Technical Data Sheet

Human Total IgG Flex Set

Product Information

Material Number:	**558679**
Size:	100 Tests
Bead Position:	C6
Assay Range:	1.7-430 ng/mL
Reactivity:	QC Testing: Human

Component Description:	Human Ig Standard
Component Mat. No:	51-9004553
Component Storage Buffer:	Lyophilized in an aqueous buffered solution containing BSA and ProClin™ 150.
Component Description:	Human Total IgG PE* Detection Reagent
Component Mat. No:	51-9005018
Component Storage Buffer:	Aqueous buffered solution containing BSA and ≤0.09% sodium azide.
Component Description:	Human Total IgG Capture Bead C6
Component Mat. No:	51-9005020
Component Storage Buffer:	Aqueous buffered solution containing BSA and ≤0.09% sodium azide.

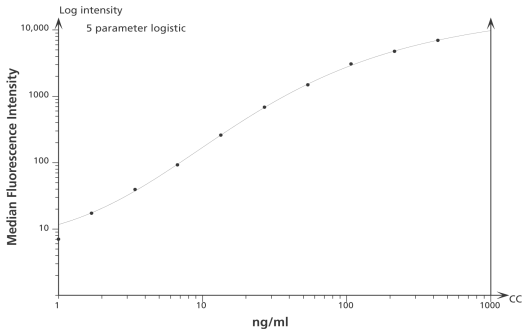

Figure 1. Example BD CBA Human Total IgG Flex Set standard curve. *Data acquired on a BD FACSArray bioanalyzer and analyzed using the FCAP Array Software (Cat. No. 641488).*

Description

The BD™ CBA Human Total IgG Flex Set is a bead-based immunoassay capable of measuring human total immunoglobulin G (IgG) in serum and plasma samples. Human reactivity was determined by testing samples with the BD CBA Human Total IgG Flex Set. The biology and function of IgG has been extensively reviewed in the literature. For more information on bead-based immunoassays, refer to the product insert for the BD CBA Human Immunoglobulin Master Buffer Kit (Cat. No. 558683).

This BD™ CBA Flex Set contains one vial each of Capture Bead and PE Detection Reagent and two vials of Standard. The Capture Bead and PE Detection Reagent components of this flex set have been formulated to a 50x concentration to ensure product performance when multiplexed. The Standard component is lyophilized and when reconstituted in 1.0 ml Assay Diluent has a total IgG protein concentration of 13,760 ng/ml. Discard unused reconstituted standard, do not store or reuse. Store lyophilized standard and other components at 4°C. Protect PE Detection Reagent from prolonged exposure to light.

Application Notes

Recommended Assay Procedure: The BD CBA Human Total IgG Flex Set must be used in conjunction with a BD CBA Human Immunoglobulin Master Buffer Kit (Cat. No. 558683, 100 tests), a flow cytometer, and the FCAP Array™ Software (Cat. No. 641488). Detailed instructions on the use of this product can be found in the manual for the BD CBA Human Immunoglobulin Master Buffer Kit. When following the directions in the Master Buffer Kit, the top standard point for the BD CBA Human Total IgG Flex Set will be 430 ng/ml. An example standard curve is shown in Figure 1.

Due to the levels of immunoglobulin protein in typical samples and specific assay conditions, the BD CBA Human Total IgG Flex Set should not be used in the same assay well with any other BD CBA Flex Set assay. It should only be run as a single-plex assay. For an updated assay

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compatibility chart for the BD CBA Human Immunoglobulin Flex Sets, please refer to the BD CBA Flex Set System homepage at http://www.bdbiosciences.com/flexset.

Performance

Limit of Detection: The theoretical limit of detection is 0.34 ng/ml and was determined by evaluating the estimated result of the average MFI of the negative control (0 pg/ml, *n*=30) + 2 standard deviations.

Specificity		Inter-Assay Reproducibility				Intra-Assay Reproducibility		
		Mean (ng/ml)	Standard Deviation	%CV		Mean (ng/ml)	Standard Deviation	%CV
Human Total IgG	Sample 1	6.5	0.3	5%		6.4	0.5	7%
	Sample 2	25.3	1.9	8%		25.2	2.8	11%
	Sample 3	110.3	6.7	6%		110.2	9.6	9%

Reproducibility: *The inter-assay and intra-assay reproducibility were determined for the BD CBA Human Total IgG Flex Set by evaluating ten replicates of three different sample levels (inter-assay) and two replicates of three different sample levels from four separate experiments (intra-assay) respectively.*

Sample Dilution	Human Total IgG	
	Detected (ng/ml)	% of Expected
Starting Dilution	36.8	97%
1 : 2	17.1	90%
1 : 4	8.1	86%
1 : 8	4.0	85%

Linearity: *The International Reference Preparation for proteins in human serum, certified reference material 470 (CRM 470), was diluted to the starting dilution (37.81 ng/ml) and serially diluted. The diluted sample was assayed and the results were compared with the original expected concentration.*

Product Notices

1. Source of all serum proteins is from USDA inspected abattoirs located in the United States.
2. ProClin is a trademark of Rohm and Haas Company.
3. This product contains human blood, serum, cells, or materials derived from them, which are potentially hazardous materials. Use universal precautions when handling. Handle as if product were capable of transmitting disease. Material used in this product has been tested using FDA approved methods and found negative for Human Immunodeficiency Virus (HIV-1/HIV-2), Hepatitis B Surface Antigen (HBSAG) and antibody to Hepatitis C Virus (HCV). However, no known test method can offer complete assurance that specimens of human origin will not transmit infectious disease. When handling or disposing, follow precautions described in CDC and FDA recommendations and OSHA Bloodborne Pathogen recommendations.
4. Caution: Sodium azide yields highly toxic hydrazoic acid under acidic conditions. Dilute azide compounds in running water before discarding to avoid accumulation of potentially explosive deposits in plumbing.
5. Warning: CBA lyophilized standard contains 0.02% (w/w) of a CMIT/MIT mixture (3:1), which is a mixture of:
   5-chloro-2-methyl-4-isothiazolin-3-one [EC No 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC No 220-239-6] (3:1).
   Hazard statement: May cause an allergic skin reaction.
   Precautionary statements: Wear protective gloves/eye protection. Wear protective clothing. Avoid breathing mist/vapours/spray. If skin irritation or rash occurs: Get medical advice/attention. IF ON SKIN: Wash with plenty of water. Dispose of contents/container in accordance with local/regional/national/international regulations.

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