Technologies available at ICAR-NIVEDI for Commercialization

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1 Protein-G based indirect ELISA kit for Bovine Brucellosis

2 Indirect ELISA kit for Sheep and Goat Brucellosis

3 Indirect ELISA assay for population survey of bluetongue

4 IBR Avidin Biotin ELISA (AB ELISA)

5 Indirect ELISA for detection of CSFV in pigs (CSF Ag Check kit)

6 PPR Ab Chek kit (PPR Avidin-Biotin recombinant competitive ELISA (PPR ABrC-ELISA)

Protein-G based indirect ELISA kit for Bovine Brucellosis

- **Problem Description:**

Brucellosis in Indian livestock is responsible for a median loss of US $ 3.4 billion/annum (INR 22554 crores) and it is also well-known zoonotic disease. Veterinary institutions were procuring imported ELISA kits for brucellosis surveillance/ diagnosis till the year 2012 as indigenously developed surveillance test kits were not available in India. The screening and diagnosis using imported ELISA kits results in increased testing cost/ sample and it has direct impact on national exchequer. Hence, research was initiated to develop indirect ELISA to make it available locally at much lesser cost than imported kits.:

- **Solution Description:**

India has huge bovine population and brucellosis is considered second most important disease of economic importance after FMD. To screen huge bovine population against brucellosis, ELISA diagnostic kit was standardized, evaluated and validated. The kit has 98% and 92% sensitivity and 95% and 98% specificity in cattle and buffaloes, respectively. The patent has been obtained for the kit [Patent No. 335659 dated 20.04.2020]. A total of 298 kits were supplied to 60 veterinary institutions from the year 2012 to till date with the limited laboratory scaling facility. ICAR –NIVEDI Protein-G based iELISA kits are very popular in the country and these kits have facilitated brucellosis screening in1.60 lakh bovines in various institutions. The NIVEDI-iELISA kit cost / sample testing is approximately Rs 35.10 (in duplicate samples) against Rs 178.26/ sample by imported ELISA kits (in duplicate samples).

Indirect ELISA kit for Sheep and Goat Brucellosis

- **Problem Description:**

Brucellosis in Indian livestock is responsible for a median loss of US $ 3.4 billion/annum (INR 22554 crores) infecting multiple livestock species including sheep and goats. The international health agencies recommend ELISA tests with a high degree of sensitivity and specificity for surveillance of brucellosis. Large number of institutions in the country were procuring OIE recommended imported ELISA kits for surveillance/ diagnosis of small ruminant brucellosis till the year 2010. Dependence on imported kits and increased cost of testing with imported kits had direct impact on national exchequer. Hence ELISA test kits were essential in the country.

- **Solution Description:**

Till 2007-2008, the iELISA kit for brucellosis screening in small ruminants was not available in the country and hence initiative was taken to develop the iELISA kit and patent was obtained (Patent No No.250709). The kit is based on the smooth lipopolysaccharide antigen (instead of crude antigen) which helps to detect antibodies against smooth *Brucella* species such as *Brucella abortus*, *B. melitensis* and *B. suis* with relative diagnostic sensitivity and specificity of 96% and 99%, respectively. Using the iELISA kit, 43609 serum samples of small ruminants were tested in the institute and documented high seroprevalence of 11% in sheep and comparatively less in goats 4.5%. Presently 93 kits were sold through the institute and so far by using the kit, probably 50220 serum samples have been screened by various institutions.

IBR Avidin Biotin ELISA (AB ELISA)

- **Problem Description:**

IBR is a highly contagious disease of bovines causing abortions, reduction in milk yield thereby leading to economic loss. The infected bulls excrete the virus in the semen and such semen upon insemination in cows leads to transmission of virus/disease. All the infected animals become latently infected and continue to shed the virus whenever animal is under stress. Infected animals mount an immune response and elicit antibodies and detection of such antibodies is an indicative of infection/animal might have experienced the infection previously.:

- **Solution Description:**

IBR is endemic in India. Screening of bulls and other bovines would be of much help in segregation/isolation. This kit detects IBR antibodies and is developed using indigenous antigen, which is cost effective. Imported kits are 10 times more expensive.

