The test card consists of colloidal gold labeled SARS-CoV-2 N protein monoclonal antibody which is pre-coated on the combination pad, matched SARS-CoV-2 N protein monoclonal antibody immobilized on the Test area (T) and corresponding antibody in the quality control area (C).

During testing, if N protein in the sample combines with the colloidal gold labeled SARS-CoV-2 N protein monoclonal antibody which is pre-coated on the combination pad, the conjugates migrate upward under capillary effect, and subsequently captured by the N protein monoclonal antibody immobilized in the Test area (T). The higher the contents of N protein in the sample, the more the conjugates captures and the darker the color in the test area is. If there is no virus in the sample or the virus content is lower than the detection limit, then there is no color demonstrated in the test area. (Regardless of the presence or absence of the virus in the sample, a purple stripe will appear in the quality control area (C). The purple stripe in the quality control area (C) is a criterion for the judgment of whether or not there is enough sample and whether or not the chromatography procedure is normal.

### Limitation of Procedure
1. The test results of this product should be comprehensively judged by the physician in combination with other clinical information, and should not be used as the only criterion;
2. The product is used to test the SARS-CoV-2 antigen of the clinical sample.

### Product Performance Index
1. **Physical Property**
   1.1 Appearance
      - The test card should be clean and integral, no burrs, no damage, no pollution; the material should be firmly attached; the label should be clean and not damaged. The sample dilution should be clear without impurities and flocs.
   1.2 Liquid migration speed
      - The liquid migration speed should be no less than 10mm/min.
   1.3 Membrane Strip Width
      - The membrane strip width for the testing card should be ≥ 5mm.
   1.4 Preparation of the quantity of the diluent for the samples
      - The volume of the diluent for the sample is no less than the indicated value.
   2. **Detection Limit**
      - For the detection of sensitivity reference material, the positive detection rate should be no less than 90%.

### Technical Specification
- **Diagnostic Sensitivity:** The detection sensitivity of this test kit is 0.99999, which can detect at least 99.999% of the positive samples.
- **Diagnostic Specificity:** The specificity of this test kit is 0.99999, which can distinguish at least 99.999% of the negative samples.

### Precautions
1. **Labeling:**
   - The test is only suitable for professionals to use in vitro auxiliary diagnosis. Do not use expired products.
   - Do not freeze or use after the expiration date (see the packaging for the expiration date).
2. **Avoid excessive temperature and humidity in the experimental environment.**
   - The reaction temperature should be 15 ~ 30 °C and the humidity should be below 70%.
3. **Avoid excessive temperature and humidity in the experimental environment.**
   - The reaction temperature should be 15 ~ 30 °C and the humidity should be below 70%.
4. **Prevent cross-contamination:**
   - Remove the test card from its package, and use a new package for the next test.
5. **Ensure proper protection:**
   - During the collection procedures for samples, take care to make proper protection, and avoid direct contact with the sample. In case of accidental contact, disinfection treatment should be carried out in time and necessary measures should be taken.
6. **Sample collection:**
   - Nasal swab sample: During sampling, the swab head should be completely inserted into the nasal cavity and gently rotated 5 times. After removal, the swab head should be sampled in the other nasal cavity in the same way to ensure that enough samples are taken.
7. **Sample preparation:**
   - After sample collection, please complete the test within 1 hour.
   - The sample should come to room temperature before testing.

### Explanation of Symbols
- **Invalid:**
   - There is no purple stripe in the quality control area (C), or there is blue stripe in the quality control area (C).
   - If the double-sided adhesive protective layer is torn off after adding diluent, it is easy to cause liquid splashing.

### Basic Information
- **Manufacturer:** Lepu Medical Technology Co., Ltd.
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