



CODA-CERVA

Veterinary and Agrochemical Research Centre

**INITIAL CONTROL FOR DIAGNOSTIC REAGENTS
TO BE USED IN BELGIAN OFFICIAL ANIMAL DISEASE CONTROL PROGRAMMES**

**ELISA KITS FOR THE DETECTION OF gE SPECIFIC ANTIBODIES AGAINST INFECTIOUS BOVINE
RHINOTRACHEITIS (BHV1) IN BOVINE TANK MILK (IBRgE)**

PUBLICATION / INVITATION

**Initial control : Cert_IBR_gE_AbELISA_MILK
Ref. No. 16203**

THIS PROCEDURE DOES NOT CONCERN ANY SELECTED TENDER

A. GENERAL CONTROL PROCEDURE

In the frame of the official programs for animal disease control, the CODA-CERVA (Veterinary and Agrochemical Research Centre) in consultation with the Federal Agency for the Safety of the Food Chain (FASFC) calls for candidacy for the initial control of commercial diagnostic reagents. Successful initial control will give access to the **Belgian market**. Diagnostic reagents (kits) used within a Belgian official animal disease control program, commissioned by the FASFC, have to be controlled by the CODA-CERVA and this is conducted according to the procedure PRO/4.3/03. Briefly, this procedure consists of 2 phases.

Phase 1 is the actual **initial control** (validation) of the diagnostic reagents (kits) with as a result the official publication of the list of producers/distributors and/or the commercial names of the diagnostic reagents (kits) which comply with the scientific minimum criteria which were predefined by the CODA-CERVA and the expert committee. This procedure does not concern any selected tender. **Phase 2** consists of a compulsory **batch control** by the CODA-CERVA, for each lot/batch of the validated diagnostic reagents (kits) destined for the Belgian market.

When a initial control is completed, producers/distributors may request a **supplementary initial control** for a failed diagnostic reagent once, within one year after the end of the original procedure. Producers/distributors wishing to add a reagent to the list of validated reagents, may request a supplementary initial control at any time. At the latest at the end of each year, CODA-CERVA will collect and plan all these supplementary initial controls for the next year.

**To participate in any initial control of commercial diagnostic reagents for official programs,
the participant must register by sending an email to Isabelle Behaeghel at Diagnostic.Control@codacerva.be**

The initial control (validation) procedure consists of:

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Central office
Veterinary departments:
Groeselenberg 99, B-1180 Brussels
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Agrochemical departments:
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Experimental centre
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e-mail info@codacerva.be - <http://www.codacerva.be>

ref_IBRgE_BulletinEng_ref 16203





- 1. Registration.** The producers/distributors must register explicitly for each separate initial control and may also request a supplementary initial control via Isabelle behaegel: Diagnostic.Control@coda-cerva.be. The compulsory information includes:
 - The name and address of the company
 - Statement: 'producer' or 'distributor for ...'
 - Designated contact person and his/her coordinates
 - The number of participating kits/protocols and their names
 - The types of kits participating (indirect, sandwich,...)
- 2. Submission of Administrative Dossier and Technical Batch/lot.** The registered producers/distributors wishing to participate have a maximum of **3 months (60 working days)** to prepare and submit:
 - The **Administrative Dossier: email 1 electronic copy** of the completed Checklist + all requested and relevant Annexes through Isabelle Behaeghel at Diagnostic.Control@coda-cerva.be, who will register and confirm reception. Additionally, 2 identical official dossiers must be sent to Isabelle behaegel, CODA-CERVA, Groeselenberg 99, B-1180 Brussels, Belgium. It concerns 1 official paper dossier (**hard copy**) + 1 official electronic dossier (burned on **CD-ROM**). The 2 official dossiers are put in a first envelope which is sealed. On this envelope the following statements need to appear: 'Administrative Dossier –Initial Control IBRgE ELISA kits – Ref. No. 16203' and 'Opening of the Dossier – **25/01/2018**'. This envelope is enclosed in a second envelope with subsequent statements: 'URGENT - Administrative Dossier - Initial Control IBRgE Ab ELISA kits – dossier 16203 - and 'Opening of the Dossier – 05/12/2017' in the upper left corner. The address of the destination must also be mentioned here. Your dossier will be accepted as long as the deadline **25/01/2018 – 10 AM** has not been passed. The **Checklist**, the **Guidance document** and the **Minimum Criteria** document can be requested from Isabelle Behaeghel (Diagnostic.Control@coda-cerva.be) after the registration.
 - The **Technical Batch/lot:** on the same day **25/01/2018 – 10am** one particular batch/lot must be submitted, **minimum 10 plates per protocol** , supplied free of charge to: Isabelle Behaeghel at Diagnostic.Control@coda-cerva.be, CODA-CERVA, Groeselenberg 99, B-1180 Brussels, Belgium. Isabelle Behaeghel will register and confirm the reception.
- 3. Administrative Evaluation.** Performed by the concerning Belgian National Reference Laboratory of CODA-CERVA, the Operational Unit ENZOREM (Enzootic and (re)emerging viral diseases), whereby the administrative dossier of the producer/distributor (completed Checklist + Annexes) is checked against the administrative minimum criteria determined by the expert committee. The **Checklist**, the **Guidance Document** and the **Minimum Criteria** document can be accessed as soon as the registration is approved.
- 4. Technical Evaluation.** Performed by the concerning Belgian National Reference Laboratory of CODA-CERVA, the Operational Unit ENZOREM (Enzootic and (re)emerging viral diseases), whereby the requested diagnostic reagents (kits) are checked against the technical minimum criteria as fixed by CODA-CERVA and the expert committee and as communicated in the **Minimum Criteria** document (English), which can be accessed as soon as the registration is approved.

