INSTRUCTIONS FOR USE

ID GENE LYO™ FMDV TRIPLEX

REAL-TIME RT-PCR KIT FOR THE QUALITATIVE DETECTION OF THE FOOT AND MOUTH DISEASE VIRUS RNA

PATHOGEN	Foot and Mouth Disease Virus (FMDV)	
NUCLEIC ACID TYPE	RNA	
SPECIES	Sheep, cattle, goats, cervids, suids, camelids and other FMDV-susceptible species	
TARGET SEQUENCES	• Target sequence specific to the Foot and Mouth Disease Virus genome • Endogenous Non-Target Positive Control NTPCen: sequence specific to the above-mentioned validated animal species (ubiquitous cellular gene) • Exogenous Non-Target Positive Control NTPC-FMDV: sequence specific to a non-pathogenic RNA virus	
TYPES OF SAMPLES	• Whole blood (in EDTA tubes) and Serum • Milk • Organs and Tissues (e.g. tongue and epithelium from unruptured or recently ruptured vesicles) • Swabs (oral and oropharyngeal) • Vesicular fluids • Viral cultures • Environmental samples (boot swabs) • Nucleic acid storage cards (individual samples or pools of up to 5)	
ASSOCIATED PRODUCT	ID Gene™ Mag Fast Extraction Kit (product code: MAGFAST)	
PRODUCT CODES AND FORMATS	IDFMDVL-50 50 tests	IDFMDVL-100 100 tests

April 2025

Changes have been made to the IFU, please refer to the history of revisions for details.

In vitro use

IDFMDVL version 0125 EN, revision April 2025

With you at every step

RISKS AND PRECAUTIONS FOR USE

Read the instructions carefully before use. For each batch of kit, use only the version of the leaflet mentioned on the Quality Control Sheet. A general guide to the use of molecular biology techniques and Material Safety Data Sheets (MSDS) are available on request from info@innovative-diagnostics.com.

Caution: Some components contain hazardous chemicals. Wear protective Personal Protective Equipment. Follow Good Laboratory Practice (GLP) and safety guidelines. Dispose of reagents and biological waste in accordance with applicable regulations.

GENERAL INFORMATION

Characteristics

The ID Gene Lyo™ FMDV Triplex (product code: IDFMDVL) kit is a qualitative triplex real time RT-PCR kit that simultaneously detects:

- a target sequence specific to the Foot and Mouth Disease Virus (FMDV) genome, in the FAM™ channel,
- a sequence specific to the Endogenous Non-Target Positive Control (NTPCen), a ubiquitous gene inherently present in cells from sheep, cattle, goats, cervids, suids, camelids and other disrupted FMDV-susceptible species, in the VIC®/ HEX™ channel. For more information about the animal species in which the NTPCen target is detectable, please refer to our internal validation.
- a sequence specific to the Exogenous Non-Target Positive Control (NTPC-FMDV), in the Cy5 channel.

This kit can be used on the following matrices:

NATURE OF THE SAMPLE
Whole blood and Serum
Milk
Organs and Tissues (e.g tongue and epithelium from unruptured or recently ruptured vesicles)
Swabs (oral and oropharyngeal)
Vesicular fluids
Viral cultures
Environmental samples (boot swabs)
Nucleic acid storage cards (individual samples or pools of up to 5)

The ID Gene Lyo™ FMDV Triplex kit is provided with an amplification reaction mixture in freeze-dried format, for greater stability over time and improved resistance to transport conditions. It is transported at room temperature, making shipping simpler, more economic and more environmentally friendly.

Kit composition, reagents preparation and storage conditions

The ID Gene Lyo™ FMDV Triplex kit contains the reagents listed below:

