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EliGene® STD GAR/URE/MYC RT

REF 90089-RT (for 50 samples)

Kit components:

5 x 150 µl **STD1 Mix**
2 x 50 µl **PC DNA STD1**
5 x 200 µl **IAC DNA**
Instruction for Use

Storage and shelf life after first opening:

All components of the kit must be transported and stored at -20 °C. Kit and remaining MasterMixes must be stored at -20 °C in a dark.

Intended use

EliGene® STD GAR/URE/MYC RT kit is intended for DNA diagnostics of pathogenic species *Mycoplasma hominis*, *Mycoplasma genitalium*, *Ureaplasma urealyticum*, *Ureaplasma parvum* and *Gardnerella vaginalis* from isolated DNA sample.

Principle of the method

This diagnostic kit is based on RealTime PCR. In this kit specific primers and dual labeled fluorescent probes for the detection of DNA are used.

Channel	FAM	HEX	Texas Red	Cy5
DNA target	Ureaplasma	IAC	Mycoplasma	Gardnerella

Introduction

Mycoplasma is a genus of bacteria belonging to the family of Mycoplasmataceae, which include a group of microorganisms, which may be responsible for diseases of the respiratory and genital tract. These bacteria are found approximately in 70 % of sexually active individuals.

Mycoplasma hominis is associated with pelvic inflammatory diseases, bacterial vaginosis, postpartum fevers, sepsis, and central nervous system infections leading to serious consequences.

Mycoplasma genitalium provides strong evidence for its role in non-chlamydial and non-gonococcal urethritis (NCNGU) in men and cervicitis in women.

Ureaplasma is bacterium belonging to the family *Mycoplasmataceae.* It is a spherical-shaped, facultative anaerobic microorganism that characteristically lacks a cell wall. A characteristic feature of this microorganism is a synthesis of urease. ***Ureaplasma*** species colonize the lower urogenital tract in many healthy persons, yet, they can also cause urethritis, endometritis, chorioamnionitis, spontaneous abortion, arthritis and urinary calculi in susceptible adults, as well as prematurity/low birth weight, bacteraemia and meningitis. Clinical studies have demonstrated that infants born to infected mothers become infected with these bacteria, and colonization of the respiratory tract of infants has been associated with pneumonia, respiratory distress and meningitis. *Ureaplasma sp.* is the main cause of non-gonococcal, non-chlamydial urethritis, acute prostatitis and acquired arthritis in men.

Gardnerella vaginalis are gram-variable pleomorphic rods growing in a carbon dioxide enriched atmosphere (5-10 %) or in a microaerophilic atmosphere and in some strains only under anaerobic conditions. Due to difficult

cultivation culture testing often leads to false negative results. Therefore, PCR diagnostics is the most appropriate method for the primary detection of infection. In women, Gardnerella vaginalis infection manifests as unpleasant vaginal secretions, vaginal inflammations, urethritis with pain or discomfort when urinating. Vaginal discharge may or may not be present. In men, the infection manifests as urethritis, pain when urinating, urethral pain or discomfort in the urethra. Untreated infection can result in prostatitis.

Primary sample collection, handling and storage

Clinical material:	Recommended DNA isolation procedure:
Urine, swabs	Manual: EliGene® Urine Isolation Kit
	Automatic: **ZEPHYRUS Magneto** (ELISABETH PHARMACON)

WARNING: To keep the sensitivity of the test we recommend to strictly follow the pre-analytical procedures mentioned in this instruction. Specially do not change the recommended procedures of isolation as for stated amount of specimen, centrifugation force, etc. For the DNA isolation other isolation kits can be used, but the pre-analytical procedures of storage, transport and centrifugation must be held.

Cervical swabs, urethral swabs:

These samples should be collected according to standard protocol in collection tubes with transport medium (remel MicroTest M4RT Transport or remel MicroTest M4 Transport). Samples in such transport medium should be transported to the laboratory at 4 °C. Samples can be stored at 4 °C up to seven days.

Recommended procedure for swab samples processing:

1. Vortex the collection tubes well for at least 10 seconds before the DNA isolation. Open the tube and by pressing the swab along the tube wall press out all solution from the swab. Discard the swab.
2. Centrifuge the collection tubes for 15 minutes at 6000 x g. If there is not centrifuge for collection tubes, split the medium into two 1.5 ml microtubes and centrifuge. Microtubes can be centrifuged 10 minutes at 10000 x g.

Manual isolation:

1. Aspirate supernatant and add 200 µl of MI3 solution from EliGene® Urine Isolation Kit and 180 µl of molecular grade water to the pellet and re-suspend the pellet by pipetting (if you used for the centrifugation two microtubes firstly re-suspend the pellet in one tube with total volume of buffer with water and consequently in other microtubes with the buffer mixture from the first one). Add 10 µl of Proteinase K and 20 µl of Internal Control (IAC DNA) and continue according to instructions in standard protocol of EliGene® Urine Isolation Kit.
2. Use 50 µl of Elution buffer. Use isolated DNA for the detection immediately after DNA isolation or store DNA hours to one week at 4 °C. For longer period than one week freeze DNA at -20 °C.

Automatic isolation:

1. Open the tubes and carefully aspirate all supernatant. Then re-suspend pellets in 180 µl of PBS by vortexing and add 20 µl of Internal Control (IAC DNA).
2. Isolate DNA from the sample by using MAGNETO BodyFluid DNA/RNA isolation kit according to protocol for plasma samples with elution to 50 µl of Elution buffer.

Urine:

According to standard protocol, take the sample of the urine into sterile tube. Use sterile tubes without conservation additives. Samples must be stored and transported at 4 °C. It is possible to store the samples at 4 °C

up to 7 days.

The samples of urine must be centrifuged at 6000 x g for 15 minutes before the DNA isolation. Use 8 – 15 ml of urine sample. **Do not use lower centrifugation force or shorter time of centrifugation!** In the case that laboratory do not have centrifuge for large volumes, aliquot urine sample to lower volumes but total sample volume must be at least 8 ml.

Manual isolation:

1. Aspirate supernatant. Take care; all urine must be aspirated before the re-suspending! Resuspend pellet in 180 µl of molecular grade water with 200 µl of MI3 solution from EliGene® Urine Isolation Kit and add 10 µl of Proteinase K and 20 µl Internal Control (IAC DNA). Vortex for 15 seconds. Continue according to instructions in standard protocol in EliGene® Urine Isolation Kit.
2. Use 100 µl of Elution buffer. Isolated DNA use for the detection immediately after DNA isolation or store DNA hours to one week at 4 °C. For longer period than one week freeze DNA at -20 °C.

Automatic isolation:

1. Open the tubes and carefully aspirate all supernatant. Re-suspend pellets in 180 µl of PBS by vortexing and add 20 µl of Internal Control (IAC DNA).

   WARNING: The rest of urine in the tube can influence the purity of isolated DNA.
2. Isolate DNA from the sample by using MAGNETO BodyFluid DNA/RNA isolation kit according to protocol for plasma samples with elution to 50 µl of Elution buffer.

Additional required equipment

- Automatic pipette 5–20 µl and sterile tips with filter DNA-, RNA- free, DNase-, RNase- free (we recommend plastic with CE certificate for diagnostic purposes).
- Sterile stand DNA-, RNA- free, DNase-, RNase- free.
- Equipment for RealTime PCR – the kit is designed for Quant Studio 5 (Thermofisher Scientific), CFX96 Touch Real-Time PCR Detection System (Bio-Rad), MIC qPCR Cycler (Bio Molecular Systems).
- Sterile plastic (strips, plates, tubes) DNase-, RNase- free compatible with given RealTime PCR system.
- Lab safety gloves.

Configuration of Real Time PCR instrument

Follow the cycler manufacturer's manual when using the kit. Below is a list of cyclers that have been used in testing EliGene® STD GAR/URE/MYC RT kit.

- For *Ureaplasma (urealyticum,parvum*) detection the probe labeled with FAM is used (exc. 494 nm – em. 518 nm)
- For *Mycoplasma* (*hominis, genitalium*) detection the probe labeled with TexasRed is used (exc. 589 nm – em. 615 nm)
- For *Gardnerella vaginalis* detection the probe labeled with Cy5 is used (exc. 650 nm – em. 670 nm)
- For Internal Control the probe labeled with HEX is used (exc. 520 nm – em. 548 nm)

QuantStudio 5 (ThermoFisher Scientific):

Select the options Experiment type, “Presence/Absence”, Chemistry “TaqMan Probes” and Run Mode

"Standard". As reporter dyes use FAM (Ureaplasma) and VIC/HEX (IAC DNA), ROX (Mycoplasma), Cy5 (Gardnerella) and select NONE as the passive reference dye.

Set up the following temperature profile:

Holding stage

95°C	2 min	Ramp rate (1.6°C/s)	

Cycling stage- 45 Cycles

95°C	10 s	Ramp rate (1.6°C/s)	
55°C	20 s	Ramp rate (1.6°C/s)	Data collection ON
67°C	30 s	Ramp rate (1.6°C/s)	

Post-Read Stage

40°C	1 min	Ramp rate (1.6°C/s)	

Collect emission signal at the cycling stage at 55 °C.

