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## ANNEX III

Standards for Aujeszky's disease serological tests — Protocol for the enzyme linked immunosorbent assay (ELISA) for detecting antibodies to Aujeszky's disease virus (whole virus), to glycoprotein B (ADVgB), to glycoprotein D (ADV-gD) or to glycoprotein E (ADV-gE)

The institutes listed in paragraph 2(d) shall evaluate Elisa ADV-gE tests and kits 1. against the criteria in paragraph 2(a), (b) and (c). The competent authority in each Member State shall ensure that only Elisa ADV-gE kits that meet these standards shall be registered. The examinations listed in 2(a) and (b) must be carried out prior to approval of the test and the examination in 2(c), at least, must thereafter be carried out on each batch.

2.	Standardisation, sensitivity and specificity of the test.		
(a)	The sensitivity of the test must be of such a level that the following Community reference sera are scored positive:		
	— Community reference serum ADV 1 at 1:8 dilution,		
	<ul> <li>Community reference serum ADV-gE A,</li> </ul>		
	<ul> <li>Community reference serum ADV-gE B,</li> </ul>		
	<ul><li>Community reference serum ADV-gE C,</li></ul>		
	<ul><li>Community reference serum ADV-gE D,</li></ul>		
	<ul> <li>Community reference serum ADV-gE E,</li> </ul>		
	— Community reference serum ADV-gE F.		
(b)	The specificity of the test must be of such a level that the following Community		

- y reference sera are scored negative:
  - Community reference serum ADV-gE G,
  - Community reference serum ADV-gE H,
  - Community reference serum ADV-gE J.
  - Community reference serum ADV-gE K,
  - Community reference serum ADV-gE L,
  - Community reference serum ADV-gE M,
  - Community reference serum ADV-gE N,
  - Community reference serum ADV-gE O,
  - Community reference serum ADV-gE P,
  - Community reference serum ADV-gE Q.
- For batch control, Community reference serum ADV 1 must be scored positive at 1:8 (c) dilution and one of the Community reference sera from ADV-gE G to ADV-gE Q, as listed in point (b), must be scored negative.
  - For batch control of ADV-gB and ADV-gD kits, Community reference serum ADV 1 must be scored positive at the dilution of 1:2 and Community reference serum Q referred to in (b) should be scored negative.
- (d) I<sup>FI</sup>The institutes listed below will, in addition, be responsible for checking the quality of the ELISA method in each Member State, and in particular for producing and standardising national reference sera according to the Community reference sera.

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AT	AGES: Österreichische
***	Agentur für Gesundheit und Ernährungssicherheit GmbH —
	Institut für veterinärmedizinische
	Untersuchungen Mödling (Austrian
	Agency for Health and Consumer
	Protection — Institute for veterinary
	investigations Mödling)
	Robert Koch-Gasse 17 A-2340 Mödling
	Tel. +43 (0) 505 55-38112
	Fax +43 (0) 505 55-38108
	Email: vetmed.moedling@ages.at
BE	CODA — CERVA — VAR
	Veterinary and Agrochemical Research
	Centre
	Groeselenberg 99 B-1180 Brussels
CY	
CY	State Veterinary Laboratory Veterinary Services
	1417 Athalassa
	Nicosia
CZ	Státní veterinární ústav Olomouc
	Jakoubka ze Stříbra 1
	779 00 Olomouc
	Telefon: 585 557 111 Fax 585 222 394
	email: svuolomouc@svuol.cz
DE	Friedrich-Loeffler-Institut
	Bundesforschungsinstitut für
	Tiergesundheit
	Südufer 10
	D-17493 Greifswald — Insel Riems
	Tel. + 49 38351 7-0 Fax + 49 38351 7-1219, 7-1151, 7-1226
DV	
DK	National Veterinary Institute Technical University of Denmark
	Lindholm Island
	DK-4774 Kalvehave
	Denmark
	Switchboard: +45 88 60 00
	Fax +45 88 79 01 Email: vet@vet.dtu.dk
EE	Veterinaar- ja Toidulaboratoorium
LL	Kreutzwaldi 30,
	51006 Tartu,
	· · · · · · · · · · · · · · · · · · ·

