TEST CHANGE

Streptococcus pneumoniae Antibodies, IgG (23 Serotypes)

2005779, PNEUMO 23

Specimen Requirements:	
Patient Preparation:	
Collect:	Serum separator tube. Postimmunization~~Post-immunization~~ specimen should be drawn 30 days after immunization and, if shipped separately, must be received within 60 days of preimmunization~~pre-immunization~~ specimen.
Specimen Preparation:	Separate serum from cells ASAP or within 2 hours of collection. Transfer 1.5 mL serum to an ARUP standard transport tube~~Standard Transport Tube~~. (Min: 0.25 mL) MARK SPECIMENS CLEARLY AS "PRE" OR "POST" SO SPECIMENS WILL BE SAVED AND TESTED SIMULTANEOUSLY~~.~~
Transport Temperature:	Refrigerated. "Pre" and "post" pneumococcal vaccine specimens can be submitted separately or together for testing.
Unacceptable Conditions:	Plasma or other body fluids. Contaminated, hemolyzed, or severely lipemic specimens.
Remarks:	
Stability:	After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 60 days~~1 year~~ (avoid repeated freeze/thaw cycles).
Methodology:	Quantitative Multiplex Chemiluminescent Immunoassay~~Bead Assay~~
Performed:	Tue, Fri
Reported:	1-5 days
Note:	
CPT Codes:	86317 x23
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 . . . . . .Non-Responder	Less than twofold increase and postvaccination concentration less2-fold
Weak Responder . . . . . 2-fold to 4-fold	
Good Responder . . . . . Greater	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/mL4-fold	

A response to 50-70 percent or more of the serotypes in the vaccine challenge is considered a normal humoral response. (Daly, 2014)response1. Antibody concentration greater than 1.0- -1.3 ugug/mL is generally considered long-term protection. (Daly, 2015)protection2.

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.

Reference Interval: