



LoopDeetect / TTG

Instruction manual

Version 1.0 – january 2022

For exclusive use with the LoopDeeLab device



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I. Information on the manual

The present manual is the property of Loop Dee Science SAS. Any copy or reproduction of the manual without prior consent from Loop Dee Science SAS is forbidden. All new users must carefully read the present manual for conducting tests using the LoopDeetect / TTG kit and the LoopDeeLab diagnostic device.

The test kits proposed by Loop Dee Science SAS are Molecular Biology kits based on isothermal amplification technology¹ - an innovative DNA and RNA amplification technique enabling the amplification and detection of target genetic material over a short analysis time.

The LoopDeetect/TTG kit is only for demonstration. This kit has not been validated and is not commercially approved. The analyses that are performed with this system are for demonstration purposes only. Under no circumstances should a result from this system be considered valid.

To ensure optimal test results, the protocol for the use of the device must be meticulously followed. The LoopDeetect/TTG kit with LoopDeeLab analysis device must be exclusively used and all associated recommendations for use need to be vigilantly adhered to.

The use of this kit and of the LoopDeeLab requires prior reading and understanding of the LoopDeeLab instructions for use (<https://www.loopdeescience.com/hwda>), together with the LoopDeetect/TTG kit's instructions for use.

¹ **Legal information:** Loop Dee Science holds a licence to exploit the patents WO 00/28082, WO 01/77317 and WO 02/24902 owned by Eiken Chemical CO., Ltd.

II. Description of symbols

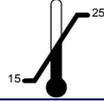
Symbol	Description
	Consultation of instructions for use
	Manufacturing date and manufacturer name
	Product batch number
	Use-by date
	Contents sufficient for 1 assay
	Storage temperature limit
	Product reference
	Keep dry
	Do not store to direct sunlight and heat
	Single use

Table 1: Description of symbols

III. Kit presentation :

The kit LoopDeetect/TTG is an analysis kit for the specific detection of a single strand DNA in fuel sample. The kit contains the consumables and the reagents for 50 analysis.

The LoopDeetect/TTG kit contains all the necessary elements for conducting analysis (Table 2):

Elements	Quantity
Filter tip 10 μ L	2
Filter tip 100 μ L	1
Tube 1.5 mL	1
"Reaction" pouch - Reaction tube (containing the reaction mix in lyophilised form) - Desiccant pouches	1
Waste bag	1

Table 2: Elements provided in the kit necessary for carrying out an analysis

It is imperative to only use the elements of the kit for carrying out the sampling and analysis. Other external items to this device such as swabs or reagents may be incompatible and thus cause erroneous results.

IV. Equipment required for conducting the test

The following equipment is not supplied with LoopDeetect/TTG kits

- 1 LoopDeeLab
- 1 centrifuge for 1,5ml microtubes with variable speed of rotation (obligation protocol : 1000rpm during 30s and 2000rpm during 30s)
- 1 vortex with variable speed of rotation (obligation protocol : 2000rpm and \geq 2500rpm)
- 1 variable volume pipette (with volumes from 1 μ L-10 μ L)
- 1 variable volume pipette (with volumes from 10 μ L-100 μ L)
- 1 variable volume pipette (with volumes from 100 μ L-1000 μ L)
- Filter tips 1000 μ L
- 1 microtubes rack (Provided with the LoopDeeLab)
- 1 timer

V. Handling conditions

- Analysis must be conducted at room temperature ranging from +15°C to +25°C (59°F to 77°F).
- All handling surfaces must be tidied, cleaned and disinfected prior to use of the LoopDeetect /TTG
- The LoopDeeLab analysis device must be maintained in perfect operating condition.
- Pipettes must be calibrated and in perfect working order. Accuracy checks should be carried out regularly.

VI. Precautions for safe use

Loop Dee Science SAS recommends the use of certain personal protective equipment (PPE) during the use of the LoopDeetect/TTG kit:

- Disposable gloves.
- Gown.
- Protective goggles.

VII. Storage and disposal

- This kit must be kept in its original packaging, in a dry place, and within a temperature range from 15°C to 25°C (59°F-77°F).
- Use quickly after opening.
- Dispose of all consumables along with biological waste, whether used or not, and/or soiled during the test. Provided packaging may be used as a recipient for disposal pending transfer to a biological waste recipient.
- Re-sealable bags are provided in the kit, it is recommended that all consumables are disposed of in these bags and that the bags are resealed before being disposed of in the waste bin.

VIII. Manipulation protocol :

A. Emulgation buffer preparation

- Gently shake the emulgation buffer before open.
- Take a 1,5ml empty tube.
- Fill the tube with 380µl of emulgation buffer.
- Prepare 1 tube per sample.

B. Sample preparation (cf. Appendix – operating procedure diagram)

- Vortex the fuel sample
- Add 5µl of fuel sample in the emulgation buffer. Close the tube.
- Centrifuge the sample 30s at 2000rpm
- Vortex the sample at max speed during 30s.
- Centrifuge the sample 30s at 1000rpm
- Vortex the sample at 2000rpm during 5min.

C. LoopDeeLab analysis (cf. Appendix – operating procedure diagram)

- Take the reaction tube containing the lyophilized mix
- Add 24µl of dilution buffer (from the dilution buffer tube)
- Add 1µl from emulsified sample in the reaction tube. Close the tube.
- Put the tube in the LoopDeeLab.
- Close the LoopDeeLab.
- Push the start button to start the run.
- At the end of the analysis, read the result :
 - Red LED : Positive result
 - Green LED : Negative result.