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- 5. The publication of validated kits and of their producers/distributors.** After the administrative and technical evaluation of all the diagnostic reagents (kits), the concerning Belgian National Reference Laboratory of CODA-CERVA, the Operational Unit ENZOREM (Enzootic and (re)emerging viral diseases), will draw up the list of all the diagnostic reagents (kits) which meet the minimum criteria (= validated diagnostic reagents/kits), as well as the names of their producers/distributors. A specific report/certificate will also be forwarded to each producer/distributor who has participated in the initial control. Subsequently, the list and reports of validated diagnostic reagents (kits) and the names of their producers/distributors will be transmitted to the FASFC and CODA-CERVA will publish the list of the validated diagnostic reagents (kits) on its website.
- 6. Feedback and Complaints.** Each participant will have the possibility to reply to or to put in a complaint about the report after receiving the individual report. CODA-CERVA will treat each reply or complaint within 30 days, after which CODA-CERVA will invite personally the producer/distributor to discuss the report and the results.

The integral initial control (validation) procedure as described above (Phase 1) will be completed within 12 months after the date of the publication of the call for the initial control procedure, and within 12 months after the date of acknowledgement of participation for the additional initial control procedure.

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Bull_Cert_IBRgE_AbELISA_2017_ref 16203



B. SPECIFIC DETAILS FOR [Cert_IBRgE_AbELISA_Milk_2017](#) (ref. no. 16203)

PARAMETER	NAME / TYPE	CODE
Additional control Initial	Original	Cert_IBRgE_AbELISA_Milk_2017 (ref. no. 16203)
Diagnostic Reagent	Antibody ELISA	Ab ELISA
Detection	gE Antibodies against infectious bovine rhinotracheitis (Bovine Herpesvirus 1)	IBRgE
Target Species	Bovines	B
Target Matrix	Tank milk samples	MI
Estimated Market	10000-20000 samples per year	/
Protocols	Overday (short) - Overnight (long)	OD – ON
Administrative Dossier To submit to Isabelle Behaeghel	NameFirm_Cert_IBRgE_Checklist.xlsx	Send to: Diagnostic.Control@coda-cerva.be 1 dossier = 1 checklist + Annexes per kit Send to: Isabelle Behaeghel, CODA-CERVA, Groeselenberg 99, B-1180 Brussels, Belgium 1 electronic copy + 1 paper copy of dossier Deadline date: 25/01/2018 (10 am)
Technical Batch To submit to Isabelle Behaeghel	One specific batch Minimum 10 plates per protocol	Send to: Isabelle Behaeghel, CODA-CERVA, Groeselenberg 99, B-1180 Brussels, Belgium Deadline date: 25/01/2018 (10 am)
REPORT EXPECTED BY	Acknowledged application date + 1 year	Deadline date: 25/10/2018

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**SHOULD YOU HAVE ANY QUESTIONS REGARDING THIS INITIAL CONTROL,
PLEASE DO NOT HESITATE TO CONTACT
Diagnostic.Control@coda-cerva.be**

With kind regards,

Isabelle Behaeghel: Coordination of Veterinary Diagnosis

ENZOREM: Operational Unit of Enzootic and (re)emerging viral diseases

CODA-CERVA: Centrum voor Onderzoek in Diergeneeskunde en Agrochemie - Centre d'Étude et de Recherches Vétérinaires et Agrochimiques

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