

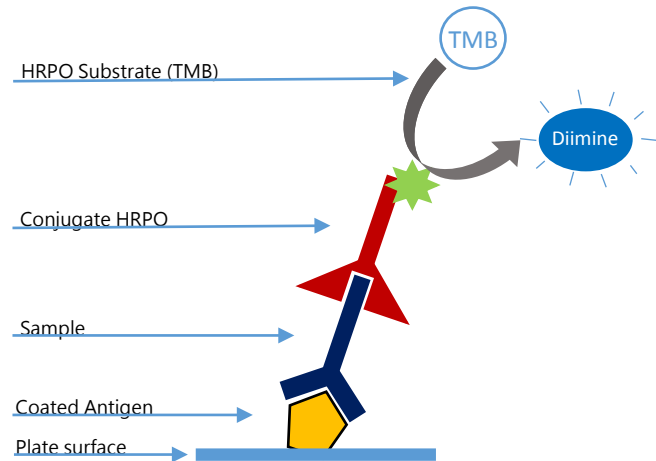
# INGENASA

## INgezim Brucellosis Bovina 2.0

R.12.BB2.K1



**INgezim Brucellosis Bovina 2.0** is an immunoenzymatic assay based on an indirect ELISA technique, which uses a monoclonal antibody (Mab) specific for bovine immunoglobulins.



### TECHNICAL BASIS OF THE KIT

1. Plates are coated with inactivated *Brucella abortus* antigen (LPS). Samples are added to the wells and incubated.
2. If the sample contains antibodies to *Brucella abortus*, they will bind to the antigen.
3. When a MAb-PO specific for bovine IgG is added, it will bind to the IgGs of the sample previously bound to the antigen. This binding is detected by the development of a colorimetric reaction after the addition of the substrate.

### APPLICATION

Detection of specific antibodies to *Brucella* in sera samples, individually assayed or assayed in pools up to 8 samples.

### INTERPRETATION OF THE RESULTS

The assay uses two different cut offs depending on the kind of samples. Samples will be considered **Positive** if their OD value is higher than the cut off. Samples will be considered **Negative** if their OD value is lower than the cut off.

### VALIDATION

#### 4. Diagnostic sensitivity.

It was determined analyzing 60 bovine positive sera by isolation, 15 bovine positive sera by Complement Fixation (CF) and 40 pools of 8 sera including 1 positive by isolation. The results obtained indicated more than 98% sensitivity in relation to isolation (individual samples), more than 99,5 % in relation to CF (individual samples), more than 96% in relation to isolation (pools of 8) and more than 92,5% in relation to CF (pools of 8).

#### 5. Diagnostic specificity.

1440 bovine sera from Spanish free zones, 376 sera negative by CF, 80 sera negative by Rose of Bengal (RB), 54 sera negative by isolation, 254 sera negative by CF and RB and 33 pools of 8 sera negative by CF and RB were analyzed. The results obtained indicated more than 99% specificity in relation to isolation (individual samples), 96% in relation to CF (Individual samples), more than 99% in relation to RB (individual samples) 96,7% in relation to CF and RB (Individual samples), 96,7% in relation to CF and RB (pools) and higher than 99% with field samples.

#### 6. Analytical sensitivity and specificity.

The assay fulfils the requirements of the Spanish (RD 1047/2003, Orden ARM/2166/2009) and European Regulations (Commission Directive 535/2002 and Decision 984/2008EC) Normative respect of the OIE Reference Sera.

### COMPOSITION OF THE KIT

- 96 wells microtitration plates
- Vials with positive control
- Vials with negative control
- Vials with conjugate
- Bottle with washing solution
- Bottle with diluent
- Bottle with substrate
- Bottle with stop solution



REGISTRATION NUMBER 1716-RD

PRODUCT MANUFACTURED BY INGENASA



Shelf life: **18 months**  
 Store at 2°C-8°C

Ed.020217