The complete temperature profile can be up-loaded from Run Template "EliGene _STD1_QS5_v00.edt". The Run Template can be imported to the software from the CD included in the kit.

CFX96 Touch (Bio-Rad):

Select the option "Startup Wizard", set up "New Experiment" and create new protocol by selecting "Create New Protocol".

Set up the following temperature profile:

Step 1	95°C	2 min
Step 2	95°C	10 s
Step 3	55°C	20 s + Plate Read
Step 4	67°C	30 s
Step 5	*GOTO Step 2*	*44x*
Step 6	40°C	60 s

Set "Sample volume" at 20 µl.

Collect emission signal at the Step 3 at 55° C.

For filter settings use the "Scan Mode" All Channels but in Plate Manager select for the samples only fluorophores FAM, HEX, TxRed, Cy5. Then assign the samples with positions as an "Unknown" sample or "Standard". The complete temperature profile can be up-loaded from Run Template "EliGene_STD1_CFX96_v00.pcrl". The Run Template can be imported from the CD included in the kit.

MIC qPCR (Bio Molecular Systems Pty Ltd):

In Run Setup Create a new Run Profile for the MIC instrument. Enter the Sample Volume of 20 µl and Temperature Control "Fast TAQ (v3)".

Set up the following temperature profile:

Holding stage

95°C 2 min

Cycling stage – 45 cycles

95°C 10 s

55°C 20 s Acquire on "Green", "Yellow", "Orange", "Red"

67°C 30 s

Holding stage

40°C 60 s

The complete temperature profile can be up-loaded from Run Template "EliGene_STD1_MIC_v00.mictemplate". The Run Template can be copied from the CD included in the kit.

Reagent preparation

- To avoid the contamination keep all tubes closed and follow the instructions.
- Before the usage, all reagents must be completely thawed, briefly mixed on vortex and shortly spun.
- In the step of Proteinase K addition of Isolation protocol add 20 µl of Internal Control (IAC DNA) to isolated sample. In no case add the internal control to isolated DNA just before the analysis.
- **If you do not use all the volume of MasterMix, store the tube at dark at temperature 4°C up to 14 days. For long-term storage use the freezer (-20 °C, dark). MasterMix should not go through more than five freeze-thaw cycles.**

Preparation of Reaction Mix for the instruments QuantStudio 5, CFX96 and MIC qPCR

1. Detection: Take one microtube with STD 1 Mix and after the thawing pipette 15 µl of the mix to amplification microtube or plate and add 5 µl of isolated DNA. During the pipetting of samples be careful to avoid cross-contamination of samples.
2. Positive control: Take one microtube with STD 1 Mix and after the thawing pipette 15 µl of mix to amplification microtube or plate and add 5 µl of PC DNA STD 1. During the pipetting of positive control be careful to avoid contamination of other samples. Use separate pipette for positive controls!

Insert the micro tubes or plate with samples to the RealTime PCR instrument and run the program according to chapter "Configuration of Real Time instrument" above.

Result reading

QuantStudio 5 (ThermoFisher Scientific):

In "**Analyse Settings**" edit the original parameters for Ct for individual channels (FAM, VIC, ROX, Cy5). Enter the Threshold level for each channel to a value equal to 1/3 of the maximal intensity of positive control, select "Automatic Baseline" option and analyze results by selecting "**Apply**".

Positive result for *Ureaplasma urealyticum/parvum*: The positive result is characterized by the growth of fluorescence signal in FAM channel. In a case of negative results, the amplification will not occur.

Positive result for *Mycoplasma hominis/genitalium*: The positive result is characterized by the growth of fluorescence signal in ROX channel. In a case of negative results, the amplification will not occur.

Positive result for *Gardnerella vaginalis*: The positive result is characterized by the growth of fluorescence signal in Cy5 channel. In a case of negative results, the amplification will not occur.

The Internal Control (IAC DNA) must be amplified in each sample. The Internal Control amplification is characterized by the growth of fluorescence signal in VIC (HEX) channel.

CFX96 Touch Real-Time PCR Detection System (Bio-Rad):

In Data Analysis window choose "Quantification". In "Settings" menu choose option "Baseline Setting" and select "Baseline Subtracted Curve Fit" option and "Apply Fluorescence Drift Correction" option.

In Data Analysis window select a single fluorophore (FAM, HEX, TxRed, Cy5) by the clicking the box next to the fluorophore name located under the amplification chart and read the results for individual samples.

