

Technical Data Sheet

Human IgE Flex Set

Product Information

Material Number:	558682
Size:	100 Tests
Bead Position:	E9
Assay Range:	2.0-500 ng/mL
Reactivity:	QC Testing: Human



Component Description: Human IgE Standard
 Component Mat. No: 51-9005031
 Component Storage Buffer: Aqueous buffered solution containing fetal bovine serum and $\leq 0.09\%$ sodium azide.

Component Description: Human IgE PE* Detection Reagent
 Component Mat. No: 51-9005034
 Component Storage Buffer: Aqueous buffered solution containing BSA and $\leq 0.09\%$ sodium azide.

Component Description: Human IgE Capture Bead E9
 Component Mat. No: 51-9005036
 Component Storage Buffer: Aqueous buffered solution containing BSA and $\leq 0.09\%$ sodium azide.

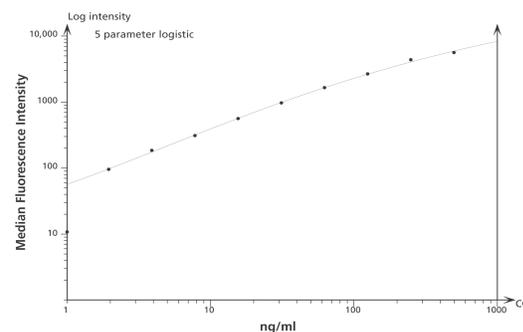


Figure 1. Example BD CBA Human IgE Flex Set standard curve. Data acquired on a BD FACsArray bioanalyzer and analyzed using the FCAP Array Software (Cat. No. 641488).

Description

The BD™ CBA Human IgE Flex Set is a bead-based immunoassay capable of measuring human immunoglobulin E (IgE) in serum and plasma samples. Human reactivity was determined by testing samples with the BD CBA Human IgE Flex Set. The biology and function of IgE has been extensively reviewed in the literature. For more information on bead-based immunoassays, refer to the product insert for the BD CBA Human Soluble Protein Master Buffer Kit (Cat. No. 558264 or 558265).

Preparation and Storage

This BD™ CBA Flex Set contains one vial of each component listed above. All components of this flex set have been formulated to a 50x concentration to ensure product performance when multiplexed. Store at 4°C. Protect Capture Beads and the PE Detection Reagent from prolonged exposure to light.

Application Notes

Recommended Assay Procedure: The BD CBA Human IgE Flex Set must be used in conjunction with a BD CBA Human Soluble Protein Master Buffer Kit (Cat. No. 558264, 100 tests, or 558265, 500 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 Soluble Protein Master Buffer Kit. The top standard point for the BD CBA Human IgE Flex Set is 500 ng/ml and should be prepared in the following way:

For single-plex Human IgE Flex Set experiments, make the top standard dilution by mixing 20 μ l of the Human IgE Standard with 980 μ l of Assay Diluent from the Human Soluble Protein Master Buffer Kit in a tube labeled Top Standard. Perform additional standard dilutions using the top standard dilution by following the instructions in the Human Soluble Protein Master Buffer Kit manual.

For multi-plex experiments including the Human IgE Flex Set, reconstitute the lyophilized standard proteins as directed in the Human Soluble

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Protein Master Buffer Kit manual, but use 20µl less Assay Diluent per ml used for reconstitution (e.g., if reconstituting lyophilized pellets in 1 ml of Assay Diluent, use 980µl instead). Transfer 980µl of the reconstituted proteins to a tube labeled Top Standard and add 20µl of the Human IgE Standard. Perform additional standard dilutions using the top standard dilution by following the instructions in the Human Soluble Protein Master Buffer Kit manual.

An example standard curve is shown in Figure 1.

The BD CBA Human IgE Flex Set should not be used in the same assay well with any non-BD CBA Human Soluble Protein Flex Set reagents (such as BD CBA Mouse Soluble Protein, Human Immunoglobulin or Cell Signaling Flex Sets). The BD CBA Human IgE Flex Set can not be used in the same assay well with any other Human immunoglobulin Flex Set assay or with the Human Ig Master Buffer Kit. For an updated assay compatibility chart for the BD CBA Human Soluble Protein 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 0.07 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 IgE	Sample 1	7.0	0.5	7%	6.8	0.5	8%
	Sample 2	28.8	2.2	8%	26.2	1.6	6%
	Sample 3	146.5	6.3	4%	142.4	8.2	6%

Reproducibility: The inter-assay and intra-assay reproducibility were determined for the BD CBA Human IgE 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 IgE	
	Detected (ng/ml)	% of Expected
Starting Dilution	194.9	97%
1 : 2	103.1	103%
1 : 4	45.6	91%
1 : 8	22.4	89%

Linearity: The Second World Health Organization IgE standard 75/502 was diluted to the starting dilution (200 ng/ml) and serially diluted. The diluted sample was assayed and the results were compared with the original expected concentration.

Product Notices

- Source of all serum proteins is from USDA inspected abattoirs located in the United States.
- 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.
- 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.
- 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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