

Acute Phase
Cancer
Cardiovascular Disease
Cytokines Chemokines,
Growth Factors
Diabetes
Gene Expression
Genotyping
Immunoglobulin Isotyping
MicroRNA Expression

Bio-Plex Pro™ Human Isotyping Panel

MAGNETIC SEPARATION ENABLED

IgG₁, IgG₂, IgG₃, IgG₄, IgA, IgM, IgE, IgG Total

- Validated on human plasma, serum, and cell culture samples
- Magnetic or vacuum assay separation
- All-in-one kit format



High-Performance Multiplex Immunoassays for Research

The Bio-Plex Pro human isotyping panel is designed to meet the needs of the most discerning researcher. These eight magnetic bead-based immunoassays offer robust and reproducible measurement of seven different immunoglobulin subclasses or isotypes.

Bio-Plex isotyping assays have been developed to provide reliable performance for your research needs. Isotyping profiles are typically associated with the following areas of research:

- Allergic response
- Immunodeficiency disorders
- Autoimmune diseases
- Cancer
- Infectious diseases
- Drug and vaccine development

These assays incorporate several features to enhance both quality and ease of use.

- All-in-one kit format for both multiplex and singleplex assays
- One diluent optimized for use with samples, standards, and controls
- Assay quick guide to get you started right away
- 1-level quality control
- Compatible with Bio-Plex® 200, Bio-Plex 3D, and Bio-Plex® MAGPIX™ systems

Benefits of Magnetic Bead-Based Assays

Magnetic bead-based assays enable automation of wash steps with a Bio-Plex Pro series or similar wash station. This innovation greatly simplifies assay processing and eliminates the need for a vacuum manifold. After adopting the magnetic assay workflow, many users experience improved assay precision, in particular with viscous samples.

Rigorous Assay Validation

All Bio-Plex Pro assays undergo a rigorous evaluation that includes the following parameters:

- Specificity (cross-reactivity)
- Accuracy (recovery) in key sample matrices
- Inter- and intra-assay precision
- Sensitivity (limit of detection, LOD)
- Assay working range (LLOQ/ULOQ)
- Linearity of dilution
- Parallelism and matrix effect
- Performance characteristics in real samples

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Assay Performance Definitions

The following parameters are indicative of assay performance, as shown in Table 1.

Assay working range — the range of concentrations within which the assay is both precise and accurate. Boundaries of the assay working range are defined by the lower limit of quantitation (LLOQ) and the upper limit of quantitation (ULOQ)

Precision — the coefficient of variation (%CV) at concentrations within the assay working range

Accuracy (recovery) — percentage of the observed concentration relative to the expected concentration of a known amount of analyte within the assay working range

Sensitivity (limit of detection, LOD) — the concentration of analyte for which the fluorescence intensity signal is two standard deviations above the background signal

Table 1. Representative assay performance.

Target	Assay Working Range*, ng/ml		Assay Sensitivity*, ng/ml	Assay Precision	
	LLOQ	ULOQ	LOD	Intra-Assay %CV	Inter-Assay %CV
6-plex assays					
IgG ₁	0.13	2,107	0.0264	2	4
IgG ₂	2.74	11,227	0.6615	4	5
IgG ₃	0.07	863	0.0030	3	5
IgG ₄	0.02	200	0.0021	4	5
IgA	0.13	532	0.1034	5	3
IgM	0.78	6,376	0.1473	3	4
Singleplex assays					
IgE	0.02	406	0.0040	3	14
IgG Total	3.00	30270	2.1603	4	3

* LLOQ, ULOQ, and LOD are mean values calculated from two to five plates. LLOQ and ULOQ are defined as the boundary standard curve points that meet precision and accuracy specifications of 10% intra-assay CV and 80–120% recovery.

