

The register of diagnostic kits Register of diagnostic kits certified by WOA as validated as fit for purpose

'Fit for purpose' means that the kit has to be validated to such a level to show that the kit's results can be interpreted to have a defined meaning in terms of diagnosis or another biological property being examined.

AVIAN INFLUENZA

Name of the Diagnostic Kit	Avian Influenza Disease Antibody Test Kit
Name of the Manufacturer	BioChek UK Ltd
Contact	info@biochek.com
Type of Kit	ELISA
Purpose(s) Validated	see Resolution No 27 adopted in May 2008 by the World Assembly of the OIE Delegates
Date and Number of Registration	Registration Number: 20080203 May 2008: Resolution No 27 2013: Resolution No 26 2018: Resolution No 19 2024: Resolution No 34
Validation Studies Abstract	AS Avian Influenza Disease Antibody Test Kit
User's Manual/Kit Insert	User's Manual

WHITE SPOT DISEASE

Name of the Diagnostic Kit	IQ 2000TM WSSV Detection and Prevention System
Name of the Manufacturer	GeneReach Biotechnology Corp
Contact	sales@genereach.com
Type of Kit	PCR
Purpose(s) Validated	see Resolution No 27 adopted in May 2008 by the World Assembly of the OIE Delegates
Date and Number of Registration	Registration Number: 20080203 May 2008: Resolution No 27 2013: Resolution No 26 2018: Resolution No 19
Validation Studies Abstract	AS IQ 2000
User's Manual/Kit Insert	User's Manual

WHITE SPOT DISEASE

Name of the Diagnostic Kit	IQ Plus™ WSSV Kit with POKKIT System
Name of the Manufacturer	GeneReach Biotechnology Corp
Contact	sales@genereach.com
Type of Kit	Insulated isothermal PCR
Purpose(s) Validated	see Resolution No 26 adopted in May 2013 by the World Assembly of the OIE Delegates
Date and Number of Registration	Registration Number: 20130108 May 2008: Resolution No 26 2018: Resolution No 19
Validation Studies Abstract	AS IQPlus
User's Manual/Kit Insert	User's Manual IQPlus User's Manual Pockit System

BOVINE SPONGIFORM ENCEPHALOPATHY

Name of the Diagnostic Kit	Prionics® – Check WESTERN
Name of the Manufacturer	Thermo Fisher Prionics
Contact	info@prionics.com
Type of Kit	Western Blot
Purpose(s) Validated	see Resolution No 27 adopted in May 2008 by the World Assembly of the OIE Delegates
Date and Number of Registration	Registration Number: 20080102 (discontinued from 31/12/2020) May 2008: Resolution No 27
Validation Studies Abstract	AS Prionics® – Check WESTERN
User's Manual/Kit Insert	User's Manual

TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHY

Name of the Diagnostic Kit	TeSeETM Western Blot
Name of the Manufacturer	Bio-Rad
Contact	tse@bio-rad.com
Type of Kit	Western Blot
Purpose(s) Validated	see Resolution No 26 adopted in May 2009 by the World Assembly of the OIE Delegates
Date and Number of Registration	Registration Number: 20090105 May 2009: Resolution No 26 2014: Resolution No 29 2019: Resolution No 31

Validation Studies Abstract [AS TeSeE WB](#)

User's Manual/Kit Insert [User's Manual](#)

SALMONELLOSIS

Name of the Diagnostic Kit Check&Trace Salmonella Test

Name of the Manufacturer Check-Points B.V.

Contact serovar@check-points.com for technical questions
info@check-points.com for general questions

Type of Kit Multiplex LDR PCR reaction followed by detection on a diagnostic micro array

Purpose(s) Validated see [Resolution No 24](#) adopted in May 2011 by the World Assembly of the OIE Delegates
see [Resolution No 20](#) adopted in May 2020 by the World Assembly of the OIE Delegates

Date and Number of Registration Registration Number: 20110106
May 2011: [Resolution No 24](#)
2015: [Resolution No 34](#)
2020: [Resolution No 20](#)

Validation Studies Abstract [AS CTS ; AS CTS – Supplementary Data](#)

User's Manual/Kit Insert [User's Manual](#); [User's Manual \(short protocol\)](#)

SALMONELLA ABORTUS OVIS

Name of the Diagnostic Kit Salmonella Abortusovis Test

Name of the Manufacturer DIATHEVA s.r.l.

