

## Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)

### List of Applied Standards

We, Beijing Hotgen Biotech Co., Ltd., herewith declare that the standards listed in the below table apply to this product Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold).

No.	Standard Code	Name
1	EN ISO13485:2016	Medical Devices- Quality management systems - Requirement for regulatory purposes
2	EN ISO14971:2012	Medical devices- Application of Risk management to medical devices
3	EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling) – Part 1: Terms, definitions and general requirements
4	EN ISO 18113-2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling) – Part 2: In vitro diagnostic reagents for professional use
5	EN 13612:2002/AC:2002	Performance evaluation of in vitro diagnostic medical devices
6	EN 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
7	EN ISO 15223-1:2016	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied--Part 1: General requirements
8	EN ISO 23640:2015	In vitro diagnostic medical devices-Evaluation of stability of in vitro diagnostic reagents
9	EN 13975:2003	Sampling procedures used for acceptance testing of in vitro diagnostic medical devices. Statistical aspects
10	EN ISO 17511:2003	In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials
11	EN 62366:2008	Medical devices- Application of usability engineering to medical devices