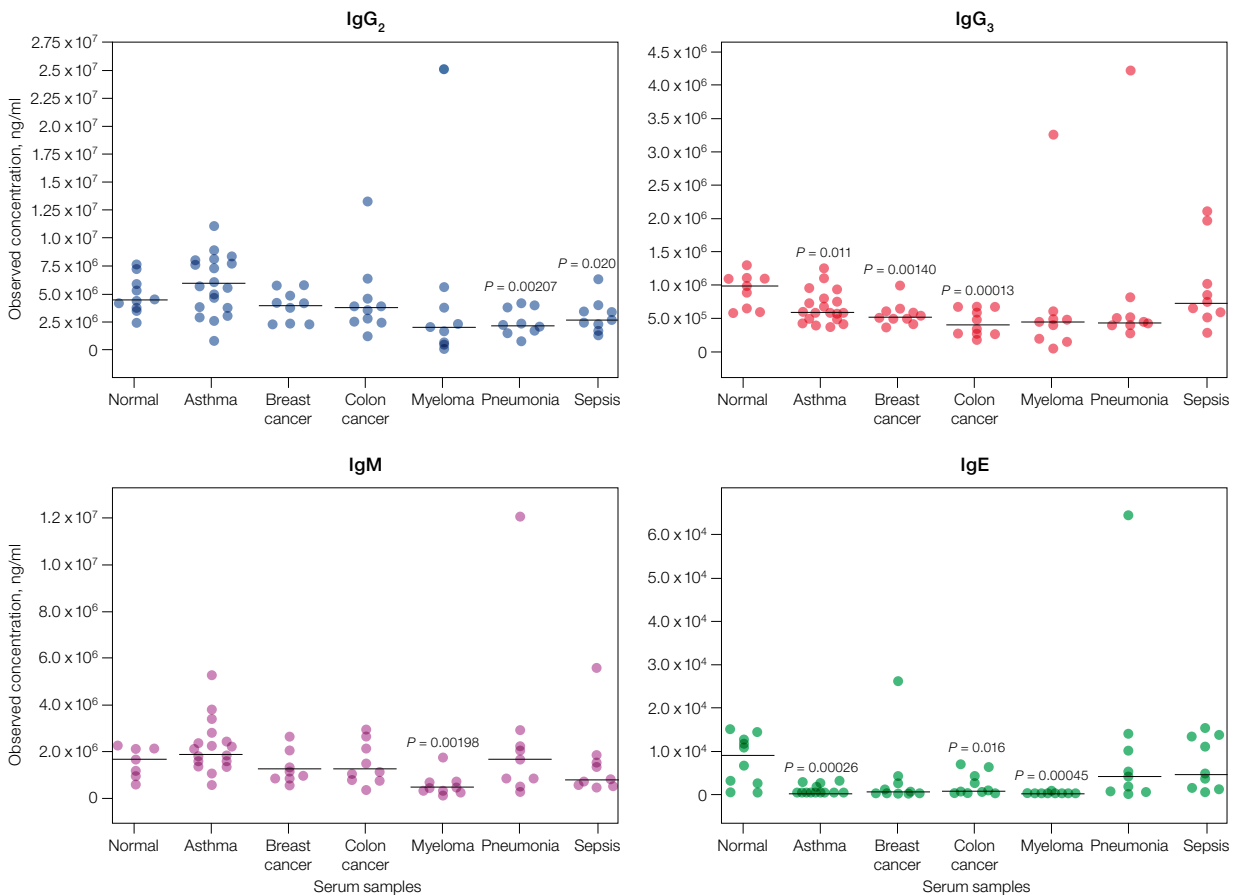


Fig. 1. Immunoglobulin levels in sera from individuals with asthma (N = 20), breast cancer (N = 10), colon cancer (N = 10), myeloma (N = 9), pneumonia (N = 9), and sepsis (N = 9). Non-matching normal (N = 10) serum samples were used as the baseline reference. The *t*-test function in Bio-Plex Data Pro™ software was used to calculate statistical differences. Only *p* values with statistical significance are shown.

