TEST CHANGE

Humoral Immunity Panel II

0050981, HUMPAN II

Specimen Requirements:	
Patient Preparation:	
Collect:	Serum separator tube.
Specimen Preparation:	Transfer two 1 mL aliquots of serum to individual ARUP standard transport tubes.~~Standard Transport Tubes.~~ (Min: 0.1 mL/aliquot)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Plasma.
Remarks:	
Stability:	After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 60 days~~1 year~~ (avoid repeated freeze/thaw cycles).
Methodology:	Semi-Quantitative Multiplex Chemiluminescent Immunoassay~~Bead Assay~~
Performed:	Mon-Sat
Reported:	1-4 days
Note:	
CPT Codes:	86317 x16
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

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. ~~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.~~

Diphtheria Antibody, IgG	Antibody concentration of >0.1 IU/mL is usually considered protective.
Tetanus Antibody, IgG	Antibody concentration of >0.1 IU/mL is usually considered protective.

Reference Interval: