

ELISA and Immuno Flow Through (IFT) Assays for Human Brucellosis

Brucellosis is a disease caused by bacteria that belonging to the genus *Brucella* that is gram negative, facultative and intracellular. It is an emerging zoonosis and economically important infection of human and livestock with worldwide distribution. The human infection is known to occur through consumption of infected raw milk, milk products and undercooked or raw meat. The exposure to infected aerosol by abattoir workers, veterinarians and laboratory technicians can result in transmission of this disease to humans. *Brucella* spp particularly *B. melitensis*, *B. abortus* and *B. suis* represents a significant and *B. abortus* is mostly encountered in animals. Several serological tests are used in the diagnosis of human brucellosis, like Rose bengal plate agglutination test (RBPT), Standard tube agglutination test (STAT), Coombs test, 2-Merceptoethanol (2-ME), Complement fixation test (CFT), Enzyme linked immunosorbent assay (ELISA) and FPA. Detection of antibodies against *Brucella* species using lipopolysaccharide (LPS) is found satisfactory for diagnosis of the disease but mostly shows cross reactivity with other closed related bacterial species. Indirect plate ELISA, using recombinant antigen of *Brucella* species is found to be a more sensitive, economical and rapid test for screening of human brucellosis under field and laboratory conditions.

This ELISA and Immuno Flow Through (IFT) test systems are based upon the reaction of primary antibodies present in the serum samples with the recombinant *Brucella* antigen adsorbed on the polystyrene surface in plate ELISA and on nitrocellulose membrane in case of IFT. The unbound immunoglobulins were washed off in the washing step after incubation with serum sample. In the next step an enzyme/gold labelled anti-human globulin (conjugate) binds to the antigen-antibody complex and revealed with development of brown dot in IFT and as blue colour in plate ELISA. This ELISA system on microtitre plate will be highly useful in rapid screening of large number of samples for the diagnosis of human brucellosis in the endemic areas. The flow through format is a rapid, point of care bed side test that can be used for the diagnosis of Brucellosis. As on date no indigenous ELISA or IFT test for human brucellosis is available and these tests will be replacement for the agglutination tests that lack in sensitivity in specificity. Further the highly expensive imported tests can be replaced with these low cost indigenous tests.

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