INITIAL CONTROL FOR DIAGNOSTIC REAGENTS TO BE USED IN BELGIAN OFFICIAL ANIMAL DISEASE CONTROL PROGRAMMES

ELISA KITS FOR THE DETECTION OF SPECIFIC ANTIBODIES AGAINST the *Mycobacterium tuberculosis* complex IN BOVINE SERUM

MINIMUM CRITERIA DOCUMENT

Initial control : Cert_TUB_AbELISA_serum_2021
Ref. no. 16206

1. SPECIFIC DETAILS INITIAL CONTROL		
PARAMETER	**NAME / TYPE**	**CODE**
Initial control	Original	
Diagnostic Reagent	Antibody ELISA (no multiplex ELISA)	Ab ELISA
Detection	Detection of bovine tuberculosis	TUB antibody ELISA
Target Species	Bovine	B
Target Matrix	serum	SE
Estimated Market	65000- 99000 samples per year	/
Protocols	Overday (short)	OD
Administrative Dossier To submit to Diagnostic Control		Send to: Diagnostic.Control@sciensano.be **1 dossier = 1 checklist +Annexes per kit** Send to: Isabelle Behaeghel/Simon Van den Bergh, SCIENSANO, Groeselenberg 99, B-1180 Brussels, Belgium **1 electronic copy + 1 paper copy of dossier** **Deadline date: 01/03/2022**
Technical Batch To submit to Sylvie Marché, David Fretin	One specific batch Minimum 10 plates per protocol	Send to: Sylvie Marché, David Fretin, SCIENSANO, Groeselenberg 99, B-1180 Brussels, Belgium **Deadline date: 01/03/2022**

A. Administrative Minimum Criteria evaluated in Administrative Dossier

Nr	Criterion	Required	Explanation	
A1	**Checklist (Administrative Dossier)**	Satisfactory Completion	Satisfactory completion of the required fields of the Checklist and all required information and annexes must be provided in the Administrative Validation Dossier.	
A2	**ISO 9001 Certification**	Certificate	ISO 9001 Certification must be presented in a checklist annex, as a minimum to be eligible to participate in this certification of diagnostic reagents.	
A3	**Fit for purpose**	OIE guidelines	The requested diagnostic reagents (kits) must be "fit for purpose", i.e. the Belgian market / Official Programme. Therefore, producers must present sufficient studies, including studies performed in the Belgian population or using animals that are representative for this target group. The "purposes" have been defined by SCIENSANO, in concertation with FASFC and the expert committee, based on OIE guidelines.	
		YES/NO	**Purposes applicable**	**species - matrix**
		YES	1. Demonstrate freedom from infection in a defined population (country/ zone/ compart-ment/ herd) (prevalence apparently zero)	Bovine serum
		YES	1a. Free with or without vaccination	Bovine serum
		YES	1b. Historical freedom	Bovine serum
		YES	1c.Re-establishment of freedom after outbreaks	Bovine serum
		NO	2. Certify freedom from infection or agent in individual animals for trade/movement purpose	Bovine serum
		YES	3. Eradication of infection from defined populations	Bovine serum
		NO	4. Confirmatory diagnosis of suspect or clinical cases (includes confirmation of positive screening test)	Bovine serum
		NO	5. Estimate prevalence of infection or exposure to facilitate risk analysis (surveys, herd health status, disease control measures)	Bovine serum
		NO	6. Determine immune status of individual animals or populations (post-vaccination)	Bovine serum

Diagnostic reagents of producers/distributors who do not meet the administrative minimum criteria, will not be admitted to the technical evaluation or the Belgian market

B. Technical Minimum Criteria evaluated in Administrative Dossier

Nr	Criterion	Required	Explanation	
B1	**Sample sizes accuracy (D Se and D Sp)**	OIE guideline	To assure that the criteria of Diagnostic Specificity (DSp) and Diagnostic Sensitivity (DSe) can at least be assessed within a **95% confidence** interval and with **5% error** allowance, studies designed to calculate these parameters must have a sufficient sample size per criterion, as described in OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, 2016. Chapter 1.1.6. Principles and methods of validation of diagnostic assays for infectious diseases, **Table 1, page 9)**	
B2	**Analytical Sensitivity (ASe)**	/	Must be filled out in checklist + Annexes must be provided	
B3	**Analytical Specificity (ASp)**	/	Must be filled out in checklist + Annexes must be provided	
B4	**Diagnostic Sensitivity (DSe)**	**D Se ≥68%**	serum	In comparison with the tuberculine skin test. Must be filled out in checklist + Annexes must be provided,
B5	**Diagnostic Specificity (DSp)**	**D Sp ≥96%**	serum	In comparison with the tuberculine skin test. Must be filled out in checklist + Annexes must be provided,
B6	**Repeatability intraplate (CVrepeat)**	**CV ≤15%**	Must be filled out in checklist + Annexes must be provided,	
B7	**Repeatability intralaboratory = Reproducibility (CVrepro)**	**CV ≤20%**	Must be filled out in checklist + Annexes must be provided,	

Diagnostic reagents of producers/distributors who do not meet the administrative minimum criteria will not be admitted to the technical evaluation or the Belgian market.

C. Technical Minimum Criteria evaluated by SCIENSANO ELISA for detection of bovine tuberculosis in bovine serum				
Nr	**Criterion**	**Required**	**Explanation**	
C1	**Analytical Sensitivity (ASe)**	/	Cf. checklist (administrative dossier)	
C2	**Analytical Specificity (ASp)**	/	Cf. checklist (administrative dossier)	
C3	**Diagnostic Sensitivity (DSe)**	**D Se ≥ 68%**	sera	A control panel of 53 field sera from positive skin test animals : 36 out of 53 samples must be positive
C4	**Diagnostic Specificity (DSp)**	**D Sp ≥ 96%**	sera	A control panel of 100 negative field sera: at least 96 samples must be negative
C5	**Repeatability intra-run (CVrepeat)**	**All CVrepeat's ≤ 15%**	CV Pos	1 positive serum is repeated 20 times on 3 plates. CV repeat 's are calculated on raw OD values and S/P values and separately for each plate
C6	**Repeatability inter-run (CVrepro)**	**One CVrepro ≤ 20%**	CV Pos	1 positive serum is repeated 20 times on 3 plates. The CV repro is calculated on raw OD values and S/P values across all plates and time points together
		Pos/neg according to manufacturer's instructions	Kit controls	Results will be validated according to the manufacturer's instructions (kit controls / first line controls)

SHOULD YOU HAVE ANY QUESTIONS, PLEASE DO NOT HESITATE TO CONTACT US VIA Diagnostic.Control@sciensano.be FOR THIS CERTIFICATION

With kind regards,

Isabelle Behaeghel/Simon Van den Bergh : Coordination of Veterinary Diagnosis of SCIENSANO

DIAGNOSTIC CONTROL: Coordination of Veterinary Diagnosis

BACTERIOLOGY VETERINARY: Departement of Scientific Direction Animals infectious diseases, national reference laboratory for Qfever

SCIENSANO builds on the more than 100 years of scientific expertise of the former Veterinary and Agrochemical Research Centre (CODA-CERVA) and the ex-Scientific Institute of Public Health (WIV-ISP)

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