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**CERTIFICATE OF ANALYSIS**

**PRODUCT:** Wondfo 2019-nCoV Antigen Test (Lateral Flow Method)  
**CatalogNo:** W196

**Characterization:** Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) is used for qualitatively detection of 2019-nCoV novel Coronavirus antigen *in vitro* using oropharyngeal swabs and nasopharyngeal swabs.

**Performance:** The principle for the test is based on colloidal gold immune chromatography sandwich methods. It is the qualitative detection of 2019-nCoV novel Coronavirus antigen using oropharyngeal swabs and nasopharyngeal swabs as specimen.

When the analyte concentration in the specimen is higher than the limit of detection (LOD) of the test, the analyte will form a complex with colloidal gold labeled antibody. Then, the complex will flow across the nitrocellulose (NC) membrane to the test line(T line). Within T line, the complex will bind with the pre-coated antibody to form the antibody-antigen-antibody complex, which will be indicated by T line turning red, representing the positive result. When there is no analyte or the analyte concentration is lower than the limit of detection (LOD), T line will not turn red, representing the negative result.

Control line (C line) will turn red regardless of analyte presence or concentration.

**Package:** Packaging procedure strictly follows the *Production Manual* and packaging control is carried out by the quality control system. Test cartridge Individual package: sealed pouch contains 1 test and 1 desiccant. Kit package: 20 tests /kit.

**Expiry:** Expiration date is showing on the package.

**Storage:** Stored between 2~30°C. Do not freeze.

**Precaution:** The product is offered without warranty for any other specific use than that specified in the instruction of use.

Product approved and released based on information gained from manufacturer by:



Quality Manager

Guangzhou Wondfo Biotech Co., Ltd.