REFERENCE	VOLUME	DESCRIPTION	TEMPERATURE AND TIME OF CONSERVATION		PREPARATION OF REAGENTS
			ON RECEIPT	AFTER RECONSTITUTION	
ARM-FMDVL Freeze-dried Amplification Reaction Mixture	Vial with freeze-dried content Red cap 825 µL final x1: 50 tests x2: 100 tests	Reaction mixture containing Reverse Transcriptase, Taq polymerase, primers, hydrolysis probes, nucleotides.	**Freeze-dried**: refer to the expiry date on the vial. Store at ≤ -16°C, protected from light 	Refer to the expiry date on the QC sheet and the vial[(1)] Store at ≤ -16°C, protected from light 	Reconstitute according to the procedure detailed at the beginning of the 'Amplification protocol' chapter
ARM-TUBE Empty microtube	Microtube White cap x1: 50 tests x2: 100 tests	Labelled empty plastic microtube designed to contain the ARM-FMDVL after reconstitution	N/A		
RB2 Resuspension Buffer 2	Microtube Red cap 1000 µL x1: 50 tests x2: 100 tests	ARM-FMDVL Resuspension Buffer containing stabilizing agents	Store at ≤ -16°C	N/A	Ready-to-use
NTPC-FMDV Exogenous Non-Target Positive Control	1 vial with freeze-dried content 2200 µL	Non-pathogenic virus	**Freeze-dried:** refer to the expiry date on the vial Store at -16°C	Store for a maximum of 12 months[(1)] Store at -16°C	Add 2200 µL of Nuclease-free water (RNase/DNase-free). Allow to resuspend for 10 min at room temperature, then vortex. Check that the pellet is completely dissolved before use.
PAC-FMDV Positive Amplification Control	Microtube Blue cap 100 µL	Synthetic nucleic acids containing target sequences specific to FMDV, the NTPCen and the NTPC-FMDV	Store at ≤ -16°C	N/A	Ready-to-use

Note: Shipping of the kit is performed at room temperature. Upon receipt, the entire kit should be stored ≤ - 16°C.

[(1)] It is recommended to prepare aliquots (minimum 100 µL) to avoid more than 3 freeze/thaw cycles per aliquot. Thaw the aliquot preferably at 5°C (± 3°C), or at room temperature (21°C ± 5°C) if used as soon as thawing is complete.

Equipment, materials, reagents and consumables required to be supplied by the user

All material used should be of suitable quality for molecular biology.

Equipment and materials:

- Real-time PCR thermal cycler with channels capable of reading the following fluorophores: FAM™, HEX™ or VIC® and Cy5.
- Precision pipettes capable of delivering volumes from 1 µL to 1000 µL.
- Personal Protective Equipment (single-use gloves and lab coat, possibly with safety glasses, mask...).
- Refrigerated rack.

Reagents:

- Water with molecular biology quality, Nuclease (DNase and RNase)-free.

Consumables:

- Nuclease-free filter tips.
- 96-well PCR plates and suitable adhesive films or PCR microtubes (with optical quality compatible with the thermal cycler) and suitable caps.

EXTRACTION AND AMPLIFICATION CONTROLS

It is strongly recommended to use the following controls for each round of analysis:

CONTROL		DESCRIPTION
To be prepared	**NEC** Negative Extraction Control	This control, to be treated in the same way as samples from the pre-treatment stage (if this is necessary), may consist of: • Nuclease (RNase/DNase)-free water or any other buffer used during the extraction step (NEC-process). This control is used to validate the absence of contamination during the extraction step. • or a negative matrix corresponding to the matrix of the sample under test (NEC-matrix). This control allows for the assessment of the quality of the pre-treatment and extraction, and the verification of the absence of contamination. It can be used as a reference for the analysis of exogenous signals from the samples. This control should not contain the target pathogen.
	NAC Negative Amplification Control	This control (Nuclease-free water) is used to verify the absence of contaminants during the qPCR amplification step. It should be included in each run.
Available with this kit	**PAC-FMDV** Positive Amplification Control	This control allows the validation of the amplification of the targets. It consists of synthetic nucleic acids containing the target sequences specific to the FMDV, the NTPCen and the NTPC-FMDV.
	NTPC-FMDV Exogenous Non-Target Positive Control	This is a freeze-dried Exogenous Non-Target Positive Control consisting of a non-pathogenic RNA virus that mimics the target virus. Once reconstituted, it can be added, at the pre-treatment stage for nucleic acid extraction, to each sample as well as to the NEC control. It provides the exogenous signal which can be used to assess the efficiency of the pre-treatment and extraction steps and evaluate the possible presence of RT-qPCR inhibitors, in each sample and in the extraction controls. Its use is strongly recommended when testing samples containing a limited number of cells (e.g. milk, swab).
Intrinsic to the samples	**NTPCen** Endogenous Non-Target Positive Control	This Endogenous Non-Target Positive Control is inherently present in the cells of many FMDV-susceptible species*. It is used to: • monitor the quality of the sample and of the pre-treatment and extraction processes, by assessing: - the integrity of the nucleic acids obtained from animal cells, - the abundance of cells in the sample (e.g. swabs), - cell lysis. • confirm the presence of the sample nucleic acid extract in the PCR well/microtube. *When testing animal species other that those validated, and if the NTPCen target is not being recognised, it is strongly recommended to use the NTPC-FMDV to help with result interpretation.

