CEPI

Product Profile for Sourcing of Serum from Recovered Patients after Rift Valley fever (RVF) Disease

Annex I

Background

This Product Profile defines the necessary characteristics for the sourcing of serum from recovered patients after Rift Valley fever (RVF) disease. The sourced and selected serum collection is intended for the development of an International Antibody Standard for use as reference in various assays for evaluation of RVF vaccines and immune responses towards them.

Table I. Product Profile for Sourcing of Serum from Recovered Patients after RVF Disease

Category	Minimal	Preferred	Evidence required
Origin	Undiluted sera from human recovered patients diagnosed with RVF in one geographic area The serum must not be pooled	Undiluted sera from several human survivors diagnosed with RVF in two or more geographical areas. The serum must not be pooled	Required: country of origin; ethical approval and informed consent forms (signed or equivalent). If available: Description of clinical illness; diagnostic details; time between discharge and sampling; virus strain identity or sequence data.
Product characteristic	Serum confirmed to contain antibodies against RVF	Serum analyzed and confirmed with high antibody titer and neutralizing activity against RVF virus and/or pseudo type virus	Describe laboratory capacity and assays performed on site Alternatively, which type of assays will be performed on samples at other sites.
Volume of serum collected per participant	Minimum 10 mL of serum	100 mL or more of serum	Confirm and describe if collection is projected to be done by blood collection or plasmapheresis
Total volume of serum collection	500 mL	Collection from more than one site, 500 mL or more from each site; 2.5-liter total volume	Confirm and describe
Safety	Laboratory-confirmed absence of RVF virus through accepted methods (RT-PCR)	Also tested for other blood borne pathogens and possible contaminants such as HIV, HCV and HBV.	Describe measures taken and methods to be used. If considering pathogen inactivated sera, then it needs to be shown that it doesn't affect antibody function.