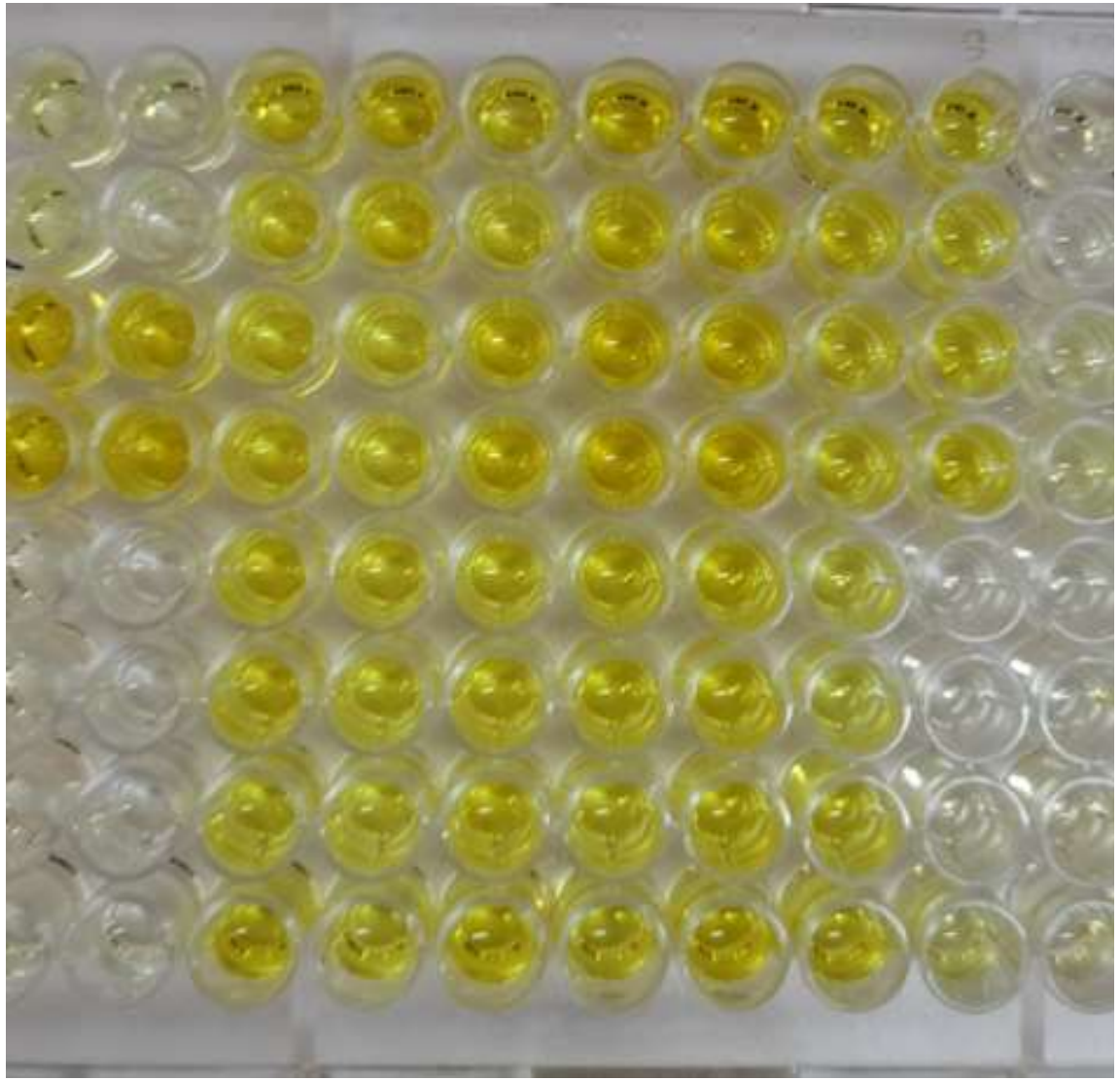
Indirect ELISA for detection of CSFV in pigs (CSF Ag Check kit)

