Hangzhou Clongene Biotech Co., Ltd.
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TO WHOM IT MAY CONCERN,

We, Hangzhou Clongene Biotech Co., Ltd., the manufacturer of COVID-19 Antigen Rapid Test, has received the new minimum criteria for SARS-CoV-2 antigen tests effective January 14, 2021 from BfArM. Please kindly check our reply below:

a) which antigen protein(s) are detected in your test and

Reply: The COVID-19 Antigen Rapid Test is a lateral flow immunoassay intended for the qualitative detection SARS-CoV-2 nucleocapsid protein (also known as nucleoprotein or protein N) antigens, which has been described in [VERWENDUNGSZWECK] of the package insert.

b) if the antigen test in question detects the SARS-CoV-2 surface protein ("spike"), whether the antigen detection also reliably detects the spike protein from SARS-CoV-2 genetic variants. Please provide a comprehensible justification for this.

Reply: Not applicable.

Corresponding information on the mode of action of the test must also be included in the package insert in accordance with the specifications of the IVD Guideline.

Reply: The COVID-19 antigen Rapid Test is a lateral flow immunoassay based on the principle of the double-antibody sandwich technique. SARS-CoV-2 antigens bind to anti-SARS-CoV-2 nucleocapsid protein monoclonal antibody conjugated with color microparticles in the test strip forming an immune complex. The immune complex is then captured by the pre-coated SARS-CoV-2 nucleocapsid protein monoclonal antibody at the test line on the membrane as it migrates through the test strip. The principles of the test has been described in [PRINZIP] of the package insert.

Yours sincerely,

19/01/2021

Mr. Shujian Zheng

Managing Director

杭州隆基生物技术有限公司
HANGZHOU CLONGENE BIOTECH CO., LTD.