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Český institut pro akreditaci, o.p.s.
Olšanská 54/3, 130 00 Praha 3

issues

according to section 16 of Act No. 22/1997 Coll., on technical requirements for products, as amended

CERTIFICATE OF ACCREDITATION

No. 490/2021

Výzkumný ústav veterinárního lékařství, v.v.i.
with registered office Hudcova 296/70, 621 00 Brno - Medlánky, Company Registration
No. 00027162

to the Testing Laboratory No. 1354
Laboratories Centre

Scope of accreditation:

Diagnostic activity in the field of infectious and non-infectious diseases and food hygiene using culture, serological, microscopic, PCR methods to the extent as specified in the appendix to this Certificate.

This Certificate of Accreditation is a proof of Accreditation issued on the basis of assessment of fulfillment of the accreditation criteria in accordance with

ČSN EN ISO/IEC 17025:2018

In its activities performed within the scope and for the period of validity of this Certificate, the Body is entitled to refer to this Certificate, provided that the accreditation is not suspended and the Body meets the specified accreditation requirements in accordance with the relevant regulations applicable to the activity of an accredited Conformity Assessment Body.

This Certificate of Accreditation replaces, to the full extent, Certificate No.: 290/2020 of 6. 5. 2020, or any administrative acts building upon it.

The Certificate of Accreditation is valid until: **6. 5. 2025**

Prague: 14. 9. 2021



Lukáš Burda
Director of the Department
of Testing and Calibration Laboratories
Czech Accreditation Institute
Public Service Company

**The Appendix is an integral part of
Certificate of Accreditation No. 490/2021 of 14/09/2021**

Accredited entity according to ČSN EN ISO/IEC 17025:2018:

Výzkumný ústav veterinárního lékařství, v.v.i.

Laboratories Centre
Hudcova 296/70, 621 00 Brno

Testing laboratory locations:

1. **Laboratory – Animal Health and Food Safety** Hudcova 296/70, 621 00 Brno
2. **Laboratory – Fish Viral Diseases** Hudcova 296/70, 621 00 Brno
3. **Laboratory – Spermatology and Andrology** Hudcova 296/70, 621 00 Brno
4. **Laboratory – Bovine Diseases** Hudcova 296/70, 621 00 Brno
5. **Laboratory – Electron Microscopy** Hudcova 296/70, 621 00 Brno

The Laboratory provides expert opinions and interprets test results.

1. Laboratory – Animal Health and Food Safety

Tests:

Ordinal number ¹	Test procedure/method name	Test procedure/method identification ²	Tested object
1	Detection of human noroviruses, hepatitis A virus, hepatitis E virus and SARS-CoV-2 ³ by real time RT-PCR method	SOP 108/ A	Biological material, food, smears from the environment, water

¹ asterisk at the ordinal number identifies the tests, which the Laboratory is qualified to carry out outside the permanent laboratory premises

² if the document identifying the test procedure is dated, only these specific procedures are used. If the document identifying the test procedure is not dated, the latest edition of the specified procedure is used (including any changes); source literature is specified in the table no. 1

³ for SARS-CoV-2 determination the test is carried out only in food, smears from the environment, drinking, process and waste water

2. Laboratory – Fish Viral Diseases

Tests:

Ordinal number ¹	Test procedure/method name	Test procedure/method identification ²	Tested object
1	Reserved		
2	Processing of fish tissues for virological examination and isolation of viruses pathogenic to fish on cell lines	SOP 201/ A	Biological material
3	Detection of selected sections of DNA and RNA sequences in fish viruses ³ by PCR method	SOP 202/ A	Biological material



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Ordinal number ¹	Test procedure/method name	Test procedure/method identification ²	Tested object
4	Detection of selected sections of DNA and RNA sequences of fish viruses ⁴ by real time PCR method	SOP 203/ A	Biological material

¹ asterisk at the ordinal number identifies the tests, which the Laboratory is qualified to carry out outside the permanent laboratory premises

² if the document identifying the test procedure is dated, only these specific procedures are used. If the document identifying the test procedure is not dated, the latest edition of the specified procedure is used (including any changes); source literature is specified in the table no. 1

³ applies to koi herpesvirus (KHV), iridoviruses (genus Ranavirus), infectious pancreatic necrosis virus (IPNV), spring viraemia of carp virus (SVCV), infectious haematopoietic necrosis virus (IHNV), and viral haemorrhagic septicaemia virus (VHSV), carp edema virus (CEV) and viruses of the genus *Vesiculovirus*

⁴ applies to koi herpesvirus (KHV), infectious haematopoietic necrosis virus (IHNV), viral haemorrhagic septicaemia virus (VHSV) and carp edema virus (CEV)

3. Laboratory – Spermatology and Andrology

Tests:

Ordinal number ¹	Test procedure/method name	Test procedure/method identification ²	Tested object
1 - 4	Reserved		
5	Laboratory examination of sperm - microscopic and macroscopic	SOP 301/ A	Sperm