NUCLEIC ACID EXTRACTION

FMDV RNA must be extracted from samples and extraction controls prior to amplification by RT-qPCR.

The ID Gene Lyo™ FMDV Triplex kit has been validated for the following extraction method:

DESCRIPTION	PRODUCT NAME	PRODUCT CODE	SAMPLE TYPE
Nucleic acid extraction kit with magnetics beads	ID Gene™ Mag Fast Extraction Kit	MAGFAST	All the validated matrices listed above

Pre-treatment and extraction protocols for samples and controls, for this extraction kit are available upon request at info@innovative-diagnostics.com.

Important note

While the qPCR tests from the IDvet product range may be used with extraction kits from other suppliers, it is important to contact us BEFORE running your tests to verify compatibility.

Compatibility of the **ID Gene Lyo™ FMDV Triplex** kit was verified with the following extraction kits:

DESCRIPTION	PRODUCT NAME	PRODUCT CODE	TESTED SAMPLE TYPE	VERSION OF INSTRUCTIONS APPLIED
Nucleic acid extraction kit with magnetics beads	IndiMag® Pathogen Kit (INDICAL BIOSCIENCE) ⚠*	SP94745	-organs and tissues (tongue) -blood ⚠*	10/2018
	MagMAX™ CORE Nucleic Acid Purification Kit (ThermoFisher Scientific)	A32700	-organs and tissues (tongue) -blood	MAN0015944

⚠ **To ensure compatibility of the ID Gene Lyo™ FMDV Triplex kit with the mentioned version of the IndiMag® Pathogen Kit (INDICAL BIOSCIENCE), the test volume for whole blood **should not exceed 50 µL of sample**. Using a higher test volume can lead to inhibitions.*

As recommended in the instructions for use, 150 µL of PBS 1X should be added to 50 µL of whole blood.

Important note

Compatibility testing was performed according to recommendations for preparation and pre-treatment of samples described by each supplier in the instructions for use in force.

Test volume for the extraction of controls is described in the Table below.

CONTROL	VOLUME
NTPC-FMDV	20 µL to be added to each sample and the NEC

Important note

When using an extraction kit, first add, in the microtubes or Deepwell plates, the pre-treated samples or NEC extraction control, followed by the lysis buffer and finally 20 µL of NTPC-FMDV.
Do not add the NTPC-FMDV directly to the sample / NEC extraction control.

When a large number of samples are to be analysed, it is recommended to prepare a homogeneous mixture of lysis buffer and NTPC-FMDV by multiplying the indicated quantities by the number of samples and controls to be analysed and adding a dead volume of 10%.

The NTPC-FMDV offers the possibility of an extended evaluation of the pre-treatment and extraction steps and of the potential presence of PCR inhibitors, but its use is not mandatory (even though it is strongly recommended when testing samples with limited number of cells). The mean Cq value of the NTPC-FMDV for the Negative Extraction Control (NEC), under our operative conditions, is indicated on the batch control certificate. Laboratories may obtain slightly different values under their own conditions.

AMPLIFICATION PROTOCOL

When using the kit for the first time: reconstitution of the freeze-dried Amplification Reaction Mixture ARM-FMDVL

1. Remove the aluminium cap from the ARM-FMDVL vial.
2. Add 825 µL of Resuspension Buffer 2 (RB2) to the ARM-FMDVL vial and wait for 2 minutes at room temperature.
3. Homogenize the content of the vial by successive pipetting.
   ⚠ *Do not vortex the vial at this stage.*
4. Check that the pellet is completely dissolved, then transfer to the empty plastic microtube with a white cap included in the kit, and labelled ARM-TUBE.
   The microtube can now be vortexed and centrifuged.
5. Annotate the microtube label with the ARM- FMDVL name and batch number, its reconstitution date and its after reconstitution expiry date.

