TACB 10

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OFFICIAL FORM FOR SUBMISSION OF DOSSIER/ DOSSIER CHECKLIST FOR REGISTRATION OF VETERINARY DIAGNOSTIC KITS IN MALAYSIA

TECHNICAL INFORMATION AND DOCUMENTATION PROVIDED IN THE DOSSIER	PAGE REFERENCE NUMBER	DETAILS
1. General Information : (a) Name of product (b) Name and address of manufacturer (c) Name and address of manufacturing facility/ premise (if different from (b)) (d) Country of origin (e) Copy of manufacturing license or registration certificate of the manufacturer in the country of origin, accreditation or certification status of manufacturer (eg. GLP/GMP, ISO, etc.) (f) Name and address, SSM, Phone, Fax, Email of local agent/Malaysian company (g) Copy of letter of attorney or authorization letter by the manufacturer		

TECHNICAL INFORMATION AND DOCUMENTATION PROVIDED IN THE DOSSIER	PAGE REFERENCE NUMBER	DETAILS
2. Purpose of the diagnostic kit (a) Type of method *Indirect or competitive ELISA, conventional or real-time PCR, etc* (b) Detection method for: *Please tick (√)* [ ] Antibody [ ] Antigen [ ] Nucleic acid [ ] Others, please specify: _____ (c) Detection ability/ type: *Please tick (√)* [ ] Singleplex [ ] Multiplex, please specify: (1)_____ (2)_____ (d) Intended purpose(s) of the test/ Fitness for purpose *Please tick (√) and describe* [ ] Demonstrate freedom from infection in a defined population (country/zone/compartment/herd) [ ] Demonstrate disease free with vaccination [ ] Historical freedom [ ] Re-establishment of freedom after outbreaks [ ] Certify freedom from infection or agent in individual animals or products for trade/movement purposes [ ] Eradication of infection from defined populations [ ] Confirmatory diagnosis of suspect or clinical cases (includes confirmation of positive screening test) [ ] Estimate prevalence of infection to facilitate risk analysis (Screening/ surveys/herd health schemes/disease control) [ ] Determine immune status in individual animals or populations (post-vaccination) [ ] Establish the individual animal freedom from infection [ ] Other [please specify]:		

TECHNICAL INFORMATION AND DOCUMENTATION PROVIDED IN THE DOSSIER	PAGE REFERENCE NUMBER	DETAILS
3. Test description and requirements (a) Protocol of the test. (b) Disease target/analyte target (c) Species and specimens (d) Controls included. (e) Laboratory requirements (f) Computational requirements (if applicable) (g) Test kit format *(if applicable)* (h) General precautions/ safety aspects/disposal of reagents (i) Assay interpretation - Method to interpret results - Criteria on data validity		
4. Technical information about the diagnostic test (a) Chemical reagents (b) Equipment and consumables included (if applicable) (c) Biological components used in test (d) Control of the final product of the test (if applicable) (e) Shipping requirements (f) Troubleshooting and technical support (if applicable)		

TECHNICAL INFORMATION AND DOCUMENTATION PROVIDED IN THE DOSSIER	PAGE REFERENCE NUMBER	DETAILS
DEVELOPMENT AND VALIDATION *		
5. Assay development pathway		
(a) Fitness of assay for its intended purpose		
(b) Design, development, optimization and standardization of the assay		
6. Validation pathway stage 1: analytical characteristics		
(a) Stage 1. Repeatability data		
(b) Stage 1. Analytical specificity data (as appropriate for the test type and disease)		
(c) Stage 1. Analytical sensitivity data		
(d) Stage 1. Standard of comparison		
(e) Stage 1. Preliminary evaluation of reproducibility		
7. Stage 2 – Diagnostic characteristics		
(a) Study design(s)		
(b) Stage 2. Negative reference animals/samples		
(c) Stage 2. Positive reference animals/samples		
(d) Stage 2. Experimental animals (where used).		
(e) Stage 2. Threshold determination.		
(f) Stage 2. Diagnostic sensitivity and specificity estimates – with defined reference animals		