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	Faks: + 372 7 386 102 Email: info@vetlab.ee
ES	Laboratorio Central de Sanidad Animal de Algete Carretera de Algete, km 8 Algete 28110 (Madrid) Tel. +34 916 290 300 Fax +34 916 290 598 Email: lcv@mapya.es
FI	Finnish Food Safety Authority Animal Diseases and Food Safety Research Mustialankatu 3 FI-00790 Helsinki, Finland Email: info@evira.fi Tel. +358 20 772 003 (exchange) Fax +358 20 772 4350
FR	Laboratoire d'études et de recherches avicoles, porcines et piscicoles AFSSA site de Ploufragan/Brest — LERAPP BP 53 22440 Ploufragan
F2	F2
GR	Centre of Athens Veterinary Institutes 25 Neapoleos Street, GR-153 10 Agia Paraskevi Attiki Tel. +30 2106010903
HU	Nemzeti Élelmiszerlánc-biztonsági Hivatal, Állat-egészségügyi Diagnosztikai Igazgatóság Central Agricultural Office, Veterinary Diagnostic Directorate Address: 1149 Budapest, Tábornok u. 2. Mailing Address: 1581 Budapest, 146. Pf. 2. Tel. +36 1 460-6300 Fax +36 1 252-5177 Email: ugyfelszolgalat@nebih.gov.hu
IE	Virology Division Central Veterinary Research Laboratory Department of Agriculture and Food Laboratories Backweston Campus Stacumny Lane Celbridge Co. Kildare

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IT	Centro di referenza nazionale per la malattia di Aujeszky — Pseudorabbia c/o Istituto zooprofilattico sperimentale della Lombardia e dell'Emilia Romagna, Via Bianchi, 9; 25124 Brescia
LT	National Veterinary Laboratory (Nacionalinė veterinarijos laboratorija) J. Kairiūkščio 10 LT-08409 Vilnius
LU	CODA — CERVA — VAR Veterinary and Agrochemical Research Centre Groeselenberg 99 B-1180 Brussels
LV	Pārtikas drošības, dzīvnieku veselības un vides zinātniskais institūts 'BIOR' (Institute of Food Safety, Animal Health and Environment BIOR) Lejupes iela 3, Rīga, LV-1076 Tel. +371 76205 13 Fax +371 7620434 Email: bior@bior.lv
MT	National Veterinary Laboratory Veterinary and Phytosanitary Regulation Department Ministry for Sustainable Development, the Environment and Climate Change, Abattior Square, Albert Town, Triq Prince Albert, Marsa, Malta Tel. +356 22925389
NL	Centraal Instituut voor Dierziekte Controle CIDC-Lelystad Hoofdvestiging: Houtribweg 39 Nevenvestiging: Edelhertweg 15 Postbus 2004 8203 AA Lelystad
PL	Laboratory Department of Swine Diseases Państwowy Instytut Weterynaryjny — Państwowy Instytut Badawczy al. Partyzantów 57, 24-100 Puławy Tel. +48 81 889 30 00 Fax +48 81 886 25 95

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	Email: sekretariat@piwet.pulawy.pl
PT	Laboratório Nacional de Investigação Veterinária (LNIV) Estrada de Benfica, 701 P-1549-011 Lisboa
RO	Laboratorul Național de Referință pentru Herpesviroze Institutul de Diagnostic și Sănătate Animală Str. Dr Staicovici, nr. 6, cod 050557, sector 5, București telefon: 0374.322.015 fax 0214.113.394 email: office@idah.ro
SE	Statens veterinärmedicinska anstalt Department of Virology S-751 89 Uppsala Tel. (46-18) 67 40 00 Fax (46-18) 67 44 67
SI	Univerza v Ljubljani Veterinarska fakulteta Nacionalni veterinarski inštitut Gerbičeva 60, SI-1000 Ljubljana
SK	Štátny veterinárny ústav Pod dráhami 918 960 86 Zvolen Slovenska republika]

## **Textual Amendments**

- **F1** Substituted by Commission Implementing Decision (EU) 2016/1782 of 5 October 2016 amending Decision 2008/185/EC as regards the inclusion of Lithuania in the list of Member States where an approved national control programme for Aujeszky's disease is in place and updating the list of national institutes in Annex III (notified under document C(2016) 6288) (Text with EEA relevance).
- F2 Words in Annex 3 omitted (31.12.2020) by virtue of The Import of, and Trade in, Animals and Animal Products (Miscellaneous Amendments) (EU Exit) Regulations 2020 (S.I. 2020/1462), regs. 1(3), 51(10) (with regs. 69-71)

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