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SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

Certificate of Analysis

Document NO.: SARS-CoV-2-Ag-201025-01

User Department: QC Dept.

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|---|--|------------------|-------------|
| Product Name | SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) | | |
| Lot No. | 2020102405 | Specification | 20Tests/box |
| Manufacture Date | 2020.10.22 | Expire Date | 2022.10.21 |
| Inspection Date | 2020.10.25 | Report Date | 2020.10.25 |
| Inspection Item | Inspection Standard | | Result |
| 1.Exterior | The appearance of the kit should be complete without damage; the aluminum foil bag in the kit should be sealed without leaking air; the desiccant package should be complete without spilling; the composition of the buffer should be clear, transparent, and free of impurities such as floc and granular. The test reagents should be flat and flawless, the materials should be firmly attached and the contents should be complete. | | pass |
| 2.Membrane strip width | No less than 3mm. | | pass |
| 3.Liquid Flow Speed | At least 10mm/min. | | pass |
| 4.Negative Reference Product Coincidence Rate | Negative reference sample coincidence rate: 20 negative enterprise reference samples were tested and the results were all negative. | | pass |
| 5.Positive Reference Product Coincidence Rate | Positive reference sample coincidence rate: 8 positive enterprise reference samples were tested and the results were all positive. | | pass |
| 6.Lower Limit of Detectability | Enterprise reference samples of limited detection were used for testing, S1 and S2 should be positive, S3 should be negative. | | pass |
| 7.Sophisticated Detection | Enterprise reference samples of sophisticated detection were used for testing, J1 and J2 should be positive. Test results are consistent, colour intensity of test lines are the same. | | pass |
| Conclusion | According to the Enterprise Internal Standards of SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) <input checked="" type="checkbox"/> PASS <input type="checkbox"/> NOT PASS | | |
| Remark | / | | |
| Checker | Liu Min Juan | Reviewer | Nian Yaxuan |
| | | Person In Charge | Li Hongyan |