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

ELISA KITS FOR THE DETECTION OF total or gB SPECIFIC ANTIBODIES AGAINST infectious bovine rhinotracheitis (BHV1) IN BOVINE TANK MILK

PUBLICATION / INVITATION

Initial Control 22/04/2024
Additional control : Suppl_ Cert_ IBRgB_AbELISA_MILK_2017_2024 Ref. No. 16204

THIS PROCEDURE DOES NOT CONCERN ANY SELECTED TENDER

A. GENERAL CONTROL PROCEDURE

In the frame of the official programs for animal disease control, Sciensano 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. Successfull 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 Sciensano 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 Sciensano and the expert committee. This procedure does not concern any selected tender. **Phase 2** consists of a compulsory **batch control** by Sciensano, for each lot/batch of the validated diagnostic reagents (kits) destined for the Belgian market.

When an 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, Sciensano 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 Géraldine Boseret at diagnostic.Control@sciensano.be

Central office
Veterinary departments:
Groeselenberg 99, B-1180 Brussels
Tel. +32 (0)2 379 04 00
Fax +32 (0)2 379 06 70 (general)
+32 (0)2 379 04 01 (director))
+32 (0)2 379 06 64 (dispatching)

Agrochemical departments:
Leuvensesteenweg 17
B-3080 Tervuren
Tel. +32 (0)2 769 22 00
Fax +32 (0)2 769 23 05

Experimental centre
Kerklaan 68
B-1830 Machelen
Tel. +32 (0)2 251 33 26
Fax +32 (0)2 251 00 12

e-mail info@sciensano.be - http://www.sciensano.be

federal public service
HEALTH, FOOD CHAIN SAFETY AND ENVIRONMENT

The initial control (validation) procedure consists of:

1. **Registration.** The producers/distributors must register explicitly for each separate initial control and may also request a supplementary initial control via Géraldine Boseret : Diagnostic.Control@sciensano.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 Géraldine Boseret at Diagnostic.Control@sciensano.be, who will register and confirm reception. Additionally, 2 identical official dossiers must be sent to Géraldine Boseret, Sciensano, 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 – **Suppl_ Cert_ IBRgB_AbELISA_MILK_2017_2024 Ref. No. 16204'** and 'Opening of the Dossier – **22/07/2024**'. This envelope is enclosed in a second envelope with subsequent statements: 'URGENT - Administrative Dossier Supplementary initial control : **Suppl_ Cert_ IBRgB_AbELISA_MILK_2017_2024 Ref. No. 16204**- and 'Opening of the Dossier – **22/07/2024**' 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 **22/07/2024– 10:00 am** has not been passed. The **Checklist**, the **Guidance document** and the **Minimum Criteria** document can be requested from diagnostic.Control@sciensano.be after the registration.
    - The **Technical Batch/lot:** before this deadline or at the latest on the same day **22/07/2024– 10:00 am** one particular batch/lot must be received, **minimum 10 plates per protocol**, supplied free of charge to: Géraldine Boseret at diagnostic.Control@sciensano.be, Sciensano, Groeselenberg 99, B-1180 Brussels, Belgium. Géraldine Boseret will register and confirm the reception.

3. **Administrative Evaluation.** Performed by the concerning Belgian National Reference Laboratory for IBR of Sciensano, the Operational Unit VIRENBEE (Viral Reemerging, Enzootic and Bee 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 for IBR of Sciensano, the Operational Unit VIRENBEE (Viral Reemerging, Enzootic and Bee diseases), whereby the requested diagnostic

Central office
Veterinary departments:
Groeselenberg 99, B-1180 Brussels
Tel. +32 (0)2 379 04 00
Fax +32 (0)2 379 06 70 (general)
+32 (0)2 379 04 01 (director))
+32 (0)2 379 06 64 (dispatching)

Agrochemical departments:
Leuvensesteenweg 17
B-3080 Tervuren
Tel. +32 (0)2 769 22 00
Fax +32 (0)2 769 23 05

Experimental centre
Kerklaan 68
B-1830 Machelen
Tel. +32 (0)2 251 33 26
Fax +32 (0)2 251 00 12

federal public service
HEALTH, FOOD CHAIN SAFETY AND ENVIRONMENT

e-mail info@sciensano.be - http://www.sciensano.be

reagents (kits) are checked against the technical minimum criteria as fixed by Sciensano and the expert committee and as communicated in the **Minimum Criteria** document, which can be accessed as soon as the registration is approved.

