Test Definition: FHIME

Humoral Immunity Evaluation Panel

Reporting Title: Humoral Immunity Evaluation Panel
Performing Location: Focus Diagnositics, Inc.

Specimen Requirements:

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

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

Result Codes:

Result ID	Reporting Name	Type	Unit	LOINC®
Z0688	Diphtheria Antitoxoid	Alphanumeric		In Process
Z0689	H. influenzae Type B IgG	Alphanumeric		In Process
Z0690	Tetanus Antitoxoid	Alphanumeric		In Process
Z0463	Serotype 1 (1)	Alphanumeric		In Process
Z0464	Serotype 3 (3)	Alphanumeric		In Process
Z0465	Serotype 14 (14)	Alphanumeric		In Process
Z0466	Serotype 19 (19F)	Alphanumeric		In Process
Z0467	Serotype 23 (23F)	Alphanumeric		In Process
Z0468	Serotype 51 (7F)	Alphanumeric		In Process

Components:

Test ID	Reporting Name	CPT Units	CPT Code	Always Performed	Orderable Separately
Billing only	Immunoassay for infectious agent Ab	6	86317		
Billing only	Tetanus Antitoxoid	1	86774		
Billing only	Haemophilus Inf B Vaccine	1	86684		
Billing only	Diphtheria Antitoxoid	1	86648		

Reference Values:

Humoral Immunity Evaluation

Diphtheria Antitoxoid

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

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

Haemophilus influenzae Type B Antibody (IgG)

Reference Range: > or =1.00 mcg/mL post-vaccination (protective level)

Interpretive Criteria:
<0.15 mcg/mL Nonprotective Antibody Level
0.15 - 0.99 mcg/mL Indeterminate for protective antibody
> or =1.0 mcg/mL Protective Antibody Level

IgG antibody to polyribosylribitol phosphate (PRP), the capsular polysaccharide of Haemophilus influenzae type b, is measured in micrograms/mL (mcg/mL), based on correlations with a reference Farr radioimmunoprecipitation assay (RIA). The exact level of antibody needed for protection from infection has not been clarified; values ranging from 0.15 mcg/mL to 1.0 mcg/mL have been reported. A four-fold increase in the PRP IgG antibody level between pre-vaccination and post-vaccination sera is considered evidence of effective immunization.

Tetanus Antitoxoid

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

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.

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Streptococcus Pneumoniae IgG Ab (6 Serotypes), MAID

Serotype 1 (1)	mcg/mL
Serotype 3 (3)	mcg/mL

Serotype 14 (14)	mcg/mL
Serotype 19 (19F)	mcg/mL
Serotype 23 (23F)	mcg/mL
Serotype 51 (7F)	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.

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Test Performed by: Focus Diagnostics, Inc.
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