

Client: Example Client ABC123 123 Test Drive Salt Lake City, UT 84108 UNITED STATES

Physician: Doctor, Example

**Patient: Patient, Example** 

DOB 2/1/2002 Gender: Unknown

**Patient Identifiers:** 01234567890ABCD, 012345

**Visit Number (FIN):** 01234567890ABCD **Collection Date:** 00/00/0000 00:00

## **Humoral Immunity Panel I**

ARUP test code 0050980

Diphtheria Antibody, IgG

>17.1 IU/mL

INTERPRETIVE INFORMATION: Diphtheria Ab, IgG

Antibody concentration of greater than 0.1 IU/mL is usually considered protective.

Responder status is determined according to the ratio of a one month post-vaccination sample to pre-vaccination concentrations of Diphtheria IgG Abs as follows:

- If the one month post-vaccination concentration is less than 1.0 IU/mL, the patient is considered to be a non-responder.
- If the post-vaccination concentration is greater than or equal to 1.0 IU/mL, a patient with a ratio of less than 1.5 is a non-responder, a ratio of 1.5 to less than 3.0, a weak responder, and a ratio of 3.0 or greater, a good responder.
- 3. If the pre-vaccination concentration is greater than 1.0 IU/mL, it may be difficult to assess the response based on a ratio alone. A post-vaccination concentration above 2.5 IU/mL in this case is usually adequate.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

Tetanus Antibody, IgG

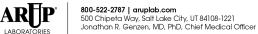
20.0 IU/mL

H=High, L=Low, \*=Abnormal, C=Critical

4848



| H=High                                  | , L=Low, *=Abnormal, C=Critical  |
|---|--|
|   |  |
| Pn serotype 9V IgG (P7,P13,P20,PNX,V15) | 55.00 ug/mL  |
| Pn serotype 9N IgG (PNX)                | 55.00 ug/mL  |
| Pn serotype 8 IgG (P20,PNX)             | 11.00 ug/mL  |
| Pn serotype 7F IgG (P13,P20,PNX,V15)    | 20.00 ug/mL  |
| Pn serotype 6B IgG (P7,P13,P20,PNX,V15) | 20.00 ug/mL  |
| Pn serotype 5 IgG (P13,P20,PNX,V15)     | 21.00 ug/mL  |
| Pn serotype 4 IgG (P7,P13,P20,PNX,V15)  | 20.00 ug/mL  |
| Pn serotype 3 IgG (P13,P20,PNX,V15)     | 20.00 ug/mL  |
| Pn serotype 1 IgG (P13,P20,PNX,V15)     | 20.00 ug/mL  |
|   | This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes. |
|   | 3. If the pre-vaccination concentration is greater than<br>1.0 IU/mL, it may be difficult to assess the response<br>based on a ratio alone. A post-vaccination<br>concentration above 2.5 IU/mL in this case is usually<br>adequate.                                   |
|   | 2. If the post-vaccination concentration is greater than<br>or equal to 1.0 IU/mL, a patient with a ratio of less<br>than 1.5 is a non-responder, a ratio of 1.5 to less<br>than 3.0, a weak responder, and a ratio of 3.0 or<br>greater, a good responder.            |
|   | <ol> <li>If the one month post-vaccination concentration is<br/>less than 1.0 IU/mL, the patient is considered a<br/>non-responder.</li> </ol>   |
|   | Responder status is determined according to the ratio of a one-month post-vaccination sample to pre-vaccination concentration of Tetanus IgG Abs as follows:   |
|   | Antibody concentration of greater than 0.1 IU/mL is usually considered protective.   |
|   | INTERPRETIVE INFORMATION: Tetanus Ab, IgG  |



| Pn serotype 12F IgG (P20,PNX)            | 55.00 ug/mL |
|--|-------------|
| Pn serotype 14 IgG (P7,P13,P20,PNX,V15)  | 55.00 ug/mL |
| Pn serotype 18C IgG (P7,P13,P20,PNX,V15) | 55.00 ug/mL |
| Pn serotype 19F IgG (P7,P13,P20,PNX,V15) | 55.00 ug/mL |
| Pn serotype 23F IgG (P7,P13,P20,PNX,V15) | 55.00 ug/mL |
| Pn Serotype Interpretation               | See Note    |



INTERPRETIVE INFORMATION: Streptococcus pneumoniae Antibodies,  ${\tt IgG}$ 

A pre- and postvaccination comparison is required to adequately assess the humoral immune response to the pure polysaccharide Pneumovax 23 (PNX) and/or the protein conjugated Prevnar 7 (P7), Prevnar 13 (P13), Prevnar 20 (P20), and Vaxneuvance (V15) Streptococcus pneumoniae vaccines. Prevaccination samples should be collected prior to vaccine administration. Postvaccination samples should be obtained at least 4 weeks after immunization. Testing of postvaccination samples alone will provide only general immune status of the individual to various pneumococcal serotypes.