Problem Description:

- More than 40% of India's pigs are domesticated in NE region of India and is their main animal husbandry practice that has fetched their livelihood. Most of the time, pig farmers lose their pigs due to sudden onset of diseases. Classical swine fever (CSF) is one major viral disease affecting pigs. Classical swine fever (CSF) is a highly contagious disease of pigs causing 100% mortality in piglets and surviving pigs will have stunted growth leading to huge economic loss.:

Solution Description:

- CSF is endemic in India. Early identification of disease in pigs by detecting viral antigen in the laboratory may lead to segregation of infected ones from the healthy pigs. Imported kits cost too much. Indigenously developed CSFV Ag Check is cost effective that detects the viral antigen in pig samples so that control measures can be put in place.



Indirect ELISA assay for population survey of bluetongue

- **Problem Description:**

Currently for the detection of antibodies to bluetongue virus, VP7 based ELISAs are in vogue world over. Such tests are useful for large scale surveys to assess the disease prevalence status. Unfortunately, VP7 based tests are not helpful for differentiating vaccinated from the infected animals. Use of non-structural protein (NSP) as an antigen can help circumventing this problem as antibodies to these proteins are generated upon infection in animals, however, those animals vaccinated with marker vaccine do not produce antibodies to these proteins. Keeping this in mind afusion protein having parts of NSP1 & NSP3 was expressed using recombinant technology and used as antigen in an indirect ELISA for the population survey of bluetongue.:

- **Solution Description:**

When an animal is infected by bluetongue virus, antibodies to both structural proteins (VP1-7) and NSPs are produced. However, unlike VP7, which is one of the components of virus outer shell, the NSPs are not packed in to the virus shell/core. Therefore, when an animal is immunized through a vaccine (marker vaccine) that is devoid of NSPs by ultrafiltration technique, there is no scope for production of antibodies to these proteins. This aspect of viral infection is exploited in the said technique to develop an assay that should be able to differentiate infected from vaccinated animals. The technology is protected by Patent (No. 419435)

Indirect ELISA assay for population survey of bluetongue

PPR Ab Chek kit (PPR Avidin-Biotin recombinant competitive ELISA (PPR ABrC-ELISA))

- **Problem Description:**

Peste des petits ruminants (PPR), otherwise called as 'Small Ruminant Plague' or Goat Plague', is a severe, highly infectious, and contagious transboundary viral disease of sheep and goats, caused by the PPR virus (PPRV). In India, at present, surveillance of PPR is carried out by serological ICAR-IVRI developed live attenuated PPRV antigen based indigenous PPRV H protein specific monoclonal antibody competitive ELISA (PPR c-ELISA). The variation in the results of sera for the detection of PPRV specific antibodies in sheep and goats by employing the nucleocapsid (N) protein or Haemagglutinin (H) protein specific recombinant antigen/antibody-based ELISA, have been observed/reported. To overcome this, ICAR-NIVEDI developed the PPR Surveillance ELISA kit (PPR Ab Chek Kit) by exploiting the polyclonal antibodies produced against expressed truncated recombinant nucleoprotein of PPRV as a competitive antibody for the detection of PPRV antibodies in the sera.:

- **Solution Description:**

Both indigenously developed and available ICAR-IVRI PPR c-ELISA kit and ICAR-NIVEDI PPR Ab Chek kit could be useful for screening small ruminants for PPR during the eradication and/or post-eradication stage of the disease in India with highest accuracy. Further, the sustainable source of safe recombinant antigens and/or antibodies-based diagnostics without the need for the live virus is always highly preferable for the detection of PPRV antibodies in the animals. The intended use is for identification of PPR virus antibodies in sheep and goats, by the detection of PPR virus nucleoprotein antibodies in the serum (Patent Filed- Application No. 202041047096)

PPR Ab Chek Kit

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