ADIAPURE™ Lysis FLEX

DIRECTE LYSIS EXTRACTION KIT
FOR THE DETECTION OF NUCEIC ACIDS
BY REAL-TIME ENZYMATIC GENE AMPLIFICATION (PCR TEST)

USING ONLY WITH ADILYO RANGE

References:
ADPLF1-500

VET

English version
NELF1-01
2020/05

ADIAPURE™ Lysis FLEX

Main change since previous version

N/A	Not Applicable (first publication)
Correction	Correction of document anomalies
Technical change	Addition, revision and/or removal of information related to the product
Administrative	Implementation of non-technical changes noticeable to the user

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

Release Date	Part Number	Change type	Change summary
2020/05	NELF1-01	N/A	First publication

I. General information

1. Purpose of the kit

ADIAPURE™ Lysis FLEX is a nucleic acids DNA extraction kit based on the chemical lysis. The nucleic acids can be used without purification with the PCR amplification kit of **ADILYO**™ range validated with the kit.

2. Description of test

Adiagene validated the ADIAPURE™ Lysis FLEX kit from swabs for the detection of DNA pathogens in combination with the **ADILYO**™ range.
The following table summarises the validated protocols.

		Swab
Avian diseases	*Mycoplasma gallisepticum*	X
	Mycoplasma synoviae	X
	Mycoplasma meleagridis	X
	Mycoplasma iowae	X

For the pool size, refer to the user manual of the ADILYO™ kit concerned.

II. Material & reagents

1. Composition of kit

The ADIAPURE Lysis FLEX kit contains the following buffers:

REF ADIADP01S1-500		
LF1	Lysis buffer	5 x 100 mL (ready-to-use)
L2	Enzyme	1 x 1.1 mL (ready-to-use)
LF3	Lysis buffer	1 x 28 mL (ready-to-use)

2. Validity and storage

On receipt, the kit should be aliquoted and stored at +2/8°C. For better stability, it is recommended to keep reagent L2 at a temperature below -15°C.
In this case, the kit is stable at least 1 year.
Do not mix reagents of two different batches.

3. Equipment required, but not supplied in the kit

Warning: The material should be Nuclease-free (e.g. autoclaved 25 minutes twice at +120°C or once 60 minutes at +121°C)

- Class II Microbiological Safety Cabinet
- Incubator, heating bath or block heater
- Vortex
- 1 - 10 µL pipette, 20 - 200 µL pipette and 200 - 1000 µL pipette
- Nuclease-free filter tips
- Nuclease-free microtubes: 1.5 mL and 2 mL
- Sterile tubes of 5, 10 or 15 mL
- Powder-free latex or nitrile gloves

III. Use of the samples and the controls

1. Precautions

Caution:
Prepare the buffers of kit according to the §II.2.
The buffers could contain toxic substances, please consult the MSDS safety data sheet.
The storage temperature must be respected.

We strongly recommend that only appropriately trained personnel perform this extraction. Ensure the accuracy and precision of the micropipettes used. The quality of the obtained results depends upon rigorous respect of good laboratory practices.
The PCR generates large amount of amplified DNA. A few molecules of amplified products are sufficient to generate a positive result. Do not open the PCR tubes after amplification.
Samples for analysis should be handled and disposed of as biological waste. **Take all measures of security and confinement required for the manipulation of the concerned biological agents.**

Before starting the process, read the entire protocol and scrupulously respect it.

2. Storage of nucleic acid extracts

Extracted DNAs are quite sensitive molecules. Crude extracts should be stored at the end of extraction on melting ice or at +2/8°C for max. 24 hours, then at <-15°C.

3. Controls preparation

Several controls should be included per trial of analysis.
The mix of the different controls included in the Adiavet kits allows validating all the steps (extraction and amplification) of the analysis process for all the samples.

- The endogenous or exogenous internal control included in the ADIAVET™ kits allows validating the extraction and amplification steps of each sample.
- The positive control included in the ADIAVET™ kits allows validating the amplification of the specific target.

Other controls should or must be added:

A. Negative control of extraction (required)

To verify the absence of cross-contamination, at least one negative control must be included per trial (e.g. AFNOR NF U47-600-1 guidelines suggest to include a negative control per 24 columns centrifuged or four negative controls per trial of 96-wells plate). The control is a negative sample, for example a buffer used for dilution.

B. Positive control of extraction (recommended)

A positif control could be added in each trial. The control is a sample including the specific pathogen. It could come from a positive sample available in the laboratory or from a negative sample spiked with a solution of the specific pathogen. This positive control will be closed to the limit of detection of the method. It will inform about the fidelity of the obtained results between different trials.

IV. Analysis protocol

1. Extraction from swab

⚠ Mix the buffers before use.

Samples	Mycoplasms
Preparation	Cut **1 to 6 swabs** in a 5 mL tube. Add **1 mL of LF1 buffer** if 1 to 3 swabs analyse **Or add 2 mL of LF1 buffer** if 4 to 6 swabs analyse Mix by vortexing 10 sec / tube Transfer **50 µL** of the surpernatant in a microtube or in a well of PCR microplate
Lysis	Add **50 µL of LF3 buffer** and **2 µL of L2 buffer*** Cover and homogenize. Incube **5 minutes at +65°C** then **15 minutes at +95°C.** Let to cool, to ensure the accuracy of subsequent pipetting.

*Just before using, a pre-mix of the both reagents could be prepared then added to each sample.

2. Amplification

For the amplification of extracted nucleic acids, please refer to “Amplification Protocol” and “Reading and Interpretation” paragraphs of the user manual **ADILYO™** of the pathogen of interest.

V. Index of symbols

Symbol	Meaning
	Catalogue number
	Manufacturer
	Upper temperature limit
	Use by date
	Batch code
	Consult Instructions for Use
	Contains sufficient for <n> tests
	Keep away from sunlight
	For veterinary in vitro use only

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