The microtube(s) containing the ARM-FMDVL after reconstitution can be stored between -16°C and -26°C. Refer to the kit Quality Control sheet for the shelf life of this component.
It is recommended to prepare aliquots (minimum 100 µL) to avoid the reaction mixture undergoing more than 3 freeze/thaw cycles.

Preparation of the RT-qPCR amplification reaction

⚠ *It is recommended to perform the preparation in a dedicated room, with laboratory areas and equipment separated from those used for preparing the Amplification Reaction Mixture ARM. The time taken for completion should not exceed 20 minutes.*

1. Prepare an experimental plan for the analysis of the samples and controls. When using 96-well PCR plates, be sure to distance the Positive Control (PAC-FMDV) from the other samples.
2. Thaw the tube of ARM-FMDVL or an aliquot, then homogenize well (by vortexing) and centrifuge briefly.
   ⚠ *Thaw the ARM extemporaneously, ideally at 5°C (± 3°C) or at room temperature (21°C ± 5°C) if used as soon as thawing is complete. Avoid prolonged exposure to light.*
   ⚠ *It is advisable to keep all components at 5°C (± 3°C) and to use a refrigerated rack for the PCR plate/microtubes during preparation.*
3. Dispense 15 µL of ARM-FMDVL per well or microtube. Use PCR plates or microtubes suitable for the thermal cycler.
   ⚠ *Refreeze the ARM tube or aliquot immediately after use.*
4. Then add to the wells or microtubes chosen for:
   - the samples: 5 µL of sample extract,
   - the Positive Amplification Control: 5 µL of PAC-FMDV,
   - the Negative Extraction Control(s) (NEC): 5 µL of NEC-matrix extract and/or NEC-process extract,
   - the Negative Amplification Control (NAC): 5 µL Nuclease-free water.
5. Cover the plate with adhesive films or the microtubes with suitable caps.
6. Briefly centrifuge the plate or microtubes to avoid air bubbles.
   ⚠ *The plate or microtubes should be stored at 5°C (± 3°C) prior to amplification, which should be carried out as soon as possible after addition of the samples and controls.*

Programming the amplification phase

1. Program the thermal cycler to read the following detectors for each well or microtube to be analysed:

TARGET	CHANNEL CAPABLE OF READING	QUENCHER*
FMDV	FAM™	Non-fluorescent
Endogenous Non-Target Positive Control NTPCen	VIC®/HEX™	Non-fluorescent (compatible VIC®/HEX™)
Exogenous Non-Target Positive Control NTPC-FMDV	Cy5	Non-fluorescent

Note: For devices requiring an internal reference for optical calibration, the amplification reaction mixture contains ROX.

⚠ ** For the quencher, setting the instrument parameters for the TAMRA™ dye instead of a non-fluorescent dye may improve data analysis with some instruments.*

⚠ *It is of utmost importance to select the fluorophores associated to the FMDV target (FAM™), the endogenous control NTPCen (VIC®/HEX™) and, if used, the exogenous control NTPC-FMDV (Cy5), before starting the amplification program (for thermocyclers that have the option to select specific reading channels).*

2. Choose from the 3 amplification programs validated by Innovative Diagnostics

⚠ *Note 1: Check that the thermocycler used enables the launch of a rapid or ultra-rapid amplification program and verify that validation criteria are met for each run.*

⚠ *Note 2: for the ThermoFisher QuantStudio 5 or 7, the "Fast Mode" should be selected, regardless of the amplification program set.*

- the ultra-rapid program (which allows RT-qPCR to be carried out in approximately 40 min),
- the rapid program (which allows RT-qPCR to be carried out in approximately 50 min),
- the standard program (which is compatible with amplification programs offered by other reagent manufacturers and therefore allows simultaneous analysis).

STAGE	ULTRA-RAPID PROGRAM	RAPID PROGRAM	STANDARD PROGRAM	NUMBER OF CYCLES
(1) Reverse Transcription	10 min at 45°C	10 min at 45°C	10 min at 45°C	1
(2) Activation of polymerase	2 min at 95°C	2 min at 95°C	10 min at 95°C	1
(3) DNA Denaturation / Elongation	5 sec at 95°C 2 sec at 60°C	10 sec at 95°C 30 sec at 60°C	15 sec at 95°C 60 sec at 60°C	40

Note: The fluorescence reading is taken at the end of the elongation phase at 60°C.

