

Humoral Immunity Status Survey 7

Reporting Title: Humoral Immunity Status Survey 7

Performing Location: Focus Diagnostics,

Specimen Requirements:

Draw blood in a plain red-top tube. Spin down and send 4 mL of serum refrigerated.

Note: Serum gel tube is acceptable

Specimen Type	Temperature	Time	
Serum	Refrigerated (preferred)	14 days	
	Ambient	7 days	
	Frozen	30 days	

Result Codes:

Result ID	Reporting Name	Туре	Unit	LOINC®
Z0685	Diphtheria Antitoxoid, ELISA	Alphanumeric		
Z0687	Tetanus Antitoxoid Ab, ELISA	Alphanumeric		
Z0453	IgA, Neph	Alphanumeric		
Z0454	IgG, Neph	Alphanumeric		
Z0455	IgM, Neph	Alphanumeric		
Z0686	Serotype 1 (1)	Alphanumeric		
Z0447	Serotype 3 (3)	Alphanumeric		
Z0448	Serotype 9 (9N)	Alphanumeric		
Z0449	Serotype 14 (14)	Alphanumeric		
Z0450	Serotype 19 (19F)	Alphanumeric		
Z0451	Serotype 23 (23F)	Alphanumeric		
Z0452	Serotype 26 (6B)	Alphanumeric		
Z0456	IgG Subclass 1	Alphanumeric		
Z0457	IgG Subclass 2	Alphanumeric		
Z0458	IgG Subclass 3	Alphanumeric		
Z0459	IgG Subclass 4	Alphanumeric		
Z0460	Total IgG	Alphanumeric		

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Result ID	Reporting Name	Туре	Unit	LOINC®
Z0461	IgE, NEPH	Alphanumeric		

Components:

Test ID	Reporting Name	CPT Units	CPT Code	Always Performed	Orderable Separately
FDA	Diphtheria Antitoxoid, ELISA	1	86648	Yes	No
FFTET	Tetanus Antitoxoid, ELISA	1	86774	Yes	No
FIGAN	IgA, Neph	1	82784	Yes	No
FIGGN	IgG, Neph	1	82784	Yes	No
FIGMN	IgM, Neph	1	82784	Yes	No
Billing only	Immunoglobulin subclasses	4	82787		
Billing only	Total IgG	1	82784		
Billing only	Strep Pneumoniae IgG Ab	7	86317		
FSP7	Strep Pneumoniae IgG Ab(7Sero),MAID			Yes	No
FIG	IgG Subclasses, NEPH			Yes	No
FIGEN	IgE, NEPH	1	82785	Yes	No

Reference Values:

DIPHTHERIA ANTITOXOID, ELISA

REFERENCE RANGE: > or =0.01 IU/mL (Post-Vaccination)

INTERPRETIVE CRITERIA:

<0.01 IU/mL Nonprotective Antibody Level > or =0.01 IU/mL Protective Antibody Level

A minimal four-fold increase between pre-immune and post-immunization sera is considered a normal response to diphtheria toxoid.

STREPTOCOCCUS PNEUMONIAE IgG AB (7 SEROTYPES), MAID

SEROTYPE 1 (1) mcg/mL SEROTYPE 3 (3) mcg/mL SEROTYPE 9 (9N) mcg/mL SEROTYPE 14 (14) mcg/mL SEROTYPE 19 (19F) mcg/mL SEROTYPE 23 (23F) mcg/mL



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SEROTYPE 26 (6B) mcg/mL

Note: Serotype designations are American nomenclature, with Danish nomenclature in parentheses.

Studies from the 1980's using radioimmunoassay suggested that vaccine-induced S. pneumoniae type-specific antibody levels of approximately 2.0 mcg/mL were protective against invasive pneumococcal disease. Newer methods (ELISA and multiplexed immunoassay) incorporating an adsorption step to remove cross-reactive antibodies yield results that are comparable to each other, but are lower than those obtained with the original radioimmunoassay. Rigorous studies of protective antibody levels as determined by the newer methods have not been performed. In addition to antibody quantity, protection also depends on antibody avidity and opsonophagocytic activity.

