

Checklist for Import of In Vitro Diagnostic (IVD) Kits for Veterinary Use in India

Category	Checklist Items	Remarks
1. General Information		
Product Name with description and Intended Use	State the name and intended use of the IVD kit.	Clearly specify the diagnostic purpose.
2. Product Description		
Kit Type	Type of diagnostic kit (e.g., Serology and Immunology Diagnostic Kits, ELISA, RT-PCR, Lateral Flow etc) or for in vivo use.	
Target Species	Specify the animal species intended for use	
Intended Application	Screening, confirmatory, or quantitative/qualitative test etc	
Kit Components	Provide a list of kit components (e.g., reagents, control samples etc). including type of antigen live pathogen /inactivated /recombinant antigen or serum or monoclonals	
Is the product marketed elsewhere? If so, provide a list of countries where the product is marketed		
3. Technical and Scientific Data		
Sensitivity and Specificity	Provide sensitivity, specificity, and validation reports.	
4. Compliance with Regulatory Standards		
International Certification	Compliance aligns with international standards such as	

	those outlined by WOAHA (World Organisation for Animal Health)	
Infectious Agent Certification	Certification confirming that the product and its components are free from infectious agents (e.g., bacteria, viruses, fungi) and comply with BSE/TSE-free requirements.	Supplier must provide certification if uses any animal origin product during manufacturing of the device.
Animal-Origin Compliance		
Risk Assessment	Submit documentation on biohazards and environmental risks.	
5. Validation and Field Trials		
Validation Data	Evidence of validation in India or internationally.	
Executive Summary: A summary of key supporting documentation. Every Please provide an introductory text or narratives to help connect the submitted documents. Any exceptions or unusual circumstance which the firm wishes to highlight, specific to the product or application, should be mentioned in the Executive Summary.		