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² if the document identifying the test procedure is dated, only these specific procedures are used. If the document identifying the test procedure is not dated, the latest edition of the specified procedure is used (including any changes)



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4. Laboratory – Bovine Diseases

Tests:

Ordinal number ¹	Test procedure/method name	Test procedure/method identification ²	Tested object
1 - 5	Reserved		
6	Bovine Viral Diarrhea (BVD) – detection of virus and antibodies by ELISA method	SOP 401/ A	Biological material
7	Infectious Bovine Rhinotracheitis (IBR) – detection of virus and antibodies by ELISA method	SOP 402/ A	Biological material
8	Paratuberculosis – detection of antibodies by ELISA method	SOP 403/ A	Biological material

¹ asterisk at the ordinal number identifies the tests, which the Laboratory is qualified to carry out outside the permanent laboratory premises

² if the document identifying the test procedure is dated, only these specific procedures are used. If the document identifying the test procedure is not dated, the latest edition of the specified procedure is used (including any changes); source literature is specified in the table no. 1

³ applies to bovine and small ruminants

5. Laboratory – Electron Microscopy

Tests:

Ordinal number ¹	Test procedure/method name	Test procedure/method identification ²	Tested object
1 - 8	Reserved		
9	Electron microscopic diagnostics of viruses by negative staining method	SOP 501/ A	Biological material

¹ asterisk at the ordinal number identifies the tests, which the Laboratory is qualified to carry out outside the permanent laboratory premises

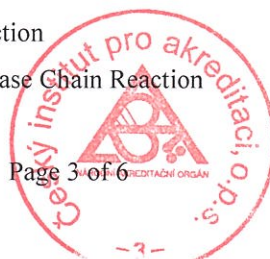
² if the document identifying the test procedure is dated, only these specific procedures are used. If the document identifying the test procedure is not dated, the latest edition of the specified procedure is used (including any changes); source literature is specified in the table no. 1

Explanatory notes:

DNA Deoxyribonucleic Acid

PCR Polymerase Chain Reaction

qPCR Quantification Polymerase Chain Reaction



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SOP	Standard Operating Procedure
mRNA	Messenger Ribonucleic Acid
ELISA	Enzyme-Linked Immunoassay
STa	Thermostable Enterotoxin
LT	Thermolabile Enterotoxin
PFGE	Pulsed Field Gel Electrophoresis
Biological material	Suspensions of cells, skin, faeces, body liquids, tissues, secretions of mucous membranes and glands
water	Drinking, surface, waste, process
Food	Food of animal or plant origin

Table no. 1: Source literature

Test procedure/method identification	Source literature
SOP 108/ A	<p>ISO/TS15216-2: 2013 (E). Microbiology of food and animal feed – Horizontal method for determination of hepatitis A virus and norovirus in food using real time RT-PCR – Part 2, Method for qualitative detection.</p> <p>da Silva AK, Le Saux JC, Parnaudeau S, Pommepuy M, Elimelech M, Le Guyader FS. 2007. Evaluation of removal of noroviruses during wastewater treatment, using real-time reverse transcription-PCR: different behaviors of genogroups I and II. <i>Appl Environ Microbiol.</i> 73(24):7891-7.</p> <p>Svraka S, Duizer E, Vennema H, de Bruin E, van der Veer B, Dorresteijn B, Koopmans M. 2007. Etiological role of viruses in outbreaks of acute gastroenteritis in The Netherlands from 1994 through 2005. <i>J Clin Microbiol.</i> 45(5):1389-94.</p> <p>Kageyama T, Kojima S, Shinohara M, Uchida K, Fukushi S, Hoshino FB, Takeda N, Katayama K. 2003. Broadly reactive and highly sensitive assay for Norwalk-like viruses based on real-time quantitative reverse transcription-PCR. <i>J Clin Microbiol.</i> 41(4):1548-57.</p> <p>Loisy F, Atmar RL, Guillon P, Le Cann P, Pommepuy M, Le Guyader FS. 2005. Real-time RT-PCR for norovirus screening in shellfish. <i>J Virol Methods.</i> 123(1):1-7.</p> <p>Costafreda MI, Bosch A, Pintó RM (2006). Development, evaluation, and standardization of a real-time TaqMan reverse transcription-PCR assay for quantification of hepatitis A virus in clinical and shellfish samples. <i>Appl Environ Microbiol.</i> 72 (6): 3846-55.</p> <p>Vasickova P, Kralik P, Slana I, Pavlik I (2012). Optimisation of a triplex real time RT-PCR for detection of hepatitis E virus RNA and validation on biological samples. <i>J Virol Methods.</i> 180: 38-42.</p> <p>Jothikumar N, Cromeans TL, Robertson BH, Meng XJ, Hill VR (2006). A broadly reactive one-step real-time RT-PCR assay for rapid and sensitive detection of hepatitis E virus. <i>J Virol Methods.</i> 131, 65-71.</p> <p>Gyarmati P, Mohammed N, Norder H, Blomberg J, Belak S, Widen F</p>