Evaluation of the response to pneumococcal vaccination is best accomplished by comparing pre-vaccination and post-vaccination antibody levels. A 2- to 4-fold increase in type-specific antibodies measured 4-6 weeks after vaccination is expected in immuno-competent adults. The number of serotypes for which a 2- to 4-fold increase is observed varies greatly among individuals; a consensus panel has suggested that individuals older than 5 years should respond to at least approximately 70% of pneumococcal serotypes. Adults >65 years old may exhibit a smaller (<2-fold) increase in type-specific antibody levels.

This test was developed and its performance characteristics have been determined by Focus Diagnostics. Performance characteristics refer to the analytical performance of the test.

TETANUS ANTITOXOID, ELISA

REFERENCE RANGE: > or =0.50 IU/mL (Post-Vaccination)

INTERPRETIVE CRITERIA:

<0.05 IU/mL Nonprotective Antibody Level 0.05 - 0.49 IU/mL Indeterminate for protective antibody > or =0.50 IU/mL Protective Antibody Level

A minimal four-fold increase between pre-immunization and post-immunization sera is considered a normal response to tetanus toxoid. Levels greater than or equal to 0.50 IU/mL are generally considered protective, whereas levels less than 0.05 IU/mL indicate a lack of protective antibody. Levels between 0.05 and 0.49 IU/mL are indeterminate for the presence of protective antibody and may indicate a need for further immunization to tetanus toxoid.

IgA, NEPH IgG, NEPH IgM, NEPH

REFERENCE RANGES: mg/dL

IMMUNOGLOBULINS: IgG IgA IgM

CORD BLOOD 510 - 1275 0 0 - 19
1 - 3 Months 127 - 553 0 - 19 10 - 78
4 - 6 Months 119 - 425 2 - 35 15 - 72
7 - 14 Months 230 - 808 10 - 50 21 - 109
15 - 35 Months 365 - 1063 17 - 70 23 - 134
3 - 12 Years 467 - 1275 23 - 208 27 - 184
ADULT 680 - 1445 70 - 407 33 - 248
CSF 0.0 - 6.6

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IgG SUBCLASSES, NEPH

Reference ranges: mg/dL

Age	lgG1	lgG2 lg	gG3 lg	gG4 T	otal IgG
(years)					
0-2 years	170-950	21-440	13-69	1-120	230-1400
2-4 years	290-1065	28-315	3-71	1-90	353-1350
4-6 years	330-1065	56-345	7-126	2-116	463-1504
6-8 years	225-1100	42-375	9-107	1-138	288-1374
8-10 years	390-1235	61-430	10-98	1-95	390-1653
10-12 years	380-1420	73-455	16-19	4 1-153	3 579-1742
12-14 years	165-1440	71-460	11-178	8 1-143	3 772-1793
14-18 years	155-1020	43-495	7-209	4-163	223-1540
Adult	240-1117	124-549	21-13	4 7-89	680-1445

Decreased or absent IgG subclass levels have been associated with recurrent pyogenic infections and repeated respiratory tract infections. IgG2 deficiency is associated with IgA deficiency, and with decreased immune responses to carbohydrate antigens (for example, pneumococcal and Haemophilus influenzae polysaccharides). A decreased level of a specific IgG subclass may not be reflected in the total IgG quantitation.

IgE, NEPH

IgE levels are significantly elevated in most patients with allergic rhinitis, extrinsic urticaria, and atopic eczema. Elevated IgE levels are also found in parasitic diseases and some types of immunodeficiency diseases (Wiskott-Aldrich Syndrome, DiGeorge syndrome, and hyper-IgE syndrome).

Test Performed by Focus Diagnostics, Inc. 5785 Corporate Avenue Cypress, CA 90630-4750