In the case of pure polysaccharide vaccine, indication of immune system competence is further delineated as an adequate response to at least 50 percent of the serotypes in the vaccine challenge for those 2-5 years of age and to at least 70 percent of the serotypes in the vaccine challenge for those 6-65 years of age. Individual immune response may vary based on age, past exposure, immunocompetence, and pneumococcal serotype.

Responder Status Antibody Ratio

Nonresponder ...... Less than twofold increase and postvaccination concentration less than 1.3 ug/mL

Good responder ...... At least a twofold increase and/or a postvaccination concentration greater than or equal to 1.3 ug/mL

A response to 50-70 percent or more of the serotypes in the vaccine challenge is considered a normal humoral response.(Daly, 2014) Antibody concentration greater than 1.0-1.3 ug/mL is generally considered long-term protection.(Daly, 2015)

## References:

- 1. Daly TM, Pickering JW, Zhang X, et al. Multilaboratory assessment of threshold versus fold-change algorithms for minimizing analytical variability in multiplexed pneumococcal IgG measurements. Clin Vaccine Immunol. 2014;21(7):982-988.
- 2. Daly TM, Hill HR. Use and clinical interpretation of pneumococcal antibody measurements in the evaluation of humoral immune function. Clin Vaccine Immunol. 2015;22(2):148-152.

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Immunoglobulin G

10000 mg/dL H (Ref Interval: 768-1632)

REFERENCE INTERVAL: Immunoglobulin G

Access complete set of age- and/or gender-specific reference intervals for this test in the ARUP Laboratory Test Directory (aruplab.com).

Immunoglobulin A

1000 mg/dL H

(Ref Interval: 68-408)



|                             | REFERENCE INTERVAL: Immunoglobulin A   |  |  |
|-----------------------------|--|--|--|
|                             | Access complete set of age- and/or gender-specific reference intervals for this test in the ARUP Laboratory Test Directory (aruplab.com).  |  |  |
| Immunoglobulin M            | 1000 mg/dL H (Ref Interval: 35-263)  |  |  |
| -                           | REFERENCE INTERVAL: Immunoglobulin M   |  |  |
|                             | Access complete set of age- and/or gender-specific reference intervals for this test in the ARUP Laboratory Test Directory (aruplab.com).  |  |  |
| Immunoglobulin G Subclass 1 | 1111 mg/dL (Ref Interval: 240-1118)  |  |  |
|                             | REFERENCE INTERVAL: Immunoglobulin G Subclass 1  |  |  |
|                             | The total IgG (mg/dL) can be derived from the sum of the subclass IgG1, IgG2, IgG3, and IgG4 values. However, a confirmatory and more precise total IgG is available by the turbidimetric method of quantitation for total IgG. Refer to test Immunoglobulin G, Serum (0050350). |  |  |
|                             | Access complete set of age- and/or gender-specific reference intervals for this test in the ARUP Laboratory Test Directory (aruplab.com).  |  |  |
| Immunoglobulin G Subclass 2 | 1111 mg/dL H (Ref Interval: 124-549)   |  |  |
|                             | REFERENCE INTERVAL: Immunoglobulin G Subclass 2  |  |  |
|                             | Access complete set of age- and/or gender-specific reference intervals for this test in the ARUP Laboratory Test Directory (aruplab.com).  |  |  |
| Immunoglobulin G Subclass 3 | >220 mg/dL H (Ref Interval: 21-134)  |  |  |
|                             | REFERENCE INTERVAL: Immunoglobulin G Subclass 3  |  |  |
|                             | Access complete set of age- and/or gender-specific reference intervals for this test in the ARUP Laboratory Test Directory (aruplab.com).  |  |  |
| Immunoglobulin G Subclass 4 | 1111 mg/dL H (Ref Interval: 1-123)   |  |  |
|                             | REFERENCE INTERVAL: Immunoglobulin G Subclass 4  |  |  |
|                             | Access complete set of age- and/or gender-specific reference intervals for this test in the ARUP Laboratory Test Directory (aruplab.com).  |  |  |