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 for IBR of Sciensano, the Operational Unit VIRENBEE (Viral Reemerging, Enzootic and Bee 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 Sciensano 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. Sciensano will treat each reply or complaint within 30 days, after which Sciensano 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 (supplementary) initial control procedure.

Central office
Veterinary departments:
Groeselenberg 99, B-1180 Brussels
Tel. +32 (0)2 379 04 00
Fax +32 (0)2 379 06 70 (general)
+32 (0)2 379 04 01 (director))
+32 (0)2 379 06 64 (dispatching)

Agrochemical departments:
Leuvensesteenweg 17
B-3080 Tervuren
Tel. +32 (0)2 769 22 00
Fax +32 (0)2 769 23 05

Experimental centre
Kerklaan 68
B-1830 Machelen
Tel. +32 (0)2 251 33 26
Fax +32 (0)2 251 00 12

federal public service
HEALTH, FOOD CHAIN SAFETY AND ENVIRONMENT

e-mail info@sciensano.be - http://www.sciensano.be

B. SPECIFIC DETAILS FOR Suppl_ Cert_IBR_AbELISA_MILK_2017_2024 (ref. no. 16204)

PARAMETER	NAME / TYPE	CODE
Additional control	Additional	**Suppl_ Cert_ IBRgB_AbELISA_MILK_2017_2024 Ref. No. 16204**
Diagnostic Reagent	Antibody ELISA	Ab ELISA
Detection	gB or total antibodies against infectious bovine rhinotracheitis (Bovine Herpesvirus 1)	IBR TOTAL-IBRgB
Target Species	Bovines	B
Target Matrix	Bulk milk (tank milk)	MI
Estimated Market	10000 to 50000 tests per year	/
Protocols	Overday (short) - Overnight (long)	OD – ON
Administrative Dossier To submit to Géraldine Boseret	"NameFirm"_ Suppl_ Cert_ IBRgB_AbELISA_MILK_2017_2024 Ref. No. 16204_Checklist.xlsx	1) Send **1 electronic copy of the dossier** via email to: Diagnostic.Control@sciensano.be 2) Send **1 electronic copy (usb/CD/DVD) + 1 paper copy of the dossier** to: Dr. Géraldine Boseret, SCIENSANO, Groeselenberg 99, B-1180 Brussels, Belgium **Deadline: 22/07/2024**
Technical Batch To submit to Géraldine Boseret	Minimum 10 plates per protocol : One specific batch with Expiry date after 31/12/2024	Send to: Dr. Gaëtan De Gryse, VIRENBEE, SCIENSANO, Groeselenberg 99, B-1180 Brussels, Belgium **Deadline: 22/07/2024**
REPORT EXPECTED BY	Acknowledged application date + 1 year	Deadline date: **22/04/2025**

THIS PROCEDURE DOES NOT CONCERN ANY SELECTED TENDER

SHOULD YOU HAVE ANY QUESTIONS REGARDING THIS INITIAL CONTROL,

PLEASE DO NOT HESITATE TO CONTACT

Diagnostic.Control@sciensano.be

With kind regards,

Dr. Géraldine Boseret: Coordination of Veterinary Diagnosis
Dr. Gaëtan De Gryse, Operational Service of Viral (re)emerging, enzootic and Bee diseases (VIRENBEE)
Sciensano