Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT W
WX0000003827 M 07/08/1978 45 Y

Referral Testing

Collected: 09/07/2023 09:01 Received: 09/07/2023 09:01

Test Name	Result	Flag	Ref-Ranges	Units	Site
S. pneumoniae IgG ABS 14 Stypes					
Serotype 1 (1)	3.4				QCRL
Serotype 3 (3)	<0.3				QCRL
Serotype 4 (4)	0.6				QCRL
Serotype 5 (5)	0.9				QCRL
Serotype 8 (8)	<0.3				QCRL
Serotype 9 (9N)	<0.3				QCRL
Serotype 12 (12F)	<0.3				QCRL
Serotype 14 (14)	11.1				QCRL
Serotype 19 (19F)	0.8				QCRL
Serotype 23 (23F)	<0.3				QCRL
Serotype 26 (6B)	1.3				QCRL
Serotype 51 (7F)	4.9				QCRL
Serotype 56 (18C)	0.6				QCRL
Serotype 68 (9V)	0.3				QCRL

Serologic correlates of protection against pneumococcal disease have not been rigorously established for all patient populations. Published data and expert consensus (including WHO) suggest protection from invasive disease usually occurs at levels >or =0.3-0.50 mcg/mL for healthy children receiving pneumococcal conjugate vaccines. Higher titers may be necessary to protect from non-invasive infection (e.g., pneumonia, otitis, sinusitis). Expert opinion suggests that a cut-off of >= 1.3 mcg/mL may be a more relevant value to assess antibody responses after pneumococcal polysaccharide vaccines or for immunocompromised patients. In addition to antibody quantity, protection also depends on antibody avidity and opsonophagocytic activity. Some experts consider that post-vaccination (4-6 weeks) IgG seroconversion and/or 2- to 4-fold rise in IgG titers for >50% to 70% of vaccine serotypes demonstrates a normal post-vaccine serologic response. Persons with high initial serotype-specific titers may have less robust responses.

Quest Diagnostics uses a multi-analyte immunodetection (MAID) method. The method employs the Luminex flow cytometric system which measures multiple analytes simultaneously. The FDA standard reference serum 89-S is used as the calibration standard. Results are reported in mcg/mL.

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This assay detects 11 of the 13 serotypes in the
13-valent conjugate vaccine, and 14 of the 23 serotypes
in the 23-valent polysaccharide vaccine.

This test was developed and its analytical performance
characteristics have been determined by Quest Diagnostics.
It has not been cleared or approved by FDA. This assay
has been validated pursuant to the CLIA regulations
and is used for clinical purposes.

For additional information, please refer to
(This link is being provided for informational/
educational purposes only.)

Test Performed at:
Quest Diagnostics Nichols Institute
33608 Ortega Highway
San Juan Capistrano, CA 92675-2042 I Maramica MD, PhD

Performing Site:
QCRL: QUEST DIAGNOSTICS REFERENCE LAB CAPISTRANO 33608 Ortega Highway San Juan Capistrano CA 92675

Reported Date: 2023.09.07 9:03 PNE14

LAB: L - LOW, H - HIGH, AB - ABNORMAL, C - CRITICAL, . - NOT TESTED

F307000006
WX0000003827
Printed D&T: 09/07/23 09:03

Ordered By: KAJAL SITWALA, MD, PhD
WX00000000002365

Kajal V. Sitwala, MD, PhD - Medical Director
Form: MM RL1