

Overview

Useful For

Assessing a patient's immunological (IgG) response to *Haemophilus influenzae* type B (HIB) vaccine

Assessing immunity against HIB

Aiding in the evaluation of immunodeficiency when the patient is tested pre- and post-vaccination

Method Name

Enzyme Immunoassay (EIA)

NY State Available

Yes

Specimen

Specimen Type

Serum

Specimen Required

Supplies: Sarstedt Aliquot Tube 5 mL (T914)

Collection Container/Tube:

Preferred: Serum gel

Acceptable: Red top

Submission Container/Tube: Plastic vial

Specimen Volume: 0.5 mL Serum

Collection Instructions: Centrifuge and aliquot serum into a plastic vial.

Forms

If not ordering electronically, complete, print, and send [Infectious Disease Serology Test Request](#) (T916) with the specimen.

Specimen Minimum Volume

Serum: 0.4 mL

Reject Due To

| | |
|-----------------|--------|
| Gross hemolysis | Reject |
|-----------------|--------|

| | |
|------------------|--------|
| Gross lipemia | Reject |
| Heat-inactivated | Reject |

Specimen Stability Information

| Specimen Type | Temperature | Time | Special Container |
|---------------|--------------------------|--------|-------------------|
| Serum | Refrigerated (preferred) | 7 days | |
| | Frozen | 7 days | |

Clinical & Interpretive

Clinical Information

Haemophilus influenzae type B (HIB) is an encapsulated Gram-negative cocco-bacillary bacterium that can cause devastating disease in unvaccinated young children, including meningitis, bacteremia, cellulitis, epiglottitis, pneumonia, and septic arthritis. The outer surface of *H influenzae* is covered by a polyribosyl-ribitol-phosphate (PRP) polysaccharide that is responsible for both pathogenicity and immunity. There are currently 6 recognized PRP serotypes, referred to as a through f, among which serotype b, prior to the availability of a vaccine, accounted for up to 95% of infections. There are also unencapsulated or nontypable strains.

Prior infection with *H influenzae* is associated with protective immunity against reinfection. One of the great advances in modern medicine has been the development of an effective vaccine against HIB, which is based on use of an unconjugated, purified PRP antigen. A patient's immunological response to HIB vaccine can be determined by measuring anti-HIB IgG antibody levels using a standardized enzyme immunoassay (EIA). Antibody levels of 1 mg/L or more at least 3 weeks after vaccination has been correlated with long-term protective immunity.

Reference Values

> or =0.15 mg/L

Reference values apply to all ages.

Interpretation

An anti-*Haemophilus influenzae* type B (HIB) IgG antibody concentration of 0.15 mg/L is generally accepted as the minimum level for protection at a given time; however, it does not confer long-term protection. A study from Finland suggested that the optimum protective level is 1.0 mg/L postimmunization.⁽¹⁾ Furthermore, studies have shown that the response to HIB vaccine is age-related.

Cautions

This assay does not provide diagnostic proof of the presence or absence of immune deficiency. Results must be confirmed by clinical findings and other laboratory tests.

Clinical Reference

1. Peltola H, Kayhty H, Virtanen M, Makela PH. Prevention of *Haemophilus influenzae* type B bacteremic infections with the capsular polysaccharide vaccine. N Engl J Med. 1984;310(24):1561-1566. doi:10.1056/NEJM198406143102404

2. Berger M. Immunoglobulin G subclass determination in diagnosis and management of antibody deficiency syndromes. *J Pediatr.* 1987;110(2):325-328. doi:10.1016/s0022-3476(87)80182-8
3. Murphy TF. *Haemophilus* species, including *H influenzae* and *H ducreyi* (Chancroid). In: Bennett JE, Dolin R, Blaser MJ, eds. *Mandell, Douglas, and Bennett's Principles and Practice of Infectious Diseases.* 9th ed. Elsevier; 2020:2743-2752

Performance

Method Description

Microwells are precoated with the *Haemophilus influenzae* type B (HIB) capsular polysaccharide antigen conjugated to human serum albumin. The calibrators, controls, and diluted patient specimens are added to the wells and antibodies recognizing the HIB antigen bind during the first incubation. After washing the wells to remove all unbound proteins, purified peroxidase-labeled rabbit antihuman IgG (gamma chain specific) conjugate is added. The conjugate binds to the captured human antibody and the excess unbound conjugate is removed by a further wash step. The bound conjugate is visualized with 3,3',5,5' tetramethylbenzidine (TMB) substrate, which gives a blue reaction product, the intensity of which is proportional to the concentration of antibody in the specimen. Phosphoric acid is added to each well to stop the reaction. This produces a yellow end point color, which is read at 450 nm. (Madore DV, Anderson P, Baxter BD, et al. Interlaboratory study evaluating quantitation of antibodies to *Haemophilus influenzae* type B polysaccharide by enzyme-linked immunosorbent assay. *Clin Diagn Lab Immunol.* 1996;3[1]:84-88. doi:10.1128/cdli.3.1.84-88.1996; Bennett JE, Dolin R, Blaser MJ, eds. *Mandell, Douglas, and Bennett's Principles and Practice of Infectious Diseases.* 9th ed. Elsevier; 2020; Package insert: VaccZyme Human Anti-*Haemophilus influenzae* type b Enzyme Immunoassay Kit. The Binding Site Group Ltd; V E016; 03/27/2015)

PDF Report

No

Day(s) Performed

Monday, Wednesday, Friday

Report Available

Same day / 1 to 4 days

Specimen Retention Time

2 weeks

Performing Laboratory Location

Mayo Clinic Laboratories - Rochester Superior Drive

Fees & Codes

Fees

- Authorized users can sign in to [Test Prices](#) for detailed fee information.

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- Clients without access to Test Prices can contact [Customer Service](#) 24 hours a day, seven days a week.
 - Prospective clients should contact their account representative. For assistance, contact [Customer Service](#).

Test Classification

This test has been cleared, approved, or is exempt by the US Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information

86684

LOINC® Information

| Test ID | Test Order Name | Order LOINC® Value |
|---------|-------------------------------------|--------------------|
| HIBSG | Haemophilus influenzae B Ab, IgG, S | 11257-3 |

| Result ID | Test Result Name | Result LOINC® Value |
|-----------|-------------------------------------|---------------------|
| HIBSG | Haemophilus influenzae B Ab, IgG, S | 11257-3 |