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PROOF OF MEETING THE CURRENT MINIMUM CRITERIA

We Joinstar Biomedical technology Co., Ltd hereby certified that our product:

COVID-19 Antigen Rapid Test (Colloidal Gold)

for sampling in the anterior nasal swab and oropharyngeal saliva sample, with the article numbers: FGCOVG1100, FGCOVG1200, FGCOVG1300, FGCOVG400, FGCOVG500, FGCOVG600 and FGCOVG700, has the identical test cassette as the Test-ID: AT236 / 20 which is already listed at the Federal Institute for Drugs and Medical Devices (BfArM) and evaluated by the Paul Ehrlich Institute (PEI)

The following clinical performance characteristics are certified:

1. **Limit of Detection:** The limit of detection (LOD) of COVID-19-Antigen-Rapd Test (Colloidal Gold) is 100pg/mL recombinant SARS-COV-2-N-Protein.

2. **Sensitivity and Specificity:** The COVID-19 Antigen-Rapid Test (Colloidal Gold) was compared with the Novel Coronavirus (SARS-COV-2) Real Time Multiplex RT-PCR Kit.

Anterior Nasal Swab:

Method		**RT-PCR**		**Total Results**
COVID-19 Antigen Rapid Test (Colloidal Gold)	**Results**	Positive	Negative	
	Positive	98	4	102
	Negative	4	496	500
Total Result		102	500	602

The total sensitivity of COVID-19 Antigen is 96.1%;95% CI:(90.26%-98.92%)
Total specificity of COVID-19 Antigen is 99.2%;95%CI:(97.96%-99.78%)
Total agreement rate of COVID-19 Antigen is 98.7%;95%CI:(97.40%-99.42%)

Oropharyngeal saliva sample:

Method		**RT-PCR**		**Total Results**
COVID-19 Antigen Rapid Test (Colloidal Gold)	**Results**	Positive	Negative	
	Positive	98	5	103
	Negative	4	495	499
Total Result		102	500	602

The total sensitivity of COVID-19 Antigen is 96.1%;95% CI:(90.26%-98.92%)
Total specificity of COVID-19 Antigen is 99.2%;95%CI:(97.96%-99.78%)
Total agreement rate of COVID-19 Antigen is 98.7%;95%CI:(97.40%-99.42%)

3. **Cross-reactivity:** The following cross-reactive substances have been tested using COVID-19 Antigen Rapid Test (Colloidal Gold) and no cross-reactivity was observed.

HCoV-229E	HCoV-OC43	HCoV-NL63	MERS-CoV
HCoV-HKU1	Human RSV	Human Enterovirus	Human Rhinovirus
Human Metapneumovirus	Mycoplasma pneumoniae	Parainfluenza virus	Adenovirus
Influenza B virus (Victoria Linie)	H1N1 (2009) influenza virus	Influenza A H3N2 virus	Avian influenza virus H7N9
Influenza B virus (Yamagata Serie)	Seasonal Influenza A H1N1	Neisseria meningitidis	Streptococccus pneumoniae
Staphylococcus aureus			

4. **Interfering Substances:** The following compounds have been tested using COVID-19 Antigen Rapid Test (Colloidal Gold) and no interference was observed.

Interfering substances	concentration
Aspirin	30 ug / dl
Ascorbinsäure	20 mg / dl

Ibuprofen	200 ug / dl
Bilirubin	60 mg / dl
Chloramphenicol	3 ug / dl

and are in accordance with the minimum criteria for Antigen Rapid Tests of the Paul-Ehrlich-Institution (PEI) in coordination with the Robert Koch-Institution (RKI) according to §1 paragraph 1 TestV.

Signed for and on behalf of the manufacturer:

Manufacturer: Joinstar Biomedical technology Co., Ltd.

Signature & stamp:

Position:

Place, Date: