Immuno Flow Through (IFT) Assays for Anthrax

Bacillus anthracis, the causative agent of anthrax, is a large, gram-positive, non-motile, spore-forming rod shaped bacterium. Besides being one of the most important biological warfare agents, it causes public health problems also in both animals as well in human in countries with warm climate. Human anthrax has three major clinical forms: cutaneous, inhalation, and gastrointestinal. Cutaneous anthrax is a result of introduction of the spore through the skin; inhalation anthrax, through the respiratory tract; and gastrointestinal anthrax, by ingestion. A virulent *B. anthracis* strain harbours two plasmids, pXO1 and pXO2, which contain genes to produce the tripartite toxins, namely protective antigen (PA), lethal factor (LF) and edema factor (EF), and a poly-γ-D-glutamic acid capsule, respectively. After anthrax infection, antibodies against PA are produced in human or animals which act as specific detection marker for anthrax infection. If untreated, anthrax in all forms can lead to septicemia and death. Early treatment of cutaneous anthrax is usually curative, and early treatment of all forms is important for recovery.

Human Anthrax IgG ELISA is a standard technique used for evaluation of patient's exposure to Anthrax or its immune status. The present test is rapid and field based test which determines the antibodies (IgG) against Protective antigen (PA) of *Bacillus anthracis* in human or animal serum or plasma.

The kit is based broadly on principle of Indirect ELISA. Patient serum/plasma is added to the antigen (PA) pre-coated membrane. Anti-PA antibodies, if present in the sample, bind to the antigen. All unbound materials are washed away. The colloidal gold conjugate is added to bind to the Antibody-antigen complex, if present. Development of brown color at the specific spot confirms the presence of anthrax specific antibody in the sample. The intensity of color developed depends on the amount of antibodies present in the sample.

The Licensee Industry shall have to obtain the necessary approval for manufacturing from the state authorities for its production.