

## عنوان مقاله:

Iran's first domestically developed ELISA Kits for diagnosis of Paratuberculosis and Brucellosis in bovinds, a major step forward in response to the fast-extending local market for veterinary diagnostics

## محل انتشار:

بیستمین کنگره بین المللی میکروب شناسی ایران (سال: 1398)

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## خلاصه مقاله:

Introduction and Objectives: In clinical perspective, early warning and diagnosis of infection is a pivotal step in successful implementation of prevention and control measures. This is where serological methods come first in provision of highly reliable results in epidemiological context. In the Iranian environment veterinary-used ELISA kits are all imported from abroad leaving a 200 million Euros market open to normally European suppliers. In 2016 when the Science and technology park initiative came into action at Razi institute, Mehr Nam ZistFanavar (MeNaZiFa), a science-based start-up in collaboration with Razi institute focused on development of its first diagnostic kit, Paratuberculosis ELISA kit. At the beginning things seemed not that straight forward but in the end the effort appeared to be a total success as in technical side principle difficulties such as non-specific reactions that typically challenge ELISAs accuracy, were well addressed. Materials and Methods: In patenting and licensing, MeNaZiFa managed to attract positive response from all referees employed by the Iranian Veterinary Organization. MeNaZiFa is now therefore among the few recognized world companies active in the production field of paratuberculosis ELISA kits holding the technical know-how. In marketing, signals from cattle industry professionals received since June 2017 when the kit was commercially launched first, are in support of the MeNaZiFa-Razi kit compared to its competing rivals both in cost and in application outcome. Production of this kit covers variety of different phases including preparation of the antigen, effective coating and blocking of the plates, preparation of diluents as well as conjugates and

establishments of Cutoff points which is software (ROC)-assisted process. Result: In clinical trial, sensitivity and specificity of the kit have been tested against a huge cattle serum collection accommodating over 10,000 samples of fresh and frozen serums from different farms. The work on this large KMF (Kit Master File) resulted in achieving a 99% level of specificity with an impressive high score of CV (9.5) compared to other available products in the Iranian market. Conclusion: The MeNaZiFa later decided to use its constructive experiences with paratuberculosis to develop a further kit, the Brucellosis ELISA kit using the B. abortus S99 strain. This time things move forward quite smoothly and hassle-free with the production and marketing licenses granted to them by IVO to cover the national market.

... Thanks to God, if things go ahead as they do now, we will soon

### **کلمات کلیدی:**

ROC- Paratuberculosis - ELISA - Brucellosis

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