

Human Serum for Use as Complement: Collection from Previously Identified Donors (Sanofi Study)

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Synopsis:

Complement-mediated bactericidal activity is the hallmark of protective immunity against disease caused by the gram-negative bacteria, *Neisseria meningitidis*. This organism is an important cause of bacterial meningitis and sepsis in infants, children and young adults. Despite the availability of antimicrobial therapy, mortality and morbidity from meningococcal disease remain high and vaccines for prevention of meningococcal disease are considered an important health priority.

A number of meningococcal vaccines are in late-stage clinical testing. For most new vaccines, efficacy for prevention of disease is proven by conducting a phase 3 randomized clinical trial where the incidence of disease in the vaccinated group is compared to that in controls given a placebo or irrelevant vaccine. However, because of the strong scientific link between serum bactericidal activity, serologic responses can serve as a surrogate of meningococcal vaccine efficacy, and can be used as a basis of vaccine licensure.

The principal serologic assay for inferring meningococcal vaccine efficacy is serum bactericidal antibody. In this assay, dilutions of a serum from a vaccinated child are mixed with bacteria and a source of complement to determine the ability of vaccine-induced antibodies to elicit complement-mediated bacteriolysis. Therefore, a suitable source of human complement that lacks meningococcal antibodies is needed. Previously we screened 300 healthy adults and identified such donors from whom blood is collected on a regular basis. This study allows for the collection of complement in sufficient quantity to conduct serological testing of vaccine candidates in all serogroups.

Aim. The overall goal is to obtain sera from healthy adults that are suitable as complement sources for performing meningococcal bactericidal, opsonic and complement deposition assays. These individuals have been identified as suitable complement sources in previous studies. They will be asked to provide approximately 1 unit of blood (450 ml) every 2 to 3 months with the overall objective of collecting approximately 2 liters of serum suitable for assaying bactericidal antibody to meningococcal strains representative of each of the four capsular groups (A, C, Y and W-135).