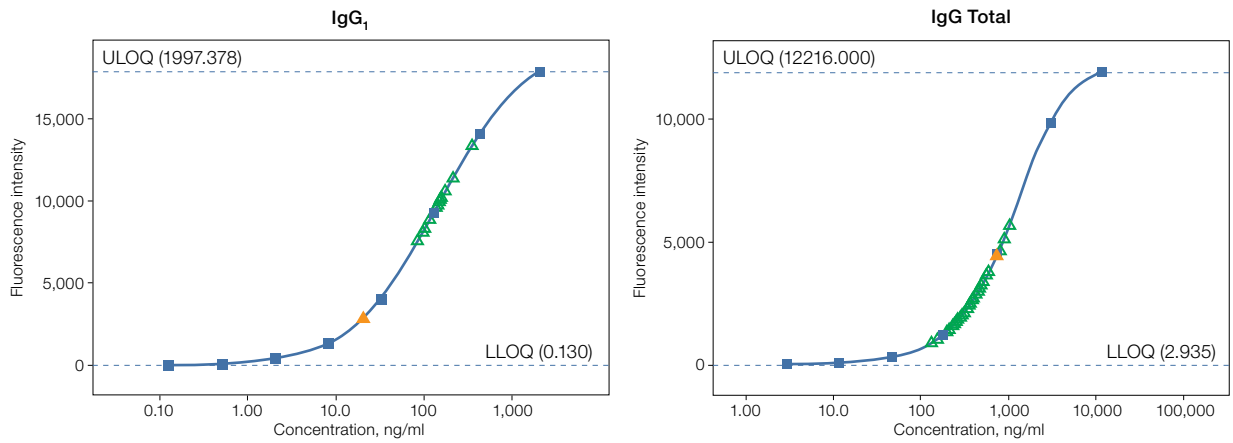


Fig. 2. IgG₁ and IgG Total assays measured in human serum and plasma samples demonstrate that a broad range of sample conditions fall well within the working range of the assay. IgG₁ concentrations were measured in 16 serum and plasma samples from normal and diseased donors (asthma, breast cancer, colon cancer, and pneumonia). IgG total concentrations were measured in 38 serum and plasma samples from normal and diseased donors (asthma, breast cancer, colon cancer, myeloma, pneumonia, sepsis, and B-cell chronic lymphocytic leukemia). Data were analyzed using Bio-Plex Manager™ software version 6.1 with a recovery range specification of 80–120%. Standard (■); samples (▲); control (▲).

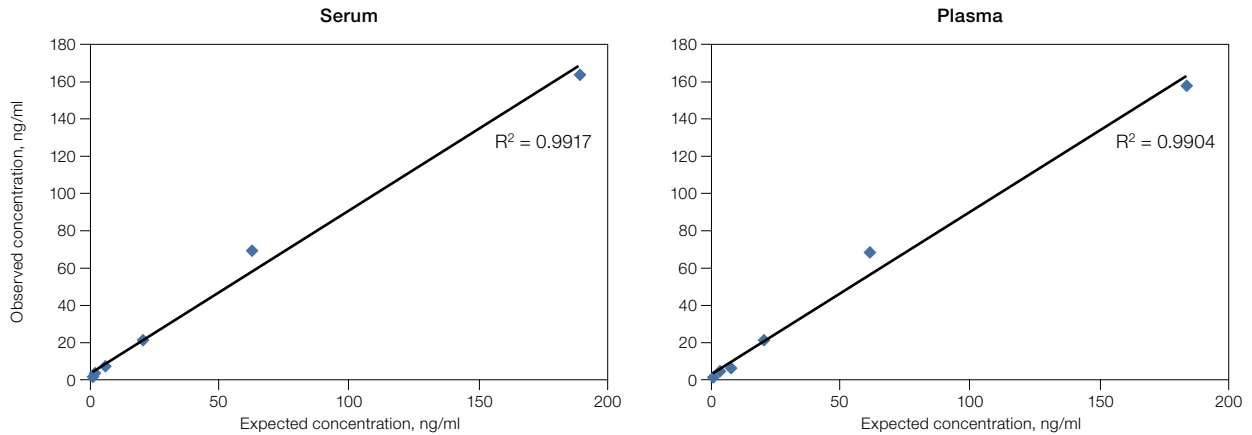


Fig. 3. Linearity of dilution determines the suitability of a standard curve for reflecting relative quantities of an analyte in a complex matrix. The observed and expected concentrations within the working range were plotted. Dilution linearity of IgG₁ is calculated from the serial dilution of serum and plasma samples in isotyping diluent. The correlation coefficient (R^2) values reflect the linearity of dilution for each assay.

