

## POOLED HUMAN COMPLEMENT MENINGOCOCCAL BACTERICIDAL ACTIVITY ASSAY

### Technology Summary

Sera from blood is processed and stored to preserve the activities of the complement system, a segment of the immune system that helps antibodies fight off infections and destroy substances that are foreign within a body. There are two complement functional tests: an intrinsic killing assay and the baby rabbit complement serum bactericidal assay (rSBA). There is a need for the development of a reliable human SBA. However, challenges exist due to the difficulty in obtaining suitable human complement (hC) proteins and the variability of the assay results due to the individual sourcing of the complement proteins.

To address these limitations, FDA researchers have developed a method to screen and pool hC sources from healthy donors to produce reliable and reproducible results. Confirmation studies have been completed using this method to assess meningococcal serogroup A vaccines in adults and toddlers. Active sera meeting the screening criteria were pooled (five or more individual donors).

### Potential Commercial Applications

- Development of hSBAs for vaccine development

### Competitive Advantages

- A method to utilize the human complement system to produce reliable, uniform results
- A method to standardize data output of immunological responses in vaccine studies

### Development Stage:

- Proof-of-concept studies to assess the immune response of PsA-TT (MenAfriVac) vaccine

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### Publications:

- Price, G., et. al. Human Complement Bactericidal Responses to a Group A Meningococcal Conjugate Vaccine in Africans and Comparison to Responses Measured by 2 Other Group A Immunoassays. Clin Infect Dis. 2015 Nov 15;61 Suppl 5:S554-62. PMID: [26553688](#)
- Bash, M., et. al. Development and use of a serum bactericidal assay using pooled human complement to assess responses to a meningococcal group A conjugate vaccine in African toddlers. Clin Vaccine Immunol. 2014 May;21(5):755-61. PMID: [24671551](#)
- Findlow, H. et. al. Investigation of Different Group A Immunoassays following One Dose of Meningococcal Group A Conjugate Vaccine or A/C Polysaccharide Vaccine in Adults. Clin Vaccine Immunol. 2009 Jul;16(7):969-77. PMID: [19474264](#)

**Product Area:** Method, immunoassay, vaccine development, assay development

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