TEST CHANGE

Humoral Immunity Panel I

0050980, HUMPAN I

Specimen Requirements:	
Patient Preparation:	
Collect:	Serum separator tube.
Specimen Preparation:	Separate serum from cells ASAP or within 2 hours of collection. Transfer 5.5 mL serum to ARUP standard transport tubes.~~Standard Transport Tubes.~~ (Min: 2.5 mL total)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Plasma.
Remarks:	
Stability:	After separation from cells: Ambient: Unacceptable; Refrigerated: 14 days; Frozen: 60 days~~6 months~~ (avoid repeated freeze/thaw cycles). (Refer to individual components for further information.)
Methodology:	Quantitative Immunoturbidimetry/Semi-Quantitative Multiplex Chemiluminescent Immunoassay~~Bead Assay~~
Performed:	Mon-Sat
Reported:	1-4 days
Note:	
CPT Codes:	86317 x16; 82787 x4; 82784 x3
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:

Test Number	Components	Reference Interval
	Immunoglobulin A	
		Age: Reference Interval (mg/dL) 0-2 years: 2-126 3-4 years: 14-212 5-9 years: 52-226 10-14 years: 42-345 15-18 years: 60-349 19 years and older: 68-408
	Immunoglobulin G	
		Age: Reference Interval (mg/dL) 0-2 years: 242-1108 3-4 years: 485-1160 5-9 years: 514-1672 10-14 years: 581-1652 15-18 years: 479-1433 19 years and older: 768-1632
	Immunoglobulin M	
		Age: Reference Interval (mg/dL) 0-2 years: 21-215 3-4 years: 26-155 5-9 years: 26-188 10-14 years: 47-252 15-18 years: 26-232 19 years and older: 35-263
	Immunoglobulin G Subclass 1	
		Age: Reference Interval (mg/dL) 0-2 years: 167-900 3-4 years: 313-941 5-9 years: 363-1276 10-14 years: 316-1076 15-18 years: 325-894 19 years and older: 240-1118
	Immunoglobulin G Subclass 2	

		Age	Reference Interval (mg/dL)	
		0-2 years	55-359	
		3-4 years	72-287	
		5-9 years	27-398	
		10-14 years	86-509	
		15-18 years	156-625	
		19 years and older	124-549	
	Immunoglobulin G Subclass 3			
		Age	Reference Interval (mg/dL)	
		0-2 years	34-85	
		3-4 years	25-117	
		5-9 years	17-169	
		10-14 years	14-201	
		15-18 years	34-246	
		19 years and older	21-134	
	Immunoglobulin G Subclass 4			
		Age	Reference Interval (mg/dL)	
		0-2 years	1-34	
		3-4 years	1-65	
		5-9 years	0-168	
		10-14 years	1-103	
		15-18 years	2-170	
		19 years and older	1-123	