

## *Information on Control of Potentially Infectious Material*

**Device:** SARS-CoV-2 IgG/IgM Rapid Test

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**Manufacturer** Zhuhai Encode Medical Engineering Co., Ltd

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## **1 Main raw materials of the product**

The raw materials in the production of SARS-CoV-2 IgG/IgM Rapid Test are divided into chemical raw materials and biological raw materials.

### **1.1 Chemical raw materials**

The chemical raw materials include sodium chloride, ethylenediamine tetraacetic acid, sodium azide, disodium phosphate, potassium dihydrogen phosphate, chlorauric acid and citric acid. All chemical raw materials used in the products shall meet the requirements of the current 《Chinese pharmacopoeia》 or 《Quality control standards for main raw and auxiliary materials of biological products in China》. Chemical reagents not included in the above standards shall not be less than chemically pure.

### **1.2 Biological materials**

Biological raw materials include recombinant coronavirus (SARS-CoV-2) antigen, sheep anti-mouse antibodies. Biological raw materials meet the requirements of 《Quality control standards for main raw and auxiliary materials of biological products in China》.

## **2 Analysis of potential infectious matter**

### **2.1 Potential infectivity of chemical raw materials**

The chemical raw materials used in the products are purchased accordance with the standard requirements and are not potentially infectious.

### **2.2 Potential infectivity of biological materials**

The recombinant antigen is not infectious. At the same time, the antigen of this product is wrapped on the test strip and does not come into direct or indirect contact with human body. Therefore, there is no potential infectious substance in the use of this product.