TEST CHANGE

Diphtheria, Tetanus, and H. Influenzae b Antibodies, IgG

0050779, DTH

Specimen Requirements:	
Patient Preparation:	
Collect:	Serum separator tube or red tube.
Specimen Preparation:	Transfer 1.5 mL serum to an ARUP standard transport tube~~Standard Transport Tube~~. (Min: 0.45 mL) Acute and convalescent specimens must be labeled as such. Clearly mark specimens as "Pre-Vaccine" or "Post-Vaccine."~~.~~ Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt of the acute specimens.
Transport Temperature:	Refrigerated.
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: 1 year (avoid repeated freeze/thaw cycles)
Methodology:	Quantitative Multiplex Bead Assay
Performed:	Sun-Sat
Reported:	1-3 days
Note:	
CPT Codes:	86317 x3
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Responder status is determined according to the ratio of a one-month, post-vaccination sample to pre-vaccination concentration of IgG antibodies as follows:

Diphtheria and tetanus:
1. If the post-vaccination concentration is less than 1.0 IU/mL, the patient is considered a nonresponder.
2. If the post-vaccination concentration is greater than or equal to 1.0 IU/mL, a patient with a ratio of less than 1.5 is a nonresponder, and a ratio of 1.5 to less than 3.0 is a weak responder, and a ratio of 3.0 or greater is a good responder.
3. If the pre-vaccination concentration is greater than 1.0 IU/mL, it may be difficult to assess the

response based on a ratio alone. A post-vaccination concentration above 2.5 IU in this case is usually adequate.

Haemophilus influenza B:
1. If the post-vaccination concentration is < 3.0 ~~µg/mL~~, the patient is considered to be a nonresponder.
2. If the post-vaccination concentration is 3.0 ~~µg/mL~~, a patient with a ratio of 4 is a good responder, a ratio of 2-4 is weak responder, and a ratio of < 2 is considered a nonresponder.

~~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.~~

Reference Interval:

Diphtheria and tetanus:
Antibody concentration of > 0.1 IU/mL is usually considered protective for diphtheria or tetanus.

Haemophilus influenzae type B:
< 1.0 µg/mL = Antibody concentration not protective.
> 1.0 µg/mL = Antibody to *H. influenzae* type B detected. Suggestive of protection.