3. Select a final volume of 20 µL.

⚠ *If different volumes are combined in the same analysis, consider the largest volume of the plate or microtube to set up the thermal cycler.*

4. Place the plate or microtubes in the thermal cycler and start the program.

⚠ *Control workflow of personnel to minimize contamination into the areas for preparation of ARM or qPCR reactions. After completion, dispose of the plates or microtubes in receptacles located in a different area.*

VALIDATION AND INTERPRETATION OF RESULTS

Assay validation

Interpretation of the results for each sample is carried out, subject to obtaining a characteristic amplification curve, using the Cq (Quantification cycle) or Ct (Threshold cycle) values obtained for each reading channel.

⚠ *For correct data interpretation, it is of utmost importance to select the fluorophores associated to the FMDV target (FAM™), the endogenous control NTPCen (VIC®/HEX™) and, if used, the exogenous control NTPC-FMDV (Cy5).*

⚠ *Unselecting a reading channel before run analysis may lead to incorrect results: variable impact depending on the thermocycler brand that is linked to the optical properties of the instrument.*

Cq values are determined from the baseline (Threshold) which, depending on the analysis software, will have to be set manually. To obtain the most reproducible results possible, it is essential that the baseline is set accurately. To assist in the positioning of the baseline, please refer to the general guide for implementation of molecular biology techniques available upon request at info@innovative-diagnostics.com.

The RT-qPCR run is validated if the controls described below provide valid results; interpretation for each sample can then be performed. If not, the samples cannot be analysed, and the pre-treatment/extraction and/or RT-qPCR amplification must be repeated.

CONTROL	FAM™ SIGNAL **FMDV** [a]	VIC®/HEX™ SIGNAL **Endogenous control NTPCen**	CY5 SIGNAL **Exogenous control NTPC-FMDV** [a]	INTERPRETATION
NEC-process	-	-	**+** [c]	Validates the presence of NTPC-FMDV specific nucleic acids and the absence of contamination in the buffers used during pre-treatment nucleic acid and extraction.
NEC-matrix	-	**+** / - depending on the proportion of cells in the sample and on the animal species [b]	**+** [c]	Can be substituted for the NEC-process. It is possible to establish reference Cq values for the endogenous VIC®/HEX™ and exogenous Cy5 signals for each matrix and extraction method [b, c].
NAC	-	-	-	Validates the absence of contamination during amplification.
PAC-FMDV	**+**	**+**	**+**	Validates the RT-qPCR amplification process.

- : not detected + : presence of a typical amplification curve

[a] *For information regarding Cq values, refer to the values given for indicative purpose on the Quality Control Sheet associated with the batch and/or, in the validation file available on request. Please note that the Cq values are dependent on the matrices tested, the extraction methods used, and the thermal cyclers utilized. Innovative Diagnostics recommends that each laboratory determines its own threshold values for all controls used during the RT-qPCR. The mean Cq value of the NTPC for the Negative Extraction Control (NEC) under our operative conditions is indicated on the batch QC certificate. Laboratories may obtain slightly different values under their own conditions.*

[b] *Please consider that the signal of the NTPCen is influenced by the number of cells in the sample, which can be variable depending on the matrix (i.e.: milk, swab). Furthermore, the NTPCen target might not be conserved in all animal species susceptible to FMDV (please refer to our internal validation report for details on the validated species).*

[c] *If the NTPC-FMDV was not introduced during the pre-treatment and/or extraction steps of these controls, then no Cy5 signal will be observed. Even though its use is recommended for an extended evaluation of the preparation steps and of the potential presence of PCR inhibitors, it is not mandatory in every run (even though it is strongly recommended when testing samples with limited number of cells).*

Recommended actions in case of non-valid controls

Please note that it is recommended to take the following actions for all samples and controls that were included in the same run of analyses.

Non-valid NEC

In case of presence of a typical amplification curve in the FMDV (FAM™) signal:

A cross contamination occurred. It is recommended to check the operating procedures and perform the pretreatment, extraction and RT-qPCR amplification again.

In case of absence of a typical amplification curve in the NTPC-FMDV (Cy5) signal:

If the NTPC-FMDV control was used, it indicates that a problem occurred during the pretreatment /extraction process, during the distribution and/or that the RT-qPCR reaction was inhibited.
Please repeat the pretreatment /extraction and RT-qPCR amplification.

