FACT SHEET

SARS-CoV-2 Antigen Rapid Qualitative Test

Test system:

The **SARS-CoV-2 Antigen Rapid Qualitative Test** is a colloidal gold immunochromatography intended for the qualitative detection of the nucleocapsid protein / antigen from SARS-CoV-2 virus in human nasal swabs, throat swabs, and sputum from individuals who are suspected of COVID-19 by their healthcare provider, before and within the first five days from the onset of symptoms.

Test principal:

The **SARS-CoV-2-Antigen-Rapid Qualitative Test** is based on a colloidal gold immunochromatography assay platform. During the performance of the test, specimen extracts are applied to the test cartridges. If there is SARS-CoV-2 antigen present in the extract, the virus antigen will bind to the SARS-CoV-2 monoclonal antibody (complex) a typically antibody-antigen binding reaction.

Test reaction:

During lateral flow, the antigen complex will move along the nitrocellulose membrane toward the end of the absorbent membran. When passing the test line (line T, coated with another SARS-CoV-2 monoclonal antibody) the complex is captured by SARS-CoV-2 antibody on test line resulting in coloring on line T which indicates that an **acute infection with SARS-CoV2** has taken place.

Positive control:

A separate **control band** (test control line C) is available and indicates the correct function and validity of the test performance: when passing line C, colloidal gold-labeled goat anti-rabbit IgG is captured by control line (line C, coated with rabbit IgG) resulting in coloring on line C. This approach guarantees the validity of the test.

Performance characteristics:

The **SARS-CoV-2-Antigen-Rapid Qualitative Test** (C-19 Quick Detect Gold IgG/IgM) test is characterized by **very good reliability** in the performance of in-vitro diagnostics for Covid-19 infections. The performance characteristics are all within or above the quality criteria required for these particular tests.

Sensitivity:	**96,09%** (~ 125 µg/ml)
Accuracy & Precision:	**98,98%**
Cross Reactivity & Interference:	**None** of the samples analyzed show **cross-reactivity or interference** with blood and plasma related agents or other chemical substances (48 carefully selected substances tested)
Specificity:	**100,0%** Different bacterial and viral agents were analyzed and compared.
LOQ (Limit of Quantitation):	The detection limit for the test is given as ~ 40-50 ng/ml. A LoD was sustainable analyzed, a few ng of virus antigen can be detected.

Regulatory background & registration of the test kit as an IVD:

The **SARS-CoV-2-Antigen-Rapid Qualitative Test** from Biotime has appropriate certificates (ISO 13458: 2016 & EN ISO 13458: 2016) and quality documentation (CoA, stability studies, according to EC Directive 98/79/EC), is registered in Austria in the EU-registry for medical devices & IVD (AT/CA01/I001 8406-00) and therefore fulfills **all legal and regulatory requirements for sales in Austria**, the EU and ROW.

At this time point, there is not enough information available that can be tell us about the total error rate of this particular tests. Possible causes or failure rates can be based on the fact that test subjects received a therapy with murine, monoclonal antibodies before use, errors can be occurred in the use of the test (operating instructions were disregarded), during the transport of the test kits (e.g. at temperature above 30°C) or errors occur during sampling of the test specimen. Therefore, only trained and experienced operators should perform sampling and test preparation.

All defined batches of this particular test kit will be randomized analyzed after entrance and marketing into the EU and a quality control system with dedicated control sera (positive & negative sera) will be established and kits will be formally released. Additionally, a routine material control system will be initiated at our company Next Pharma dedicated for material & performance checks on a routine basis.

For this reason, alps:health works on the constant improvement of the test kit performance and the informative value of our tests and will perform application studies (clinical significance) and additional quality control tests for this purpose.

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