



| Patient Information | | Specimen Information | Client Information |
|---------------------|-------------|----------------------|---|
| DOB: | AGE: | Specimen: | REQUEST A TEST - PWN HEALTH 7027 MILL RD STE 201 BRECKSVILLE, OH 44141-1852 |
| Gender: | Fasting: | Requisition: | |
| Phone: | | Lab Ref #: | |
| Patient ID: | | Collected: | |
| Health ID: | | Received: | |
| | | Reported: | |

COMMENTS: FASTING:NO

| Test Name | In Range | Out Of Range | Reference Range | Lab |
|--------------------------|----------|--------------|-----------------|-----|
| STREPTOCOCCUS PNEUMONIAE | | | | EZ |
| AB (IGG) (23 SEROTYPES) | | | | |
| SEROTYPE 1 (1) | 0.8 | | | |
| SEROTYPE 2 (2) | 1.3 | | | |
| SEROTYPE 3 (3) | <0.3 | | | |
| SEROTYPE 4 (4) | 0.6 | | | |
| SEROTYPE 5 (5) | 0.7 | | | |
| SEROTYPE 8 (8) | 0.3 | | | |
| SEROTYPE 9 (9N) | 0.3 | | | |
| SEROTYPE 12 (12F) | <0.3 | | | |
| SEROTYPE 14 (14) | 8.6 | | | |
| SEROTYPE 17 (17F) | 1.0 | | | |
| SEROTYPE 19 (19F) | 0.7 | | | |
| SEROTYPE 20 (20) | <0.3 | | | |
| SEROTYPE 22 (22F) | <0.3 | | | |
| SEROTYPE 23 (23F) | <0.3 | | | |
| SEROTYPE 26 (6B) | 1.6 | | | |
| SEROTYPE 34 (10A) | 1.4 | | | |
| SEROTYPE 43 (11A) | <0.3 | | | |
| SEROTYPE 51 (7F) | 0.4 | | | |
| SEROTYPE 54 (15B) | 1.0 | | | |
| SEROTYPE 56 (18C) | <0.3 | | | |
| SEROTYPE 57 (19A) | <0.3 | | | |
| SEROTYPE 68 (9V) | 0.3 | | | |

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 ≥ 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.

CLIENT SERVICES:

SPECIMEN:



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This assay detects all 13 serotypes in the 13-valent conjugate vaccine, and 11 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 been validated pursuant to the CLIA regulations and is used for clinical purposes.

For additional information, please refer to:
<http://education.questdiagnostics.com/faq/FAQ181>
 (This link is being provided for informational/educational purposes only.)

SEROTYPE 70 (33F) 5.3

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 $\geq 0.3-0.50$ 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.

This assay detects all of the 23 of the serotypes in the 23-valent polysaccharide vaccine and 12 of the 13 serotypes in the 13-valent conjugate 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 used for clinical purposes.

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