

DRAFT RESOLUTION No. 31

Register of aquatic animal disease diagnostic kits validated and certified by WOAAH

CONSIDERING THAT

1. During the 71st General Session of WOAAH in May 2003, the Assembly adopted Resolution No. XXIX endorsing the principle of validation and certification of diagnostic assays for animal diseases by WOAAH, and giving a mandate to the Director General to set up the specific standard procedures to be used before the final decision on the validation and certification of a diagnostic kit is taken by the World Assembly of Delegates,
2. The Resolution has established that “fitness for purpose” should be used as a criterion for validation,
3. The aim of WOAAH’s procedure for registration of diagnostic kits is to establish a register of recognised kits for WOAAH Members and for diagnostic kit manufacturers,
4. WOAAH Members need kits that are known to be validated according to WOAAH standards in order to enhance confidence in kits,
5. WOAAH’s register of recognised diagnostic kits provides greater transparency and clarity of the validation process, and means for recognising those manufacturers that validate and certify tests marketed in kit format,
6. According to WOAAH Standard Operating Procedure, registration of diagnostic kits included in the Register has to be renewed every 5 years,
7. During the 74th General Session in May 2006, the Assembly adopted Resolution No. XXXII on the importance of recognising and implementing WOAAH standards for the validation and registration of diagnostic assays by Members,
8. The *Validation Studies Abstract* is available as annex to the report of WOAAH’s Aquatic Animal Health Standards Commission meeting of 15-22 February 2023 for the Innocreate Bioscience WSSV RP Rapid Test Kit for White Spot Syndrome Virus (WSSV) infection in shrimp.

THE ASSEMBLY

DECIDES THAT

1. In accordance with WOAAH’s procedure for registration of diagnostic kits and the recommendations of the Aquatic Animal Health Standards Commission, the Director General proposes the inclusion in WOAAH’s Register of the following new aquatic diagnostic kit certified by WOAAH for a period of 5 years:

Name of the diagnostic kit	Name of the Manufacturer	Fitness for purpose
Inncreate Bioscience WSSV RP Rapid Test Kit	Inncreate Bioscience Co., Ltd.	<p>The Inncreate Bioscience WSSV RP Rapid Test Kit is a qualitative detection kit for WSSV infection in shrimp. The lateral flow immunoassay device is designed for the following purposes:</p> <ol style="list-style-type: none"><li data-bbox="721 362 1407 452">1. Field based confirmatory diagnosis of clinical cases (includes confirmation of suspect cases and a positive screening test)<li data-bbox="721 465 1407 645">2. Estimate the prevalence of infection to facilitate risk analysis in production system shrimp farms to aid in management practices. (The test kit should not be used to estimate prevalence in broodstock or post larvae shrimp for risk analysis prior to translocation to other farms or across borders).<li data-bbox="721 658 1407 743">3. For use in conjunction with other tests or diagnostic procedures as an aid in the diagnosis or other clinical or epidemiological assessments.