Contact info@diatheva.com

Type of Kit ELISA

Purpose(s) Validated see [Resolution No 20](#) adopted in May 2020 by the World Assembly of the OIE Delegates

Date and Number of Registration Registration Number: 20200215
May 2020: [Resolution No 20](#)

Validation Studies Abstract [AS Diatheva Salmonella Abortusovis](#)

User's Manual/Kit Insert [User's Manual](#); [User's Manual \(short protocol\)](#)

BOVINE TUBERCULOSIS

Name of the Diagnostic Kit	<i>Mycobacterium bovis</i> Antibody Test Kit
Name of the Manufacturer	IDEXX Laboratories
Contact	LPDCS@IDEXX.com
Type of Kit	Indirect ELISA
Purpose(s) Validated	see Resolution No 24 adopted in May 2012 by the World Assembly of the OIE Delegates see Resolution No 19 adopted in May 2017 by the World Assembly of OIE Delegates see Resolution No 30 adopted in May 2023 by the World Assembly of WOAHA Delegates
Date and Number of Registration	Registration Number: 20120107 May 2012: Resolution No 24 2017: Resolution No 19 2023: Resolution No 30
Validation Studies Abstract	AS MBAT
User's Manual/Kit Insert	User's Manual

BOVINE TUBERCULOSIS

Name of the Diagnostic Kit	BOVIGAM® – <i>Mycobacterium bovis</i> Gamma interferon test kit for cattle
Name of the Manufacturer	Thermo Fisher Scientific Prionics AG Prionics Lelystad B.V. (May 2023)
Contact	info@prionics.com
Type of Kit	Sandwich ELISA
Purpose(s) Validated	see Resolution No 34 adopted in May 2015 by the World Assembly of the OIE Delegates see Resolution No 20 adopted in May 2020 by the World Assembly of OIE Delegates see Resolution No 30 adopted in May 2023 by the World Assembly of WOAHA Delegates
Date and Number of Registration	Registration Number: 20150110 May 2015: Resolution No 34 2019: Resolution No 31 2023: Resolution No 30 ; with new additional claim: 051319
Validation Studies Abstract	AS Bovigam VAS Bovigam (May 2023)
User's Manual/Kit Insert	User's Manual

BOVINE TUBERCULOSIS

Name of the Diagnostic Kit	Enferplex Bovine TB antibody test
Name of the Manufacturer	Enfer Scientific ULC
Contact	info@enfergroup.com
Type of Kit	Indirect chemiluminescent multiplex ELISA
Purpose(s) Validated	see Resolution No 31 adopted in May 2019 by the World Assembly of the OIE Delegates see Resolution No 30 adopted in May 2023 by the World Assembly of WOAHD Delegates
Date and Number of Registration	Registration Number: 20190113 May 2019: Resolution No 31 May 2023 ((111824): additional claim, Resolution No 30
Validation Studies Abstract	AS Enferplex VAS Bovigam (May 2023)
User's Manual/Kit Insert	User's Manual User's Manual (May 2023)

NEWCASTLE DISEASE

Name of the Diagnostic Kit	Newcastle Disease Virus antibody detection ELISA
Name of the Manufacturer	BioChek UK Ltd
Contact	info@biocheck.com
Type of Kit	ELISA
Purpose(s) Validated	see Resolution No 29 adopted in May 2014 by the World Assembly of the OIE Delegates
Date and Number of Registration	Registration Number: 20140109 May 2014: Resolution No 29 2019: Resolution No 31 2024: Resolution 34
Validation Studies Abstract	AS BioChek Newcastle ELISA
User's Manual/Kit Insert	User's Manual

CONTAGIOUS EQUINE METRITIS

Name of the Diagnostic Kit	Pourquier® IIF <i>Taylorella equigenitalis</i>
Name of the Manufacturer	IDEXX Laboratories
Contact	www.idexx.com
Type of Kit	Indirect immuno fluorescence test
Purpose(s) Validated	see Resolution No 15 adopted in May 2016 by the World Assembly of the OIE Delegates see Resolution No 30 adopted in May 2021 by the World Assembly of the OIE Delegate
Date and Number of Registration	Registration Number: 20160111 May 2016: Resolution No 15 2021: Resolution No 30
Validation Studies Abstract	AS IIF
User's Manual/Kit Insert	User's Manual

