Staphylococcus Aureus and Methicillin-resistant Staphylococcus Aureus Nucleic Acid Test Kit (PCR-Fluorescent Probe Method)

1【Product Name】

Staphylococcus Aureus and Methicillin-resistant Staphylococcus Aureus Nucleic Acid Test Kit (PCR-Fluorescent Probe Method)

2【Specification】

10 tests/kit (10200163A), 50 tests/kit (10200163B)

3【Intended Use】

This kit is intended for the in vitro qualitative detection of Staphylococcus aureus DNA and methicillin-resistant Staphylococcus aureus (MRSA) DNA in samples.

Staphylococcus aureus, also known as "Staph aureus," belongs to the genus Staphylococcus. As a representative Gram-positive bacterium, it is a common foodborne pathogenic microorganism that can cause infections in humans and animals. It is a significant foodborne pathogen responsible for food poisoning and can also be transmitted to humans through animals and animal-derived products.

Methicillin-resistant Staphylococcus aureus (MRSA) is the most well-known "superbug," acquired through hospital-associated or community-associated infections. It is now extremely common and can cause infections of the skin, lungs, bloodstream, and joints.

4【Principle of the Procedure】

This kit is based on the principle of fluorescent PCR technology, utilizing specific primers and TaqMan probes designed for Staphylococcus aureus and methicillin-resistant Staphylococcus aureus (MRSA). Detection is performed using a fluorescent PCR instrument to identify the nucleic acids of Staphylococcus aureus and MRSA.

The kit incorporates an endogenous internal control system to monitor sample collection, transportation, and extraction processes.

This kit employs a fully automated nucleic acid detection analyzer paired with a cartridge to achieve automated sample purification, nucleic acid amplification, and target sequence detection in either single or complex samples. All reagent reactions take place within the cartridge, which features excellent sealing and independent chambers to effectively prevent contamination.

5【Reagents】

5.1 Materials Provided

The Staphylococcus Aureus and Methicillin-resistant Staphylococcus Aureus Nucleic Acid Test kit contains sufficient reagents to process 10 (10200163A) or 50 (10200163B) samples respectively.

Table 1. Components of Kit A

Cartridges	**10 per kit**	**50 per kit**
• Bead 1, Bead 2, and Bead 3 (freeze-dried)	1 of each per cartridge	1 of each per cartridge
• Wash Reagent	3 mL per cartridge	3 mL per cartridge
• Sonication Reagent	3 mL per cartridge	3 mL per cartridge
• Sample Processing Solution	10 per kit	50 per kit
Sample Preservation Solution	2mL x 10 tubes	2mL x 50 tubes
Disposable Transfer Pipettes	10 per kit	50 per kit
Disposable Sampling Swab	10 per kit	50 per kit
Instructions for Use	1 per kit	1 per kit

Note: The disposable transfer pipettes and swab in Kit A are externally sourced, and their shelf life is indicated on their labels.

5.2 Materials Available but Not Provided

Table 2. Contents of Kit B

Positive Control	**Components**
Lyophilized powder containing standard strains of methicillin-resistant Staphylococcus aureus (MRSA) and internal standard gene fragments	1 test per kit
Negative Control	1 test per kit
Lyophilized powder containing internal standard gene fragments	
Diluent	2 tubes per kit
Nuclease-free water 2 mL	

Kit B provides positive and negative controls designed to confirm proper kit function and to assess the testing

environment and operator performance. The controls are recommended to be used in the following situations:

1. Initial verification: Run both positive and negative controls when using the kit for the first time.
2. Troubleshooting: If questionable or inconsistent results are obtained, run both controls to evaluate the kit, the environment, and operator handling.
3. Environmental monitoring: If contamination of the testing environment is suspected, run both controls to verify result reliability.

6【Storage, Transport and Handling】

1. Kit A should be stored and transported at 2℃ to 28℃, protected from light, and free from freezing. The kits have a shelf life of 12 months when stored under the recommended storage conditions.
2. Production date and expiration date: refer to the outer packaging.

