



Fast COVID-19

Antigen Rapid Test Cassette Biozek



- Rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 antigens presents in human nasopharynx.
- Results are for the detection of SARS-CoV-2 Antigens.
- Result at 15 minutes. Do not interpret the result after 20 minutes.
- High accuracy.
- Diagnostic Specificity: 100%
- Diagnostic Sensitivity: 93,3%

CE

CODE	DESCRIPTION	PACKAGE
ANTITEST	Fast COVID-19 Antigen Rapid test Cassette Biozek	30 test/box

STANDARDS

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

EN ISO 13485:2016 Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)

EN ISO 15223-1: 2016 Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)

EN ISO 14971: 2012 Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)

EN 13641: 2002 Elimination or reduction of risk of infection related to in vitro diagnostic reagents

EN ISO 18113-1: 2011 Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)

EN ISO 18113-2: 2011 Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2009)

EN ISO 23640: 2015 Evaluation of stability of in vitro diagnostic reagents (ISO 23640:2011)