|  |               | VERIFIED/REPORTED DAT | TES              |                   |
|--|---------------|-----------------------|------------------|-------------------|
| Procedure                                | Accession     | Collected             | Received         | Verified/Reported |
| Diphtheria Antibody, IgG                 | 23-241-109381 | 00/00/0000 00:00      | 00/00/0000 00:00 | 00/00/0000 00:00  |
| Tetanus Antibody, IgG                    | 23-241-109381 | 00/00/0000 00:00      | 00/00/0000 00:00 | 00/00/0000 00:00  |
| Pn serotype 1 IgG (P13,P20,PNX,V15)      | 23-241-109381 | 00/00/0000 00:00      | 00/00/0000 00:00 | 00/00/0000 00:00  |
| Pn serotype 3 IgG (P13,P20,PNX,V15)      | 23-241-109381 | 00/00/0000 00:00      | 00/00/0000 00:00 | 00/00/0000 00:00  |
| Pn serotype 4 IgG (P7,P13,P20,PNX,V15)   | 23-241-109381 | 00/00/0000 00:00      | 00/00/0000 00:00 | 00/00/0000 00:00  |
| Pn serotype 5 IgG (P13,P20,PNX,V15)      | 23-241-109381 | 00/00/0000 00:00      | 00/00/0000 00:00 | 00/00/0000 00:00  |
| Pn serotype 6B IgG (P7,P13,P20,PNX,V15)  | 23-241-109381 | 00/00/0000 00:00      | 00/00/0000 00:00 | 00/00/0000 00:00  |
| Pn serotype 7F IgG (P13,P20,PNX,V15)     | 23-241-109381 | 00/00/0000 00:00      | 00/00/0000 00:00 | 00/00/0000 00:00  |
| Pn serotype 8 IgG (P20,PNX)              | 23-241-109381 | 00/00/0000 00:00      | 00/00/0000 00:00 | 00/00/0000 00:00  |
| Pn serotype 9N IgG (PNX)                 | 23-241-109381 | 00/00/0000 00:00      | 00/00/0000 00:00 | 00/00/0000 00:00  |
| Pn serotype 9V IgG (P7,P13,P20,PNX,V15)  | 23-241-109381 | 00/00/0000 00:00      | 00/00/0000 00:00 | 00/00/0000 00:00  |
| Pn serotype 12F IgG (P20,PNX)            | 23-241-109381 | 00/00/0000 00:00      | 00/00/0000 00:00 | 00/00/0000 00:00  |
| Pn serotype 14 IgG (P7,P13,P20,PNX,V15)  | 23-241-109381 | 00/00/0000 00:00      | 00/00/0000 00:00 | 00/00/0000 00:00  |
| Pn serotype 18C IgG (P7,P13,P20,PNX,V15) | 23-241-109381 | 00/00/0000 00:00      | 00/00/0000 00:00 | 00/00/0000 00:00  |
| Pn serotype 19F IgG (P7,P13,P20,PNX,V15) | 23-241-109381 | 00/00/0000 00:00      | 00/00/0000 00:00 | 00/00/0000 00:00  |
| Pn serotype 23F IgG (P7,P13,P20,PNX,V15) | 23-241-109381 | 00/00/0000 00:00      | 00/00/0000 00:00 | 00/00/0000 00:00  |
| Pn Serotype Interpretation               | 23-241-109381 | 00/00/0000 00:00      | 00/00/0000 00:00 | 00/00/0000 00:00  |
| Immunoglobulin G                         | 23-241-109381 | 00/00/0000 00:00      | 00/00/0000 00:00 | 00/00/0000 00:00  |
| Immunoglobulin A                         | 23-241-109381 | 00/00/0000 00:00      | 00/00/0000 00:00 | 00/00/0000 00:00  |
| Immunoglobulin M                         | 23-241-109381 | 00/00/0000 00:00      | 00/00/0000 00:00 | 00/00/0000 00:00  |
| Immunoglobulin G Subclass 1              | 23-241-109381 | 00/00/0000 00:00      | 00/00/0000 00:00 | 00/00/0000 00:00  |
| Immunoglobulin G Subclass 2              | 23-241-109381 | 00/00/0000 00:00      | 00/00/0000 00:00 | 00/00/0000 00:00  |
| Immunoglobulin G Subclass 3              | 23-241-109381 | 00/00/0000 00:00      | 00/00/0000 00:00 | 00/00/0000 00:00  |
| Immunoglobulin G Subclass 4              | 23-241-109381 | 00/00/0000 00:00      | 00/00/0000 00:00 | 00/00/0000 00:00  |

## END OF CHART