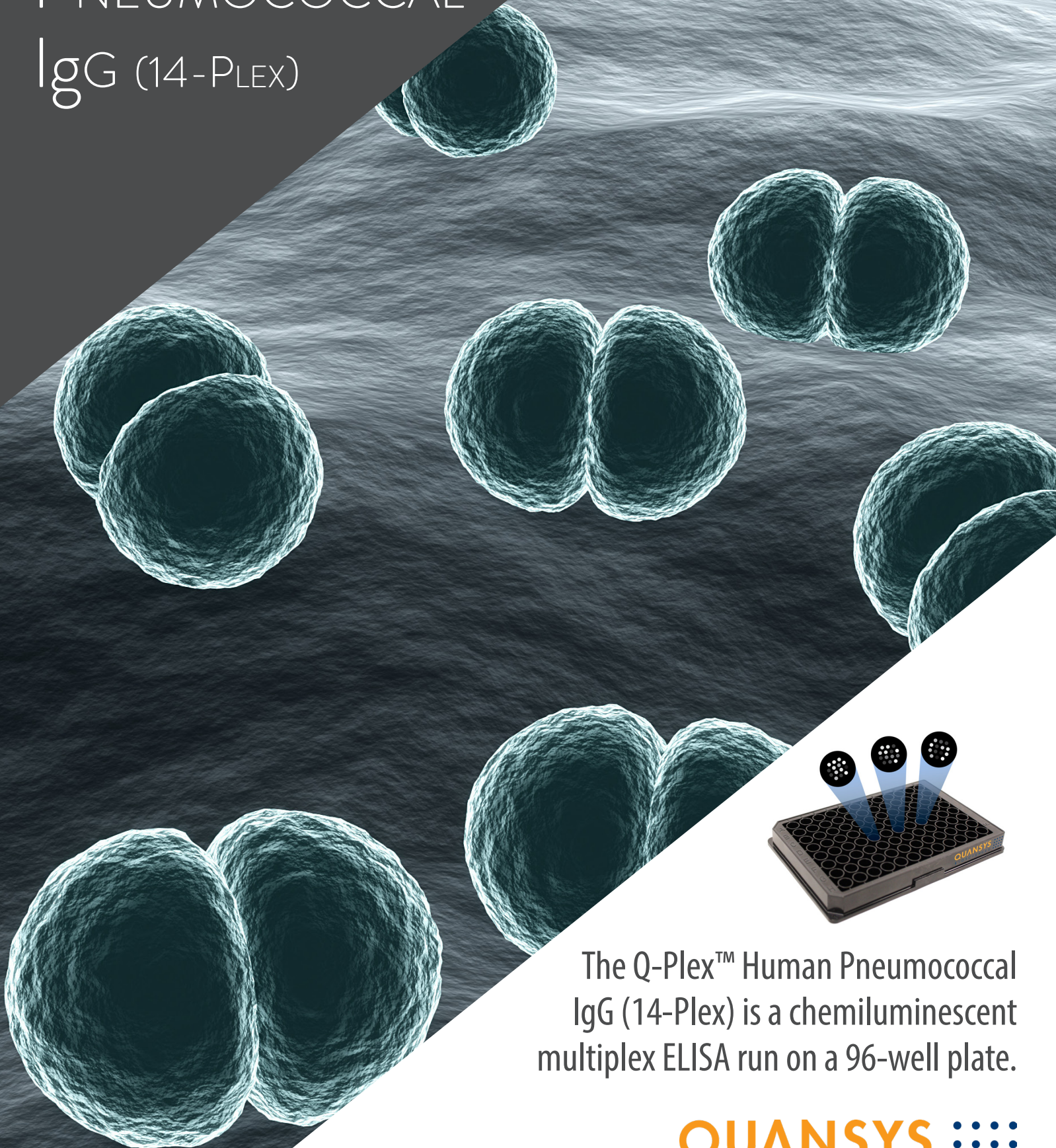


Q-PLEX™ HUMAN PNEUMOCOCCAL IgG (14-PLEX)



The Q-Plex™ Human Pneumococcal IgG (14-Plex) is a chemiluminescent multiplex ELISA run on a 96-well plate.

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Background

The bacterium *Streptococcus pneumoniae* can cause potentially deadly infections in children and the elderly, including pneumonia and meningitis. Risk of infection and disease severity varies with age of the patient and a host of other factors including geographical location, ethnic background, and time of year. More than 90 serotypes are known, though less than 25 are responsible for most cases, with virulence often differing between serotypes.

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	Vaccines
1	Indirect	0.85 - 0.00021 (µg/mL)	0.148 (µg/mL)	0.00027 (µg/mL)	0.00010 (µg/mL)	6%	7%	97%	PNX, P13, P20, V15
3	Indirect	0.15 - 0.000035 (µg/mL)	0.102 (µg/mL)	0.00019 (µg/mL)	0.000018 (µg/mL)	10%	12%	101%	PNX, P13, P20, V15
4	Indirect	0.33 - 0.000081 (µg/mL)	0.058 (µg/mL)	0.00010 (µg/mL)	0.000040 (µg/mL)	5%	6%	99%	PNX, P7, P13, P20, V15
5	Indirect	0.75 - 0.00018 (µg/mL)	0.132 (µg/mL)	0.00024 (µg/mL)	0.000092 (µg/mL)	8%	8%	102%	PNX, P13, P20, V15
6B	Indirect	0.91 - 0.00022 (µg/mL)	0.157 (µg/mL)	0.00029 (µg/mL)	0.00011 (µg/mL)	8%	9%	103%	PNX, P7, P13, P20, V15
7F	Indirect	0.83 - 0.00020 (µg/mL)	0.146 (µg/mL)	0.00286 (µg/mL)	0.00010 (µg/mL)	6%	7%	100%	PNX, P13, P20, V15
8	Indirect	1.42 - 0.00035 (µg/mL)	0.249 (µg/mL)	0.00180 (µg/mL)	0.00017 (µg/mL)	7%	8%	97%	PNX, P20
9N	Indirect	0.70 - 0.00017 (µg/mL)	0.125 (µg/mL)	0.00089 (µg/mL)	0.000086 (µg/mL)	8%	10%	102%	PNX
9V	Indirect	0.64 - 0.00016 (µg/mL)	0.112 (µg/mL)	0.00079 (µg/mL)	0.000078 (µg/mL)	8%	8%	102%	PNX, P7, P13, P20, V15
12F	Indirect	0.22 - 0.000054 (µg/mL)	0.038 (µg/mL)	0.00028 (µg/mL)	0.000027 (µg/mL)	11%	9%	93%	PNX, P20
14	Indirect	3.8 - 0.00093 (µg/mL)	0.165 (µg/mL)	0.00121 (µg/mL)	0.00046 (µg/mL)	7%	7%	98%	PNX, P7, P13, P20, V15
18C	Indirect	0.73 - 0.00018 (µg/mL)	0.129 (µg/mL)	0.00093 (µg/mL)	0.000089 (µg/mL)	5%	5%	100%	PNX, P7, P13, P20, V15
19F	Indirect	1.46 - 0.00036 (µg/mL)	0.256 (µg/mL)	0.00187 (µg/mL)	0.00018 (µg/mL)	9%	12%	100%	PNX, P7, P13, P20, V15
23F	Indirect	0.6 - 0.00015 (µg/mL)	0.102 (µg/mL)	0.00076 (µg/mL)	0.000073 (µg/mL)	10%	10%	99%	PNX, P7, P13, P20, V15

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



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