MIDDLE EAST RESPIRATORY SYNDROME

Name of the Diagnostic Kit	BIONOTE® Rapid MERS-CoV Ag Test
Name of the Manufacturer	BioNote, Inc
Contact	bionote@bionote.co.kr
Type of Kit	Immuno chromatographic assay
Purpose(s) Validated	see Resolution No 15 adopted in May 2016 by the World Assembly of the OIE Delegates see Resolution No 30 adopted in May 2021 by the World Assembly of the OIE Delegate see Resolution No 30 adopted in May 2023 by the World Assembly of the OIE Delegate
Date and Number of Registration	Registration Number: 20160212 May 2016: Resolution No 15 2023: Resolution No 30
Validation Studies Abstract	AS Rapid MERS-CoV Test . Renewal: BIONOTE® Rapid MERS-CoV Ag Test Kit
User's Manual/Kit Insert	User's Manual User's Manual (August 2023)

AFRICAN SWINE FEVER

Name of the Diagnostic Kit	VetMAX™ African Swine Fever Virus Detection Kit
Name of the Manufacturer	Thermo Fisher Scientific LSI S.A.S.
Contact	serviceclients@thermofisher.com
Type of Kit	Taqman® real time PCR
Purpose(s) Validated	see Resolution No 20 adopted in May 2020 by the World Assembly of the OIE Delegates
Date and Number of Registration	Registration Number: 20200114 14 May 2020: Resolution No 20
Validation Studies Abstract	AS VetMAX ASF
User's Manual/Kit Insert	User's Manual

AFRICAN SWINE FEVER

Name of the Diagnostic Kit	Genelix™ ASFV Real-time PCR Detection Kit
Name of the Manufacturer	Sanigen Co., Ltd.
Contact	Tel: +82-1833-8010; Fax: +82-2-573-3134
Type of Kit	Real-time PCR
Purpose(s) Validated	see Resolution No 34 adopted in May 2024 by the World Assembly of the WOAHA Delegates
Date and Number of Registration	Registration Number: 052131 30 May 2024: Resolution No 34
Validation Studies Abstract	Genelix™ ASFV Real-time PCR Detection Kit
User's Manual/Kit Insert	User's Manual

AFRICAN SWINE FEVER

Name of the Diagnostic Kit	Sentinel® ASFV Antibody Rapid Test
Name of the Manufacturer	Excelsior Bio-System Incorporation
Contact	sales@ebs.com.tw
Type of Kit	Immuno-chromatographic lateral flow assay (Rapid test)
Purpose(s) Validated	see Resolution No 34 adopted in May 2024 by the World Assembly of the WOAHA Delegates
Date and Number of Registration	Registration Number: 062233 30 May 2024: Resolution No 34
Validation Studies Abstract	Sentinel® ASFV Antibody Rapid Test
User's Manual/Kit Insert	User's Manual

FOOT AND MOUTH DISEASE VIRUS (FMDV, Serotypes A, O and Asia -1)

Name of the Diagnostic Kit	VDRG® FMDV 3Diff/PAN Ag Rapid Kit
Name of the Manufacturer	MEDIAN Diagnostics Inc.
Contact	median@mediandx.com
Type of Kit	Lateral flow test or pen-side test
Purpose(s) Validated	see Resolution No 30 adopted in May 2023 by the World Assembly of the WOAAH Delegates
Date and Number of Registration	Registration Number: 022029 29 May 2023: Resolution No 30
Validation Studies Abstract	AS VDRG FMDV
User's Manual/Kit Insert	User's Manual

INFECTION OF WHITE SPOT SYNDROME VIRUS (WSSV)

Name of the Diagnostic Kit	Inncreate Bioscience WSSV RP Rapid Test Kit
Name of the Manufacturer	Inncreate Bioscience Co., Ltd.
Contact	info@inncreatebio.com
Type of Kit	Lateral flow immunochromatographic assay (LFIA)
Purpose(s) Validated	see Resolution No 31 adopted in May 2023 by the World Assembly of the WOAAH Delegates
Date and Number of Registration	Registration Number: 082132 May 2023: Resolution No 31
Validation Studies Abstract	AS Inncreate WSSV RP
User's Manual/Kit Insert	User's Manual

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