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	<p>(2007). Universal detection of hepatitis E virus by two real-time PCR assays: TaqMan and Primer-Probe energy transfer. <i>J Virol Methods</i>. 146, 226-235.</p> <p>Martínez-Martínez M, Díez-Valcarce M, Hernández M, Rodríguez-Lázaro D. (2011). Design and Application of Nucleic Acid Standards for Quantitative Detection of Enteric Viruses by Real-Time PCR. <i>Food and Environ Virol</i>. 3, 92-98.</p> <p>Wong S., Pabbaraju K., Pang X.L., Lee B.E., Fox J.D. (2008). Detection of a broad range of human adenoviruses in respiratory tract samples using a sensitive multiplex real-time PCR assay. <i>J Med Virol</i>. 80, 856-865.</p> <p>Mikel P., Bartejsová I., Králík P. (2015). Detekce a kvantifikace lidského Adenoviru sérotypu 40 a 41 pomocí metody qPCR. Uplatněná certifikovaná metodika 53/2015. ISBN 978-80-86895-58-1</p> <p>Vašíčková P., Mikel P., Králík P. (2014). Použití externí kontroly (armored RNA) procesu analýzy vzorků na přítomnost neobalených RNA virů a jejich následnou kvantifikaci. Uplatněná certifikovaná metodika č. 52/2014. ISBN 978-80-86895-57-4</p> <p>EliGene® COVID19 BASIC A RT (Elizabeth Pharmacon), manuál výrobce</p>
SOP 201/ A	<p>Commission Decision 92/532/EEC</p> <p>Commission Decision 96/240/EC</p> <p>Commission Decision 2001/183/EC</p>
SOP 202/ A	<p>Koutná M. et al. (2003): <i>Dis. Aquat. Org.</i>, 55, 229 - 235.</p> <p>Stone D. M. et al. (2003): <i>Dis. Aquat. Org.</i>, 53, 203 - 210.</p> <p>Taksdal T. et al. (2001): <i>Bull. Eur. Assoc. Fish. Pathol.</i>, 5, 214 - 215.</p> <p>Vícenová M., Pokorová D., Reschová S., Veselý T. Stanovení viru virové hemoragické septikémie pomocí PCR- metodický návrh v RIV, 2008.</p> <p>Vícenová M., Pokorová D., Reschová S., Veselý T. Stanovení viru infekční hematopoetické nekrózy pomocí PCR- metodický návrh v RIV, 2008.</p> <p>Bercovier H. et al. (2005): <i>BMC Microbiol.</i>, 5, 1 – 9.</p> <p>Hyatt A.D. et al. (2000): <i>Arch. Virol</i>. 145, 301 - 331.</p> <p>Way, K. et al. (2017) <i>Dis. Aquat. Org.</i> 126: 155–166.</p>
SOP 203/ A	<p>Jonstrup S. P. et al (2013): <i>J. Fish. Dis.</i>, 36: 9–23.</p> <p>Purcell M. K. et al (2013) <i>Dis. Aquat. Org.</i>, 106:103-115.</p> <p>Gilad O. et al. (2004) <i>Dis. Aquat. Org.</i> 60: 179–187.</p> <p>Way, K et al. (2017) <i>Dis. Aquat. Org.</i> 126: 155–166.</p>
SOP 301/ A	<p>Věžník Z. a kol., Hodnocení semene pro asistovanou reprodukci a výběr plemenů. Striktní analýza spermatické morfologie SASMO. VÚVeL Brno, 2000, 142s. a Věžník Z. a kol., Repetitorium spermatologie a andrologie a metodiky spermatoanalýzy. VÚVeL Brno, 2004, 197 s.</p> <p>Manuál pro analýzu semene pomocí CASA systému CEROS II. HT CASA II Software Guide – Boar, Animal and Eguine Breeder, systém CEROS II, výrobce Hamilthon Thorne, Beverly, MA.</p> <p>Přinosilová P., Kubát J., Kopecká V., Šípek J., Kunetková M. 2014. Program pro detailní hodnocení morfologického obrazu spermií DeSMA (Detailed Sperm Morphology Analysis).</p>

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	World Health Organization 2010. WHO laboratory manual for the Examination of human semen. 5th ed. WHO Press, Geneva, Switzerland. 271 p. ISBN 978 92 4 154778 9.
SOP 401/ A	Manual of Diagnostic Tests and Vaccines for Terrestrial Animals OIE 2018, chapter 3.4.7. (NB: Version adopted in May 2015)
SOP 402/ A	Manual of Diagnostic Tests and Vaccines for Terrestrial Animals OIE 2018, chapter 3.4.11. (NB: Version adopted in May 2017)
SOP 403/ A	Manual of Diagnostic Tests and Vaccines for Terrestrial Animals OIE 2018, chapter 3.1.15. (NB: Version adopted in May 2014)
SOP 501/ A	Smid B. Valicek L. Kudrna J.: Rod-shaped virus-like particles in intestinal contents of pheasant chicks. Zentralbl Veterinärmed B. 1997 Sep, 44(7): 445-7, PMID:9323932 (PubMed – indexed for MEDLINE)