7【Applicable Instrument】

The Kit is compatible with the Full-Automatic Nucleic Acid Detection and Analyzer (Models: iFIND S2, iFIND S4, iFIND S8; Medical Device Registration Certificate No.: 20233221927) manufactured by RocGene (Xuzhou) Technology Co., Ltd.

8【Specimen Collection, Handling and Storage】

8.1 Specimen Type

Skin tissue mucus sample

8.2 Specimen Collection

Moisten the swab (provided in the kit) with sterile water, then collect skin samples from wounds or inflamed/pus-filled areas, ensuring the entire swab absorbs sufficient microbial material. After sample collection, break off the swab tip into the tube containing the preservation solution.

8.3 Specimen Storage

1. Maintain recommended storage conditions to preserve specimen integrity.
2. Test specimens as soon as possible after collection.
3. Storage conditions:
    - Room temperature (10–30 °C): 6 hours
    - Refrigerated (2–8 °C): 24 hours
    - Frozen (−20 ± 5 °C): one month
    - Frozen (−75 ± 5 °C): one year
4. Frozen specimens must be completely thawed and mixed before use.
5. Avoid more than three freeze–thaw cycles.

9【Assay Procedure】

9.1 Specimen Pre-processing

Mix the sample thoroughly by shaking the tube about 20 times or vortex for approximately 10 seconds.

9.2 Cartridge Preparation

1. Open the cartridge lid and remove the aluminum seal.
2. Using the provided pipette, transfer 1.5 mL of the sample (prepared according to Section 9.1) into the sample chamber (large opening) of the cartridge.

Note: Dispense the sample slowly along the chamber wall to avoid bubbles.

3. Close the cartridge lid firmly.

Note: If repeat testing is needed, store the remaining sample at 2–8 °C for up to 24 hours.

10【Run the Test】

1. Power on the RocGene iFIND® System.
2. Log in with your username and password.
3. Wait for the system to complete the self-check. Once finished, click **"OK"** to enter the **"Running"** window and select the desired instrument unit.
4. Scan or manually enter the **Cartridge ID**; When the Cartridge ID is entered correctly, the corresponding test project will be selected automatically.
5. Scan or manually enter the **Sample ID.** The Sample ID will be inserted into the middle of the default Experiment Name.

***Example*:** *If the default name is 20250907-165208 and Sample ID 88888 is entered, the name becomes 20250907-88888-165741*.

6. By default, the Experiment Name is generated from the date and time the system was powered on. Edit if needed; the name will be linked to the test results in the **"Analyze"** window.
7. Click **"Open Door"** to open the module.
8. Insert the cartridge with the amplification tube facing the inside of the module.
9. Close the door.
10. Click **"Start Run"** to initiate the assay.
11. During the run, the green indicator flashes. When complete, it remains solid.
12. After the run finishes, click **"OK"** in the prompt box.
13. Navigate to the **Analyze** window to review and confirm test results.

11【Quality Control】

Table 3. Fluorescent Channels and Targets

Channel	CY55	VIC	ATTO	ROX	CY5
Corresponding target	IC	mecC gene	mecA gene	Staphylococcus Aureus	Scc mec box

Each test includes an internal quality control (IC), which verifies that the cartridge and test process are functioning properly. If the quality control criteria are not met, the test results shouldn't be interpreted.

Internal Control (IC):

The internal control confirms that:

- the sample was added correctly,
- reagents are functioning as intended,
- the procedure was performed correctly, and
- no interfering substances prevented amplification.

External Controls:

External quality controls (see Section 5.2) are available but not provided. They may be used in accordance with local, state, or federal regulations, as applicable

12【Cut-off Values】

The positive cut-off values for Staphylococcus aureus (ROX), mecA gene (ATTO), mecC gene (VIC), and SCCmec box (CY5) were determined by ROC curve analysis using clinical specimen test results. ROX channel Ct≤36: Positive for Staphylococcus aureus; VIC channel Ct≤36: Positive for mecC; ATTO channel Ct ≤36: Positive for mecA; Cy5 channel Ct ≤38: Positive for SCCmec box.

