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CE IVD

Nucleic Acid Release Reagent
Instruction for use

Product Name

Nucleic Acid Release Reagent

Intended Use

Nucleic Acid Release Reagent is used for the pretreatment of the samples, so that the nucleic acid to be tested can be released from the binding state with other substances. In this way, nucleic acid can be easily and directly detected. The crude lysates can be directly applied in polymerase chain reaction (PCR) or RT-PCR.

Model and Package Specification

Model specification: 0.5 mL/tube, 1 mL/tube, 1.5 mL/tube, 2 mL/tube, 3 mL/tube, 6 mL/tube, 10 mL/tube.
Package specification: 1 tube-100 tubes/box.

Product Principle

Nucleic Acid Release Reagent provide a simple, safe and effective method to release nucleic acid from clinical samples containing pathogens. By dissolving protein, the secondary structure of protein disappears, leading to the structural degradation of cell or virus, and then the nucleic acid rapidly separates from the nucleoprotein. This reagent can quickly release nucleic acid from freshly collected clinical samples, and protect nucleic acid from degradation.
Clinical samples preprocessed by Nucleic Acid Release Reagent can be directly used for molecular detection, such as PCR, RT-PCR, etc., without heating or other nucleic acid extraction operations of samples.

Basic Information

Jiangsu CoWin Biotech Co., Ltd.
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Manufacturing site: 4F, TQB Building, No. 1, Yaocheng Avenue, Taizhou City, 1F and 2F, No. 58, 4F, East Side of No. 59, West Side of Koutai Road, China Medicine City, Taizhou City and East Side of Lujia Road
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Version and Effective date of the Instruction

Version: A/0
Effective Date: 2021-04-06

Main component

It is mainly composed of surfactant, inorganic salt, gelatin and so on.

Storage Conditions and Validity

The product can be stored at 2-35°C for 12 months before use, and can be transported at 2-35°C for a long time.

After use, the sample can be preserved in the product at room temperature for 1 week. If longer preservation time is needed, please store the sample below -15℃.

Method of Application

1. Swab samples

1.1 Clean hands before sampling, tear off the outer packaging of the swab, and take the swab out. Be careful not to touch the swab head.

1.2 Use a swab to sample the corresponding part according to different sampling requirements.

1.3 After sampling, quickly put the swab into the sampling tube containing nucleic acid release reagent to avoid contact with other parts.

1.4 Break the swab along the grooves in the swab rod, discard the tail, tighten the cap, and complete the sampling.

1.5 After sampling, turn the tube upside down manually and forcefully for 1 second, and then let stand for 5 minutes, the nucleic acid is released into the release agent.

2. Sputum, saliva, drawing sample

2.1 Sample according to different sampling requirements.

2.2 Place the collected sample into the sample tube containing the nucleic acid release agent to complete the sampling.

2.3 After sampling, turn the tube upside down manually and forcefully for 5 seconds, and then let stand for 5 minutes, the nucleic acid is released into the release agent.

Precautions

1. This product contains microbial inactivator and does not preserve living microorganisms.
2. Check whether the package is damaged before use. If it is damaged, it is strictly prohibited to use.

3. Improper storage of samples after collection will result in serious contamination, which will affect the final test results.
4. Failure to store the collected samples at the specified temperature will affect the final test results.
5. This product is suitable for the use of trained experimenter.Gloves and masks should be worn for protection.
6. The used product should be disposed of according to local, state, and federal regulations. Do not send down the drain or flush down the toilet. All wastes containing the material should be properly labeled.Do not use when the sample tube is expired or found to be leaking.
7. The test results of the samples are related to the quality of the samples collected, handled, and shipped. Any error in this process will result in a false negative result.False positive results can occur if cross-contamination is not properly controlled during sample handling.
8. Read the instructions carefully before use and use it within the validity.
9. Ensure biosafety requirements are met in accordance with the local regulations throughout the entire procedure.
10. The used product (include the swab) should be disposed of according to local, state, and federal regulations. Do not send down the drain or flush down the toilet. All wastes containing the material should be properly labeled.

Symbols

Symbol	Meaning	Symbol	Meaning
IVD	*In vitro* diagnostic medical device		Storage temperature limit
	Manufacturer		Expiration date
	Date of Manufacture		Do not reuse
LOT	Batch code		Consult instruction s for use
	Don’t use the product when the package is damaged	EC REP	Name and Address of European Union Representative
CE	CESymbol	REF	Catalogue Number