 seconds. Add 10 µL of sample release reagent prepared in step “1 Sample release reagent preparation” to each well of PCR tubes. Add 10 µL of the samples to the PCR tubes. Pipette the samples up and down 3-5 times to completely mix the liquid, then leave at room temperature for 10 minutes, after which it can be used for amplification.

[Performance Index]

- Packaging appearance: The packaging of the reagent is neat and the mark is clear.
- Reagent appearance: sample storage solution should be colorless and clear liquid.
- Packing volume: the reagent volume should not be less than the labeled amount.

[Sample Treatment Limitation]















This sample release reagent is not applicable for deactivated VTM sample treatment.

[Notes]


- Before using this reagent, you need to thoroughly understand the contents of the instructions;

2. This product does not have nucleic acid purification function and is suitable for molecular biology tests that do not require high purity nucleic acid;
3. This product is only used for in vitro diagnosis, please check the packaging before use, if damaged, please do not use or contact the manufacturer;
4. Any sample should be treated as an infectious sample. For safety, the operator should pay attention to personal protection;
5. Laboratory waste disposal shall be carried out in accordance with the requirements of the "Clinical Laboratory Waste Disposal Principles".

[Symbol Interpretation]

SYMBOL	DESCRIPTION	SYMBOL	DESCRIPTION	SYMBOL	DESCRIPTION
	Manufactured By		CE Mark		Temperature Limitation
	Authorized Representative		Catalog Number		Consult instructions for use
	In Vitro Diagnostic Medical Device		Potential Biological Hazards After Use		caution
	Batch Code		Do Not Reuse		Keep away from sunlight
	Expiration Date in Year-Month-Day Format		Date of Manufacture		

[Company Information]

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