# Reference List

Product: **GenBody COVID-19 Ag**

Date: **2020-06-02**

| Prepared by / date | Reviewed by / date | Approved by / date |
|---|---|---|
| **Senior Researcher** | **R&D Director** | **QMR** |
| **Seo seul ki** | **Jedae Moon** | **Jung Young Choi** |
| **2020-06-02** | **2020-06-02** | **2020-06-02** |

## 0. Revision history

| Revision History | | |
|---|---|---|
| Rev. O | 2020. 06. 02 | Release of the GenBody COVID-19 Ag's reference information |

## 1. Applied Standards

| No | Requirements and Standard No. | Titles |
|---|---|---|
| 1 | IVD directive 98/79/EC | Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices |
| 2 | EN 15223-1:2016 | Graphical symbols for use in the labelling of medical devices |
| 3 | EN 14136:2004 | Use of external quality assessment schemes in the assessment of the performance of in vitro diagnostic examination procedures |
| 4 | EN 13975:2003 | Sampling procedures used for acceptance testing of in vitro diagnostic medical devices-Statistical aspects |
| 5 | EN 13612:2002 | Performance evaluation of in vitro diagnostic medical devices |
| 6 | EN ISO 23640:2015 | Stability testing of in vitro diagnostic reagents |
| 7 | EN 13641:2002 | Elimination or reduction of risk of infection related to in vitro diagnostic reagents |
| 8 | EN ISO 13485:2016 | Medical devices Quality Management System- Requirements for Regulatory Purpose |
| 9 | EN ISO 14971:2012 | Medical devices-application of risk management to medical devices |
| 10 | EN ISO 15193:2009 | In vitro diagnostic medical devices-Measurement of quantities in samples of biological origin-Requirements for content and presentation of reference measurement procedures |
| 11 | EN ISO 15194:2009 | In vitro diagnostic medical devices-Measurement of quantities in samples of biological origin-Requirements for certified reference materials and the content of supporting documentation |
| 12 | EN ISO 18113-1:2011 | In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling) - Part 1: Terms, definitions and general requirements |
| 13 | EN ISO 18113-2:2011 | In vitro diagnostic medical device-Information supplied by the manufacturer (labeling)-Part 2: In vitro diagnostic reagents for professional use |
| 14 | EN 62366:2008 | Application of usability engineering to medical devices |
| 15 | 2009/886/EC | amending Decision 2002/364/EC on common technical specifications for in vitro diagnostic medical devices |

## 2. Table of Contents

| No. | Reference List | Location | Extra |
|---|---|---|---|
| 1 | CLSI. Evaluation of Precision Performance of Quantitative Measurement Procedures; Approved Guideline – Thrid Edition. CLSI document EP5-A3 | GenBody Biotech Institute | |
| 2 | NCCLS. Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline. NCCLS document EP6-A | GenBody Biotech Institute | |
| 3 | NCCLS. Quantitative Molecular Methods for Infectious Diseases; Approved Guideline. NCCLS document MM6-A | GenBody Biotech Institute | |
| 4 | CLSI. Interference Testing in Clinical Chemistry; Approved Guideline-Third Edition. CLSI document EP7-A3 | GenBody Biotech Institute | |
| 5 | Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline -Third Edition. CLSI document EP9-A3 | GenBody Biotech Institute | |
| 6 | CLSI. User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline EP12-A2 | GenBody Biotech Institute | |
| 7 | NCCLS. Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline - Second Edition EP17-A2 | GenBody Biotech Institute | |
| 8 | Current performance of COVID-19 test methods and devices and proposed performance criteria; European Commision, Working document of Commission services | GenBody Biotech Institute | |
| 9 | COMMUNICATION FROM THE COMMISSION Guidelines on COVID-19 in vitro diagnostic tests and their performance; Brussels, 15.4.2020 C(2020) 2391 final | GenBody Biotech Institute | |
| 10 | Instructions for Submission Requirements: In vitro diagnostics (IVDs) Detecting SARS-CoV-2 Nucleic Acid; WHO EUL | GenBody Biotech Institute | |
| 11 | Instructions for Submission Requirements: In vitro diagnostics (IVDs) Detecting Antibodies to SARS-CoV-2 virus; WHO EUL | GenBody Biotech Institute | |
| 12 | Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency; USFDA | GenBody Biotech Institute | |
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