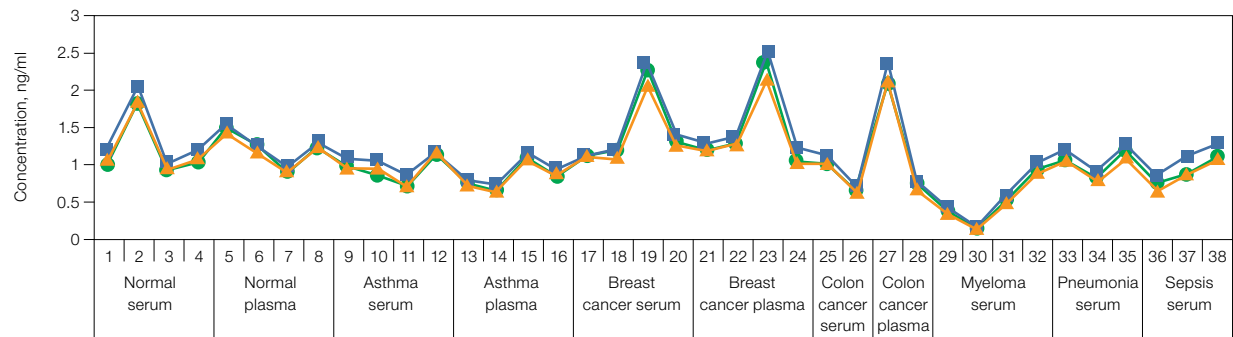


Fig. 4. The IgA assay is compatible with the Bio-Plex 200 (●), Bio-Plex 3D (■), and Bio-Plex MAGPIX (▲) systems. Serum and plasma samples obtained from normal and disease subjects were evaluated for concentrations obtained on the three platforms. Concentration values were similar for all samples tested with the Bio-Plex Pro human isotyping panel. Similar results were obtained for the other assays.

Ordering Information

Catalog # Description

Bio-Plex Pro Human Isotyping Panel Premixed All-In-One Multiplex Kit

171-A3100M **Bio-Plex Pro Human Isotyping Panel, 6-plex**, 1 × 96-well, includes coupled magnetic beads, detection antibodies, standards, 1-level quality controls, detection antibody diluent, isotyping diluent (for use with samples, standards, and controls), assay buffer, wash buffer, streptavidin-PE, 96-well flat bottom plate, sealing tape, assay quick guide, and product data sheet; for the detection of IgG₁, IgG₂, IgG₃, IgG₄, IgA, and IgM.

Bio-Plex Pro Human Isotyping All-In-One Singleplex Kits

Singleplex kits are specific for each assay indicated below and include coupled magnetic beads, detection antibodies, standards, 1-level quality controls, detection antibody diluent, isotyping diluent (for use with samples, standards, and controls), assay buffer, wash buffer, streptavidin-PE, 96-well flat bottom plate, sealing tape, assay quick guide, and product data sheet.

171-A3101M **IgA Kit**, 1 × 96-well
171-A3104M **IgM Kit**, 1 × 96-well
171-A3102M **IgE Kit**, 1 × 96-well
171-A3103M **IgG Total Kit**, 1 × 96-well

Wash Stations and Accessories

300-34376 **Bio-Plex Pro Wash Station**, includes magnetic plate carrier, waste bottle, 2 buffer bottles
300-34377 **Bio-Plex Pro II Wash Station**, includes magnetic plate carrier, vacuum manifold plate carrier, waste bottle, 2 buffer bottles
171-025001 **Bio-Plex Flat Bottom Plates**, 40 × 96-well plates
171-304500 **Bio-Plex Wash Buffer**, 1.5 L
171-020100 **Bio-Plex Handheld Magnetic Washer**, includes magnetic washer and adjustment hex tools for use in manual wash steps for all Bio-Plex magnetic assays
171-304502 **Filter Plate**, pkg of 1, 96-well plate, with clear plastic lid and tray, for Bio-Plex assays using the vacuum wash method, sealing tape not included

Software

171-001510 **Bio-Plex Data Pro Software with Bio-Plex Manager Software**, Bio-Plex Data Pro software (5 seats), for multi-experiment analysis and advanced data visualization, and Bio-Plex Manager software (5 seats), for instrument data evaluation and optimization. CDs and security HASP key included
171-001513 **Bio-Plex Data Pro Software**, (5 seats), for multi-experiment analysis and advanced data visualization
171-001523 **Bio-Plex Data Pro Plus Software**, contains all the features of Bio-Plex Data Pro Software with added visualization, sharing, and analysis functionality
171-STND01 **Bio-Plex Manager Software**, includes 1 user desktop license, to analyze Bio-Plex data and generate protocols, does not operate the instrument

The Bio-Plex suspension array system includes fluorescently labeled microspheres and instrumentation licensed to Bio-Rad Laboratories, Inc. by the Luminex Corporation.



**Bio-Rad
Laboratories, Inc.**

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