	DEPARTMENT OF AGRICULTURE, FORESTRY AND FISHERIES **DIRECTORATE ANIMAL HEALTH** **EPIDEMIOLOGY**
	PROCEDURE MANUAL: **IMPORTATION OF A NEW TEST KIT OR REAGENT**
COMPILED BY:	**Julie-Anne Koch; Keneilwe Raseleka; Riette Theron**
FIRST DOCUMENT	**August 2015**
APPROVED BY:	**Director Animal Health**
APPROVAL DATE:	**March 2018**

Note: This document replaces the document "*Pathway for Importation of a New Test – Ed 01*"

PATHWAY FOR IMPORTATION OF A NEW TEST KIT / REAGENT

Diagnostic test kits are available in several test formats, e.g. agglutination, enzyme immunoassay, immunodiffusion, immunofluorescence, etc. Typically, kits may be thought of as one or more reagents used to measure an analyte. For the purposes of this document, a diagnostic test kit is defined as the reagents, hardware, instructions and other components which are used in combination to detect the existence of antigens or antibodies; wherein the detection of antigen or antibody provides some indication of the existence of, exposure or susceptibility to, a potential disease-causing agent in animals[(1)]

The mandate of the Directorate: Animal Health is to monitor controlled and notifiable diseases (Animal Diseases Act, Act 35, 1984). This includes the diagnostic testing for these diseases.

In terms of Regulation 12 B of the Animal Diseases Act, 1984 (Act No 35 of 1984):
(1) "*A person or a laboratory that does diagnostic testing or screening for a controlled animal disease or a notifiable animal disease in any animal species, shall be registered with the Director*". A list of DAFF approved laboratories is available from the website: http://www.daff.gov.za/daffweb3/Branches/Agricultural-Production-Health-Food-Safety/Animal-Health/Epidemiology/Approved-Laboratories

A test kit may be subject to two levels of regulatory review. Test kits that are used to certify animals for export or release of animals from post import quarantine, may also be evaluated.

Primary evaluation

All diagnostic test kits for controlled and notifiable animal diseases in any animal species, regardless of proposed use, receive a primary evaluation for sensitivity, specificity and reproducibility.

- In cases where standardized methods and reagents exist it will not be possible to deviate from these (refer to the website for harmonized protocols http://www.daff.gov.za/daffweb3/Branches/Agricultural-Production-Health-Food-Safety/Animal-Health/Epidemiology: "*South African Veterinary Laboratory Scientific Forum approved SOP's (Standard Operating Procedures)*"
- The validation data must be submitted by the applicant intending to import the test kit, to the Directorate Animal Health.
- The information provided will be reviewed to determine if similar test kits (different manufacturers) are already in use in local laboratories.
- The OIE website will be consulted to determine if the method is an OIE recommended method.
- The OIE website may be consulted to determine if the test kits appears on the Register of diagnostic kits certified by the OIE as validated as fit for purpose.
- Should similar test kits already be in use in SANAS accredited and DAFF approved laboratories, the applicant may be allowed to import sufficient kits to enable the new proposed test kit to be validated by a DAFF approved laboratory against the current test kits in use.
- The time frame allowable for validation is 90 days. However an application for extension will be considered if motivation is provided.
- Should the test kit perform at an acceptable level in comparison to existing tests, the applicant may be granted permission to import further kits.

Secondary evaluation

If the test kit is currently not accepted by the Directorate Animal Health a secondary review by the South African Veterinary Laboratory Scientific Forum (SAVLSF) will take place.

- Should the SAVLSF recommend validation of the test, the Director: Animal Health will be informed of the decision.
- The planned activity will be communicated to members of MinTech by the chairman of the SAVLSF.
- A dedicated task team from the SAVLSF will manage the process by following the OIE requirements for validation (Chapter 1.1.6 Principles and Methods of Validation of Diagnostic Assays for Infectious Diseases).
- Laboratories will be selected to participate in the testing process. These will be SANAS accredited/ DAFF approved laboratories.
- The applicant requesting the validation will be required to sponsor the required amount of kits for the validation process, as well as possible operational costs where necessary.
- The process will take at least a year and may last as long as two years.
- After testing selected samples, the data will be processed into a report and analysed.
- The SAVLSF will discuss the outcome and evaluate the test performance in comparison with existing tests.
- Should the performance of the test be such that it would be valuable as an additional test, the SAVLSF will recommend that it be included in an official list of accepted tests.
- The recommendation will be sent to the Director: Animal Health.
- Once accepted, MinTech will be informed of the decision.
- The new test will then be recognised as an accepted official diagnostic test.

When applying complete the attached form (Appendix A) and forward it to:
Julie-AnneK@daff.gov.za; KeneilweR@daff.gov.za; RietteT@daff.gov.za

References:

(1) Regulatory control of veterinary diagnostic test kits - A.P. Morgan, Rev. sci. tech. Off. int. Epiz., 1998.17 (2), 562-567

(2) World Organisation for Animal Health (OIE) Manual of Diagnostic Tests and Vaccines for Terrestrial Animals 2017.

Approved by:

DAH _____ Date 2018 -05- 0 3

	DEPARTMENT OF AGRICULTURE, FORESTRY AND FISHERIES DIRECTORATE ANIMAL HEALTH EPIDEMIOLOGY
	IMPORTATION OF A NEW TEST KIT OR REAGENT

NOTE: A separate application for a veterinary import permit must be submitted. Please visit the website: http://www.daff.gov.za/daffweb3/Branches/Agricultural-Production-Health-Food-Safety/Animal-Health/importexport/permit

Importer details		
Importing Company		
Physical address		
Contact person		
Contact Number		
E-mail address		
Test kit details		
Name of test kit		
Manufacturer		
Country of origin		
Disease(s)		
Strains(s)		
Test method (ELISA, PCR, etc.)		
Species		
Description of the test		
Reason for import		
Documents included with this application		
Package insert	Yes	No
Validation report ***Compulsory document**	Yes	No
Other		