Non-valid NAC

In case of presence of a typical amplification curve in the FMDV (FAM™), NTPCen (VIC®/HEX™) and/or NTPC-FMDV(Cy5) signals:

A cross contamination occurred. It is recommended to check the operating procedures and perform the RT-qPCR amplification again.

Non-valid PAC-FMDV

In case of absence of a typical amplification curve in the FMDV (FAM™), NTPCen (VIC®/HEX™) and /or NTPC-FMDV(Cy5) signals:

A problem occurred during the distribution of the PAC or of the amplification reaction mix.
Please repeat the RT-qPCR amplification step again.

Proposed interpretation of the results

For each analysed sample, interpretation can be conducted if the sample validation criteria are met (see sections: "Assay validation" and "Recommended actions in case of non-valid controls"). The results can be interpreted according to the following criteria:

FAM™ SIGNAL **FMDV**	VIC®/HEX™ SIGNAL **Endogenous control NTPCen** [d]	CY5 SIGNAL **Exogenous control NTPC-FMDV** [e]	INTERPRETATION
+	**+** or -	-	FMDV detected in the sample.
-	**+**	**+**	FMDV not detected in the sample.
-	-		No sample / degraded sample. Please refer to "Recommended actions in case of non-interpretable results"

- : not detected + : presence of a typical amplification curve

[d] *The Cq value of the endogenous signal VIC®/HEX™ of the sample can be compared, as an indication, with the one of the associated NEC-matrix. Please consider that the signal of the NTPCen is influenced by the number of cells in the sample, which can be variable depending on the matrix (i.e.: milk, swab). Furthermore, the NTPCen target might not be conserved in all animal species susceptible to FMDV (please refer to our internal validation report for details on the validated species). The absence of a VIC®/HEX™ signal can also be explained, in the case of a very early FAM™ signal, by competition in favour of the FMDV target. As an indication, examples of values obtained under defined experimental conditions (extraction technique, thermocycler, etc.) at Innovative Diagnostics are described in the Quality Control sheet and/or in the validation file for the technique.*

[e] *If the NTPC-FMDV control was used, a weak Cy5 signal or the absence of Cy5 signal indicates that a problem occurred during the pretreatment/extraction processes, the sample distribution and/or that RT-qPCR reaction was inhibited. The absence of a Cy5™ signal can also be explained, in the case of a very early FAM™ signal, by competition in favour of the FMDV target. For information regarding Cq values, refer to the values given for indicative purpose on the Quality Control Sheet associated with the batch. Please note that the Cq values are dependent on the matrices tested, the extraction methods used and the thermal cyclers utilized. Innovative Diagnostics recommends that each laboratory determines its own threshold values for all controls used during the PCR.*

Recommended actions in case of non-interpretable results

A problem occurred during sample distribution or preparation/extraction and/or the RT-qPCR reaction was inhibited. In such event, taking the following actions is recommended:

1. Dilute the extracts to 1:10 in Nuclease-free water and perform the RT-qPCR amplification step again.
2. If the results are still non-compliant, repeat the pretreatment/extraction.
3. If the results are still non-compliant, sample quality is not sufficient for the analysis.

TECHNICAL SUPPORT AND DOCUMENTATION

For questions, technical support, and protocols please contact us at the following address info@innovative-diagnostics.com.

HISTORY OF REVISIONS

Any changes made to the instructions for use will be clearly described on the front page in a red box.
The symbols are used throughout the manual to alert the user of the changes made.

TYPE OF MODIFICATION	MODIFICATION	CHANGE OF VERSION	UPDATE OF THE REFERENCE
Correction of anomalies in the document: writing, typography, changes to page layout	Minor	No	No
Update: clarifications and addition of details on test implementation	Minor	No	Yes
Technical modification: technical modification of the kit, its composition and/or its testing procedure	MAJOR	YES	Yes

VERSION	EDIT DATE	REFERENCE	TYPE OF REVISION	REVISION MADE
0125	04/2025	doc5035	Update	• Addition of details on compatibility with competitor extraction kits • Addition of 2 testable sample types
		doc5005	Update	• Addition of notes regarding the use of rapid and ultra-rapid amplification programs
	03/2025	doc4899	Update	Clarifications and addition of details
			Technical modification	Addition of the ultra-rapid amplification program
0824	01/2025	doc4820	Not applicable (first version)	N/A

Certified management system

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