Instruction manual
**ADC54EPC_BTV4_NO_(EN)_V02**
**09/2024**

# Extraction Positive Control BTV TYPE 4

Reference: ADC54EPC

Bluetongue Virus Serotype 4 positive extraction control

For veterinary *in vitro* use only

## Kit composition

| Content | | ADC54EPC Kit<br>100 reactions |
|---|---|---|
| EPC BTV T4 | Extraction Positive Control BTV T4 | 1 lyophilized vial<br>(To reconstitute) |
| NF-Water | Nuclease free water | 1 x 1 mL tube<br>(Ready to use) |

## Associated PCR kits

| Associated kits | References |
|---|---|
| ADIAVET™ BTV REAL TIME | ADI352-100 or ADI352-500 |
| ADIAVET™ BTV TYPE 4 REAL TIME | ADI541-50 or ADI541-100 |
| ADIALYO™ BTV | ADL35Y1-100 |

## Revision history

| Date | Version | Modifications |
|---|---|---|
| 11/2023 | V01 | First version |
| 09/2024 | V02 | Modification of the NF-Water tube from 500 µL to 1 mL. |

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 4.
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 T4** » 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 T4** » with the NF Water. *Dilution should not be stored.*

#### b. Extraction

Add **5 µL** of « **EPC BTV T4 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 T4 x 1/10 »** must be positive.

### 3. Extraction step control

#### a. Extraction

Add **5 µL** of « **EPC BTV T4** » 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 oeuvre 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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