IX. Restrictions

- The LoopDeetect / TTG kit can only be used once and must be disposed of after use (refer to disposal above).
- The reaction tube must never be opened after use, for this may contaminate the working environment and distort subsequent analysis results.
- The reaction mix must only be subjected to one LoopDeeLab analysis cycle, otherwise there is a high risk of false positive results. To restart a sample, repeat the procedure using an unused kit.
- The LoopDeetect / TTG kit must never be used after its use-by date.
- The LoopDeetect / TTG kit must never be used if its packaging is damaged or incorrectly sealed.
- Do not analyse a sample without previous sample preparation.
- Do not store lyophilised tubes outside of their pouch. This presents a risk of lyophilisate deterioration.
- Do not start analysis with the LoopDeeLab empty or with an empty tube. This presents a risk of equipment deterioration.
- Do not use the LoopDeeLab to conduct tests with other kits than those provided by Loop Dee Science.
- During analysis, do not unplug, open, disconnect or stop the LoopDeeLab before the end of the run.
- Do not mix elements from kits with different batch numbers.
- Do not empty unused tubes. This presents a risk of contamination of the working environment and of false positive results for subsequent tests.
- Follow the instructions for kit use (storage, type of sample, order of test steps, time and duration of incubation, etc.).
- Test kits and the LoopDeeLab analysis device must be exclusively used as indicated on the instructions. Loop Dee Science SAS declines any responsibility for the consequences of any improper use of the LoopDeeLab device and associated test kits.
- Regularly decontaminate the equipment and workspace.
- Keep the LoopDeeLab away from sources of excessive heat and prefer cool areas for its storage and use (10°C - 25°C / 50°F - 77°F).
- The LoopDeeLab must be installed horizontally on a flat surface.
- Only analyse validated matrices. The kit's correct operation cannot be guaranteed on non-validated matrices.
- The LoopDeetect kit is not equipped with an inhibition indicator. Despite the various validation tests conducted, this kit may present a risk of yielding erroneous results (false negatives), in the case of the presence of an inhibitor.

X. Meaning of displayed colours on the LoopDeeLab indicator light

Indicator light colour	Meaning
Set blue	The LoopDeeLab is connected and ready for use.
Flashing yellow	The LoopDeeLab is conducting analysis - do not touch anything whilst the indicator light is flashing for this may disrupt correct measurement.
Set green	Analysis is complete, the sample is negative, no virus detected.
Set red	Analysis is complete, the sample is positive, virus detected.

Table 3: Meaning of LoopDeeLab indicator light colours

XI. Performance data

Not applicable

XII. Document history / Versions

Revision	When	By	Comments
1.0	18/01/2022	Rodrigue COURCHANT	Initial 'public' revision

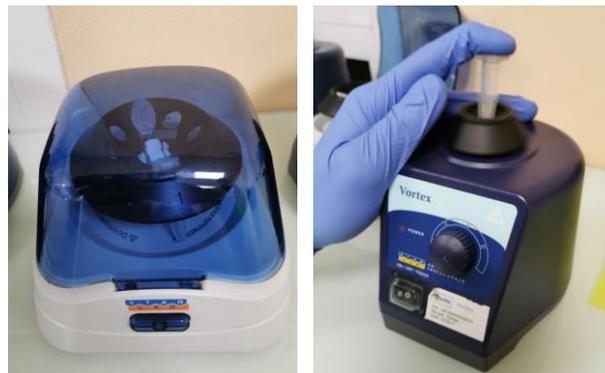
Table 4: Document history

Appendix – operating procedure diagram

1/ Add 5 μ l of fuel in 380 μ l of emulgation buffer



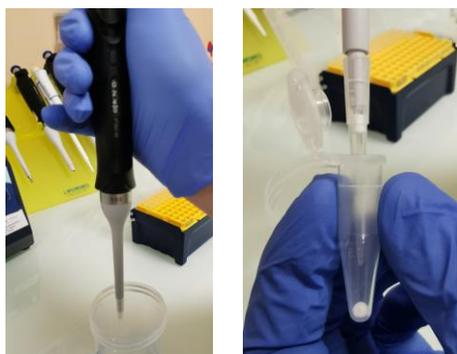
2/ Centrifuge 30s at 2000rpm ; then vortex 30s at full speed



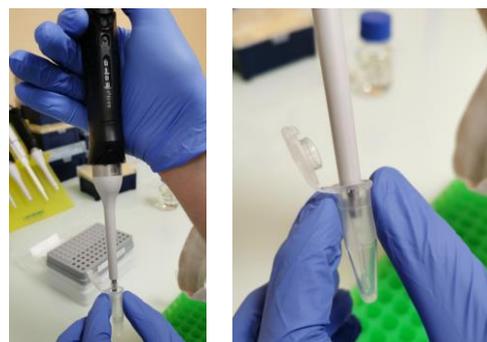
3/ Centrifuge 30s at 1000rpm ; then, vortex 5min at 2000 rpm



6/ Add 24 μ l of dilution buffer on lyophilized reagents.



7/ Add 1 μ l of sample in liquid reagent.



8/ Close the tube and put it in the LoopDeeLab.

