



## Calibration Factors Using WHO International Standard (NIBSC 20/136) for Anti-SARS-CoV-2 Immunoglobulins



The Bio-Plex Pro Human IgA, IgG, and IgM SARS-CoV-2 N/RBD/S1/S2 Serology Assays have a quantitative format option, described in the protocols for IgG, [bulletin 7459](#), and IgA and IgM, [bulletin 3224](#). An application note, [bulletin 3208](#), summarizes the performance characteristics of the quantitative Bio-Plex Pro Human IgA, IgG, and IgM SARS-CoV-2 Serology Assays. To better compare and harmonize these assays with other commercially available severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) serology assays, a set of calibration (conversion) factors have been generated using the National Institute for Biological Standards and Control (NIBSC) 20/136 reference standard.

These calibration factors will help establish a way to compare values between different SARS-CoV-2 serology assays and to harmonize the levels of anti-SARS-CoV-2 antibodies that are considered efficacious for vaccines and therapeutics and the antibody level that contributes to effective immunity against SARS-CoV-2 in epidemiological studies.

Tables 1–3 outline the equivalent binding antibody (BAU) per milliliter for each immunoglobulin class. For each assay, the standard curve point 1 was calibrated against the World Health Organization (WHO) international standard.

For IgA and IgM, the assay kit control can be used as the standard curve material. WHO/NIBSC international standard units (BAU/ml) = Bio-Plex units (ng/ml) x conversion factor.

The material for the IgG standard curve must be purchased separately. This external control is the VIROTROL SARS-CoV-2 Single Level Control. Arbitrary units (AU) per milliliter were assigned to this control. WHO/NIBSC international standard units (BAU/ml) = Bio-Plex units (AU/ml) x conversion factor.

**Table 1. Bio-Plex Pro Human IgA SARS-CoV-2 N/RBD/S1/S2 4-Plex Panel Assay calibration factors.**

Target (IgA antibody)	Bio-Rad Catalog #12014775, ng/ml	NIBSC 20/136, BAU/ml	WHO Conversion Factor
Nucleocapsid	400	111	0.2784
Receptor binding domain	300	78	0.2604
Spike 1	300	123	0.4086
Spike 2	800	540	0.6756

**Table 2. Bio-Plex Pro Human IgG SARS-CoV-2 N/RBD/S1/S2 4-Plex Panel Assay calibration factors.**

Target (IgG antibody)	Bio-Rad #200300A, AU/ml	NIBSC 20/136, BAU/ml	WHO Conversion Factor
Nucleocapsid	20,000	16.01	0.0008
Receptor binding domain	20,000	53.96	0.0027
Spike 1	20,000	43.76	0.0022
Spike 2	20,000	13.18	0.0007

**Table 3. Bio-Plex Pro Human IgM SARS-CoV-2 N/RBD/S1/S2 4-Plex Panel Assay calibration factors.**

Target (IgM antibody)	Bio-Rad #12014776, ng/ml	NIBSC 20/136, BAU/ml	WHO Conversion Factor
Nucleocapsid	1,000	289	0.2892
Receptor binding domain	1,000	14.17	0.0142
Spike 1	1,000	14.99	0.0150
Spike 2	1,000	344	0.3443

## Ordering Information

Catalog #	Description
12014665	Bio-Plex Pro Human IgA SARS-CoV-2 N/RBD/S1/S2 4-Plex Panel
12014634	Bio-Plex Pro Human IgG SARS-CoV-2 N/RBD/S1/S2 4-Plex Panel
12014666	Bio-Plex Pro Human IgM SARS-CoV-2 N/RBD/S1/S2 4-Plex Panel
12014775	Bio-Plex Pro Human IgA SARS-CoV-2 Positive Control
200300A	VIROTROL SARS-CoV-2 Single Level Control
12014776	Bio-Plex Pro Human IgM SARS-CoV-2 Positive Control

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