Annex A: Conformity Report for ELISA kits Validation

This annex is an example of 'Conformity Report' for validation of ELISA kits for brucellosis diagnostic.

Supplier / Manufacturer	IDEXX
Commercial name	IDEXX Brucellosis Serum X2 Ab
Product reference	BAT1132T
Description	Serological confirmatory diagnosis of bovine brucellosis by indirect ELISA. Individual serum, short incubation .
Animal target	Bovine
Sampling matrix	Serum
Operating Procedure	06-40639-08

EVALUATION CRITERIA	**RESULT** *(Passed / Need more data / Failed)*
Administrative file *(Name and address of the person responsible for placing the product on the market; accreditation or certification, name and address of manufacturer; accreditation or certification, trade name and denomination of the reagent, place(s) of manufacture and control, place(s) of packaging, number and size of the lot subject to control, date of the file signature of supplier's manager)*	**PASSED**
Presentation of the reagent and reference materials *(Description of the reagent, technical protocol and formulation of the results, detailed instructions for use including the different production phases, reading methods and the critical stages of the reaction, precise rules for interpreting the results, reporting of known interferences, terms and duration of storage, security form, maximum number of reactions that can be carried out under the conditions of use provided for in the instructions.* *Reference material information: name, reference code, batch number, presentation, origin, dilution matrix, special preparation conditions, homogeneity)*	**PASSED**
Label and notice *(It must be in the country's language and at least in a universal language, title, name of manufacturer, disease concerned, batch, storage/preservation conditions, volume, biosecurity conditions)*	**PASSED**
Internal control analysis certificate *(Technical file)*	**PASSED**
Manufacturing process *(The critical steps for manufacturing or imposed by a document are presented in the form of a commented diagram. When the product may present a biological risk for the user or the environment, the conditions for inactivation of the pathogen and the methods for controlling this inactivation are described.* *Primary packaging: the nature of the containers and the closing methods as well as the minimum volume per packaging unit are specified.* *Identification: the process for identifying the batch of the kit is described. In the case of further processing, the finished product is defined by a unique batch number for processing session.*	**PASSED**
Definition of the intended purpose(s)	**PASSED**

Thresholds (cut-offs) *(Results must be as defined in the WOAH manual, the manufacturer must describe the methodology followed and the results obtained)*	**Cut-off = 65%**
Analytical sensitivity (Limit of detection) *(Results must be as defined in the WOAH manual, the manufacture must specify the reference sample, dilution series, result for each replicate)*	**PASSED** **Positive at 1/16 dilution** **Negative at 1/64 dilution**
Analytical specificity *(The manufacturer must specify the determination of the number of samples, the origin and the nature of the samples, as well as the status of animals. These samples must also be analysed by another recognized method.* *Analytical specificity less than 100% may be acceptable depending on the intended use of the test.)*	**More specific than Complement Fixation Test** **CF = 1.41 %** **ELISA X2 = 47.17 %**
Diagnostic sensitivity (DSe) and specificity (DSp) *(Results are expected according to the intended purpose(s) choice as described in 3.1:* *I and II. for screening test: high DSe (low false negative); for confirmatory tests: high DSp (low false positive)* *III. moderate to high DSe* *IV and VI. high DSp* *V. moderate DSe and DSp*	**DSe = 97,7% [94.4% - 98.9%]** **DSp = 87.0% [83.6% - 90.0%]**
Intra-assay repeatability *(At least 20 repetitions by plate (3 plates), results by sample have been shown. A coefficient of variation (CV) of less than 10% is expected. The raw values of the three plates and their CVs must be comparable.)*	**PASSED**
Intra-laboratory reproducibility *(Three dilution levels of the same sample, located in the linear range, for which a level of detectability is comparable to the LOD must be tested in six different runs, over several days, in different periods of the day, by at least two different operators. A coefficient of variation (CV) of less than 20% is expected. The raw values of the three plates and their CVs must be comparable.)*	**PASSED**
Reproducibility *(Data analysis can be done quantitatively or qualitatively (positive vs negative). Qualitative results have to be concordant. For a quantitative result, a coefficient of variation (CV) of less than 20% is expected.)*	**PASSED**
Robustness *(The raw values between protocols have to be comparable.)*	**PASSED**
Verification of stability *(The raw values have to be comparable.)*	**PASSED**