13【Interpretation of Results】

When the instrument is operating normally and the internal control test results meet all requirements, test sample results are analyzed and interpreted. Results are automatically generated by the instrument.

Table 4. Interpretation of Results

ROX	ATTO	VIC	CY5	CY55	Result	Interpretation of results & action
+	-	-	+/-	+/-	MSSA	Positive for Staphylococcus aureus, Negative for Methicillin-resistant Staphylococcus Aureus
+	+	-	-	+/-	MSSA	Possible co-infection with mecA-bearing coagulase-negative staphylococci (CoNS) and methicillin-susceptible Staphylococcus aureus (MSSA)
+	-	+	-	+/-	MSSA	Possible co-infection with mecC-bearing coagulase-negative staphylococci (CoNS) and methicillin-susceptible Staphylococcus aureus (MSSA)
+	+	+	-	+/-	MSSA	Possible co-infection with mecA and mecC-bearing coagulase-negative staphylococci (CoNS) and methicillin-susceptible Staphylococcus aureus (MSSA)
+	+	-	+	+/-	MRSA	Positive for Methicillin-resistant (mecA)Staphylococcus Aureus
+	-	+	+	+/-	MRSA	Positive for Methicillin-resistant (mecC)Staphylococcus Aureus
+	+	+	+	+/-	MRSA	Positive for Methicillin-resistant (mecA and mecC)Staphylococcus Aureus
-	+/-	+/-	+/-	+	Negative	Negative for Staphylococcus aureus and Methicillin-resistant Staphylococcus Aureus
-	+/-	+/-	+/-	-	Invalid	Result Requires Repeat(Repeat sampling

Notes: The internal control (CY55 channel) signal is not required if amplification is detected in any of the ROX, CY5, VIC, or ATTO channels, as these signals may compete with the internal control.

14【Limitations】

1. The test results of this product are for clinical reference only and should not be used as the sole criterion for clinical diagnosis.
2. The primer or probe binding region is a conserved region of the pathogen, and mutations rarely occur, but genetic mutations in the epidemic process of the pathogen cannot be ruled out, resulting in false negatives.
3. Inappropriate sample collection, transportation, handling, experimental procedures, or experimental conditions, may all lead to false negative and/or false positive results.
4. Only common mutations have been validated in clinical trials, Rare or novel strains have not been clinically validated.
5. Contamination by microorganisms and amplification products may cause erroneous results. Strict attention should be paid to laboratory division and the PCR standard laboratory operation method should be followed.

15【Analytical Performance Characteristics】

1. **Limit of Detection (LoD)**
   500 CFU/mL.
2. **Specificity**
   No cross-reactivity with other skin infection-associated pathogens.

16【Warnings and Precautions】

1. For in vitro diagnostic use only. Please read the product manual carefully before operation.
2. All samples for detection should be handled as potentially infectious. Wear laboratory coats, protective disposable gloves and change the gloves often to avoid cross-contamination between samples. Handling of samples and waste must meet relevant requirements outlined in local, state and national regulations.
3. This kit does not contain active substances of human or animal origin.
4. Product performance is verified only for sputum sample and the sample collection and processing method described in section 8【Specimen Collection, Handling and Storage】. If other sample types or sample collection and processing methods are used, product performance cannot be guaranteed.
5. The kit still has a certain amount of biological load and

pollutants after use, handle the reagent with appropriate precautions and good laboratory practice.
6. Note: Improper operation during the storage, transportation and use of the reagent may affect the test results. For example, improper storage and transportation, sample collection, sample processing and test process are not standardized. Please strictly follow the instructions.

16【Key to symbols】

Symbols	Title	Symbols	Title
CE	CE Marking	IVD	In vitro diagnostic medical device
2°C 28°C	Temperature Limitation		Keep away from sunlight
	Do not use if package is damaged	2	Do not re-use
	Consult Instruction for Use		Caution
	Manufacturer	EC REP	Authorized representative in the European Community/ European Union
REF	Reference	/	/

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