

Fish disease detection and Animal Health Law (AHL)

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i A BRIEF OUTLOOK ON BIO-X FISH DIAGNOSTIC EXPERTISE

Bio-X Diagnostics has been involved in fish disease diagnostic for decades with the production of monoclonal antibodies for Immuno-Fluorescence (IF) or Elisa Kits. A real expertise has been developed for the diagnostic of fish diseases included in the new list of fish pathogen of the new Animal Health Law (AHL):



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aquaculture
diagnostics

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Pathogens	PCR	Monoclonal antibodies	ELISA	AHL classification
Koi Herpes Virus (KHV)	-	BIO 354 / Moab a-KHV	-	Category E
Infectious Hematopoietic Necrosis (IHN)	ADIAVET™ IHNV Real Time	BIO 285 / Moab anti-IHN	BIO K 273 Monoscreen™ AgELISA IHNV	Category C
Viral Haemorrhagic Septicemia (VHS)	ADIAVET™ VHSV Real Time	BIO 282 / Moab anti-VHS	BIO K 272 Monoscreen™ AgELISA VHSV	Category C
Spring Viremia of Carp (SVC)	-	-	BIO K 275 Monoscreen™ AgELISA SVCV	Category C
Infectious Pancreatic Necrosis (IPN)	ADIAVET™ IPNV Real Time	BIO 345 / Moab anti-IPN	BIO K 282 Monoscreen™ AgELISA IPNV	-

Brief summary for each disease can be downloaded from the corresponding BIO or BIO K number on our website www.biox.com

THE NEW ANIMAL HEALTH LAW REGULATORY IMPACT

Commission Implementing Regulation (EU) 2018/1882 lays down rules for the application of AHL with regards to diseases classification (ABCDE).

Commission Delegated Regulation (EU) 2020/689 establishes minimum preventive measures for the control and early detection, in aquatic animals, (Chapter 3, Category C diseases) such as Viral Hemorrhagic Septicemia (VHS) and Infectious Hematopoietic Necrosis (IHN). The article 49 defines the official diagnostic methods (described in the Annexe VI, Part II, chapter 1).

PCR assays are now considered as reference methods for listed fish disease which has lead to the development of new PCR kits :

- ADIAVET™ VHSV Real Time
- ADIAVET™ IHNV Real Time
- ADIAVET™ IPNV Real Time

Animal Health Law UE 2016/429 (Part II Chapter 3 Art 9 for aquatic animal diseases).

1ST FIRST PCR KITS VALIDATED

Due to their **category C classification**, **ADIAVET™ VHSV Real Time** and **ADIAVET™ IHNV Real Time** have been validated by French NRL ANSES for their applications.

Although IPN is not listed by AHL, the **ADIAVET™ IPNV Real Time** has also been evaluated by ANSES.

These three tests can be used alone or simultaneously.

« With this new ADIAVET™ PCR range, Bio-X Diagnostics allows entering in a new dimension for fish diseases diagnostic in compliance with the new application of Animal Health Law. »

Duplex Kit ready to use :

- Pathogenic target (FAM)
- Exogenous internal control (HEX / VIC). Can be used for different fish species.

Storage 18 months at <-15 ° C

Detection of different genotypes

Sensitive and specific

- Low detection limit
- Same analysis process (extraction protocols, non-target EPC-extraction, thermal program) as the other kits
- LD_{PCR} available for PCR method adoption
- NED available as Extraction Positive Control (EPC)
- The use of positive extraction control allows validation both the extraction and amplification phases of the PCR method. This positive control can also be used as a sentinel to establish a control card providing information on the reliability of the results obtained.

ADIAVET™ VHSV Real Time	ADIAVET™ IHNV Real Time	ADIAVET™ IPNV Real Time
Genotypes : I, II, III et IV	Genotypes : U,M,L,E et J	Genogroupes : 1, 2, 3, 4 et 5
Sensitivity : 200 copies /PCR	Sensitivity : 375 copies /PCR	-
LD _{PCR} : Ref ADC58LD	LD _{PCR} : Ref ADC57LD	LD _{PCR} : Ref ADC64LD
NED Method : Ref ADC58EPC	NED Method : Ref ADC57EPC	NED Method : Ref ADC64EPC

TO PLACE AN ORDER :

Code	Description	Number of reactions
NADI003	ADIAMAG™	200
NADI003-XL	ADIAMAG™ XL	800
ADI641-100	ADIAVET™ IPNV REAL TIME	100
ADI581-100	ADIAVET™ VHSV REAL TIME	100
ADI571-100	ADIAVET™ IHNV REAL TIME	100

Each fish disease PCR can be run alone or in the same PCR run with other pathogens due to temperature optimization of the amplification cycles.

Samples
Pool of organs (spleen, kidney, heart, brain)
Culture supernatant
NEW Genital products (sperm, egg, coelomic fluid)*

*New samples validated by French national reference laboratory, ANSES.