TECHNICAL INFORMATION AND DOCUMENTATION PROVIDED IN THE DOSSIER	PAGE REFERENCE NUMBER	DETAILS
(g) Stage 2. Diagnostic sensitivity and specificity estimates – without defined reference animals (h) Stage 2. Comparison of performance between tests		
8. Stage 3 – Reproducibility (if applicable) (a) Stage 3. Laboratory identification (b) Stage 3. Evaluation panel (c) Stage 3. Analysis of reproducibility		
9. Stage 4 - Applications (if applicable) (a) Stage 4. Test applications (b) Stage 4. Laboratories (c) Stage 4. International reference standards (d) Stage 4. Inter-laboratory testing programmes (e) Stage 4. International recognition (eg. registered under OIE)		
10. Packaging Information (a) Instructional pamphlet and specimen of label *- usage instructions/ indications/ precautions/ storage conditions* (b) Composition of final product		

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11. Reference cited in the dossier		

***Please include APPENDIX 1 PERFORMANCE SUMMARY OF VALIDATION DATA**
(Note: Must be completed, signed and endorsed by the registered veterinarian of the company/ local agent)

I, _____ (*name of applicant)* of the company/ local agent _____ hereby declare that we have read and will adhere to the Guidelines for registration of veterinary diagnostic test kits in Malaysia.

We hereby declare that all the information contained in this application form and all documentation submitted further in support of the application form are true and complete in all respects.

We understand and agree that any misrepresentation of the information furnished in this form will result in the automatic end of procedure or revocation of the potential certification obtained.

Submitted on : _____ by:

_____ Company Stamp:
(Signature)

_____
(Name of Applicant)

_____
(Position in Company)

APPENDIX 1

PERFORMANCE SUMMARY OF VALIDATION DATA

- Name of the diagnostic test:
- Manufacturer:

- Disease:
- Pathogen Agent:
- Type of Assay:
- Purpose of Assay:
- Species and Specimens:

1. Information on the test

(Provide e-mail address and/or web site where prospective customers may make enquiries and/or view information about the test.)

2. Summary of validation studies

STAGE 1 Validation

(Provide a succinct summary of Section 6. Validation Pathway stage 1: Analytical characteristics; include statistical data where applicable, e.g. coefficients of variation or upper and lower ranges.)

- Repeatability:

- Analytical specificity:

- Analytical sensitivity:

STAGE 2 Validation

Provide a succinct summary of Section 7 Satge 2- Diagnostic Characteristics; indicate approach taken in study design for the determination of diagnostic sensitivity and specificity estimates.)

- Threshold Determination, if relevant

- Diagnostic sensitivity (DSn) and specificity (DSp)estimates:
(Using tabular format below, indicate diagnostic sensitivity and specificity estimates as determined in either Section 7 (f)(g).)

Test method under evaluation		**Target Species**
Diagnostic sensitivity	N DSn CI	*(Number of animals tested)* *(DSn estimate)* *(95% confidence interval)*
Diagnostic specificity	N DSp CI	*(Number of animals tested)* *(DSp estimate)* *(95% confidence interval)*

- Comparative performance:
(Diagnostic sensitivity and specificity estimates as determined in either Section 7(f)(g)(h).)

Test method of comparison		Target Species
Diagnostic sensitivity	N DSn CI	*(Number of animals tested)* *(DSn estimate)* *(95% confidence interval)*
Diagnostic specificity	N DSp CI	*(Number of animals tested)* *(DSp estimate)* *(95% confidence interval)*

- Agreement and discrepancies:
*(*Indicate level of agreement and suggest explanations for discrepant results.)

STAGE 3 Validation

- Reproducibility:
(Briefly describe results of inter-laboratory comparisons, including number of laboratories involved and statistical data for a range of positive and negative samples as outlined in Section 8)

STAGE 4 Validation

(Validation is recognised as an ongoing process that continues for the lifetime of the test. Ultimately, confidence in test performance builds with successful application in diagnostic laboratories and programmes.)

- Applications:
(If possible, briefly describe where this test method has been integrated in diagnostic regimens and programmes as outlined in Section 9).

3. References:

(Include a short list of references, if available, relevant to the assay performance characteristics stated above.)