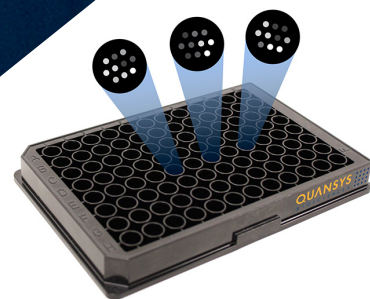


HUMAN PNEUMOCOCCAL IgG (9-PLEX)



The Q-Plex™ Human Pneumococcal IgG (9-Plex) is a chemiluminescent multiplex ELISA run on a 96-well plate.

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Principle of the Assay

The Q-Plex™ Human Pneumococcal IgG (9-Plex) is a chemiluminescent multiplex ELISA run on a 96-well plates that measure antibody levels corresponding to the serotypes found in the Pneumovax®23 vaccine.

Antibodies play an essential role in the protection against pneumococcal disease. In humans, serum antibodies typically act against the polysaccharide capsule in a serotype specific manner. There are multiple vaccination options for protection against *S. pneumoniae*, with the major difference being the number and composition of specific serotypes present in the vaccine.

Performance and Validation Data

Serotype	Assay Type	Calibrator Range	Upper Limit of Quantification (ULOQ)	Lower Limit of Quantification (LLOQ)	Limit of Detection	Precision* (Inter-assay)	Precision* (Intra-assay)	Average* Linearity
2	Indirect	2.46 - 0.00337 (µg/mL)	2.44 (µg/mL)	0.00061 (µg/mL)	0.00169 (µg/mL)	10%	12%	101%
10A	Indirect	1.29 - 0.00177 (µg/mL)	0.3 (µg/mL)	0.00032 (µg/mL)	0.000885 (µg/mL)	7%	8%	106%
11A	Indirect	0.508 - 0.00070 (µg/mL)	0.14 (µg/mL)	0.00013 (µg/mL)	0.000348 (µg/mL)	7%	8%	103%
15B	Indirect	1.69 - 0.00232 (µg/mL)	0.47 (µg/mL)	0.00044 (µg/mL)	0.001159 (µg/mL)	9%	10%	105%
17F	Indirect	0.85 - 0.00117 (µg/mL)	0.79 (µg/mL)	0.00067 (µg/mL)	0.000583 (µg/mL)	9%	8%	98%
19A	Indirect	1.39 - 0.00191 (µg/mL)	1.24 (µg/mL)	0.0061 (µg/mL)	0.000953 (µg/mL)	6%	6%	101%
20	Indirect	1.05 - 0.00144 (µg/mL)	0.26 (µg/mL)	0.00028 (µg/mL)	0.00072 (µg/mL)	6%	6%	102%
22F	Indirect	0.95 - 0.00130 (µg/mL)	0.95 (µg/mL)	0.00094 (µg/mL)	0.000652 (µg/mL)	9%	12%	107%
33F	Indirect	1.07 - 0.00147 (µg/mL)	0.27 (µg/mL)	0.00026 (µg/mL)	0.000734 (µg/mL)	6%	6%	101%

*Intra-assay and inter-assay precision are calculated with n=20 and n=10 replicates, respectively.



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