Instruction manual
ADC71EPC_BTV3_NO_(EN)_V01
01/2024

Extraction Positive Control BTV TYPE 3

Reference: ADC71EPC

Bluetongue Virus Serotype 3 positive extraction control

For veterinary *in vitro* use only

Kit composition

Content		ADC71EPC Kit 100 reactions
EPC BTV T3	Extraction Positive Control BTV T3	1 lyophilized vial (To reconstitute)
NF-Water	Nuclease free water	1 x 500 µL tube (Ready to use)

Associated PCR kits

Associated kits	References
ADIAVET™ BTV TYPE 3 REAL TIME	ADI711-50 or ADI711-100

Revision history

Date	Version	Modifications
01/2024	V01	First version

Note: minor typographical, grammar and formatting changes are not included in the revision history.

A. Test principle

The extraction positive control is made with an inactivated, lyophilized culture of bluetongue type 3.
This extraction positive control after rehydration can be used for two purposes:

- the extraction positive control can be used within each extraction series and allows the day-to-day extraction step control.
- it can be used to confirm the LOD_{METHOD}. It is calibrated between 1 and 100 the LOD_{METHOD}.

It is the responsibility of the laboratory to obtain the matrix free of bluetongue virus.

B. Storage conditions

On receipt, the kit should be stored dry at +2/8 °C.
Reconstituted reagents should be stored at <-15 °C until the expiration date.
Store away from sunlight.
Do not mix reagents of two different batches.

C. Material required but not provided

- Real-time Thermal cycler and device.
- Instrument for homogenous mixing of tubes.
- Pipettes of 1 - 10 µL, 20 - 200 µL and 200 - 1000 µL.
- Nuclease-free filtered pipette tips.
- Nuclease-free microtubes of 1,5 mL and 2 mL.
- Powdered-free latex or nitrile gloves.
- Nuclease-free water.
- Associated PCR kits.
- Kit for nucleic acids extraction.
- Matrix free of BTV.

D. Warnings and precautions

- For veterinary in vitro use only.
- For animal use only.
- For professional use only.
- All instructions must be read before performing the test and strictly respected.
- Do not use reagents after the expiration date.
- Do not use reagents if the packaging is damaged.
- Do not open PCR wells or tubes after amplification.
- Do not mix reagents from different batches.
- Used material must be disposed of in compliance with the legislation in force regarding environmental protection and biological waste management.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not totally guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious and handled observing the usual safety precautions (do not ingest or inhale).

E. Procedure

1. Reconstitution of the control

- Add **500 µL** of **« NF Water »** in « **EPC BTV T3** » vial.
- Vortex vigorously at least 20 seconds.
- After reconstitution, the control is calibrated between **10 et 100 X LOD_{METHOD}**.
- Aliquot and store at <-15°C. Do not defrost more than 3 times.

2. LOD_{METHOD} confirmation

a. Preparation

Dilute extemporaneously to 1/10 the « **EPC BTV T3** » with the NF Water. *Dilution should not be stored.*

b. Extraction

Add **5 µL** of « **EPC BTV T3 x 1/10** » to the matrix free of BTV. then make the extraction **on duplicate**.
Two independent sessions should be realized.

c. Amplification

Extracted Nucleic acids are denatured at 95°C 3 minutes and then amplified with the associated Bio-X Diagnostics PCR kits according to kit instructions.

d. Validation of results

The four results obtained with **« EPC BTV T3 x 1/10 »** must be positive.

3. Extraction step control

a. Extraction

Add **5 µL** of « **EPC BTV T3** » to the matrix free of BTV. then make the extraction.

b. Amplification

Extracted Nucleic acids are denatured at 95°C 3 minutes and then amplified with the associated Bio-X Diagnostics PCR kits according to kit instructions.

c. Validation of results

All the obtained results during the different series of extraction constitute the control chart.

Bibliography

- U47-600-1: Méthodes d'analyse en santé animale - PCR (réaction de polymérisation en chaîne) - Partie 1: exigences et recommandations pour la mise en œuvre de la PCR en santé animale.

Symbols

Symbol	Signification
	Catalog number
	Manufacturer
	Temperature limitation
	Use by
	Batch code
	Consult Instructions for Use
	Contain sufficient for "n" tests
	For veterinary in vitro use only – For animal use only
	Keep away from sunlight

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