Positive result for *Ureaplasma urealyticum/parvum*: The positive result is characterized by the growth of fluorescence signal in FAM channel (em. 518 nm). In a case of negative results, the amplification will not occur.

Positive result for *Mycoplasma hom/gen*: The positive result is characterized by the growth of fluorescence signal in TexasRed channel (em. 615 nm). In a case of negative results, the amplification will not occur.

Positive result for *Gardnerella vaginalis*: The positive result is characterized by the growth of fluorescence signal in Cy5 channel (em. 670 nm). In a case of negative results, the amplification will not occur.

The Internal Control (IAC DNA) must be amplified in each sample. The Internal Control amplification is characterized by the growth of fluorescence signal in HEX channel (em. 548 nm).

MIC qPCR (Bio Molecular Systems):

To view and analyze acquired data, click the small cross next to Cycling under Analysis module and then select the target – Non-Assay Green (FAM), Non-Assay Yellow (HEX), Non-Assay Orange (TxRed) and Non-Assay Red (Cy5). In the down right corner **increase** "**Fluorescence Cut-off Level**" **to 20 %**. A quantification cycle (Cq) value is displayed for each positive well. This is the cycle number at which the sample fluorescence rises above the threshold (the red horizontal line near the bottom of the amplification curve chart). In the Samples panel on the right, click sample names to hide or display the associated amplification curves and result data.

Positive result for *Ureaplasma urealyticum/parvum*: The positive result is characterized by the growth of fluorescence signal in Green channel. In a case of negative results, the amplification will not occur.

Positive result for *Mycoplasma hom/gen*: The positive result is characterized by the growth of fluorescence signal in Orange channel. In a case of negative results, the amplification will not occur.

Positive result for *Gardnerella vaginalis*: The positive result is characterized by the growth of fluorescence signal in Red channel. In a case of negative results, the amplification will not occur.

The Internal Control (IAC DNA) must be amplified in each sample. The Internal Control amplification is characterized by the growth of fluorescence signal in Yellow channel.

Interpretation of results

Negative result:

If the increasing of amplification signal in channel FAM, TxRed or Cy5 does not appear before cycle number 40, the result of test should be interpreted as probably *Mycoplasma (hom/gen), Ureaplasma (urealyticum/parvum) and Gardnerella vaginalis* DNA negative or with concentration of DNA below the detection limit of this kit (10 genomic DNA/reaction). The signal for Internal Control must be positive. This result does not exclude the occurrence of the above-mentioned pathogens and possible infection because results of this test are dependent on proper sample collection and elaboration. Results are also dependent on enough quantity of analyzed DNA.

Positive result:

Amplification signal in FAM channel (494-518 nm) for STD 1 Mix appears before cycle number 40. *Ureaplasma urealyticum/parvum* DNA was detected in the sample. The sample is *Ureaplasma urealyticum/parvum* DNA positive.

Amplification signal in TexasRed channel (589-615 nm) for STD 1 Mix appears before cycle number 40. *Mycoplasma hominis/genitalium* DNA was detected in the sample. The sample is *Mycoplasma hominis/genitalium* DNA positive.

Amplification signal in Cy5 channel (650-670 nm) for STD 1 Mix appears before cycle number 40. *Gardnerella vaginalis* DNA was detected in the sample. The sample is *Gardnerella vaginalis* DNA positive.

WARNING: The contamination in laboratory space is also possible. Use separate pipette for MasterMixes, separate pipette for positive controls and separate pipette for samples. Follow all recommendations for laboratories of DNA analyses.

Inhibited sample:

In the case that increasing of amplification signal specific for DNA of the above-mentioned pathogens and also increasing of amplification signal specific for internal control in HEX channel is not observed, it is necessary to repeat the analysis. The best, there is to use DNA samples prepared by new DNA isolation.

Control procedure

EliGene® STD GAR/URE/MYC RT involves Internal Control (IAC DNA) and Positive Control (PC DNA STD 1). Internal control isolation follows the quality of DNA isolation and detects mistakes in the isolation process. It detects the occurrence of an inhibition of amplification process. In the case that the sample is negative, the Cp of internal control must be Cp < 35.

Positive control follows the proper function of MasterMix. Minimal Cp of positive control must be 35 or less. The Cp higher than 35 for positive control can't be accepted and DNA detection must be repeated with new sample. In the case of repeatedly higher Cp contact manufacturer ELISABETH PHARMACON.

Use negative control for each run. As negative control use the water for molecular biology used in your laboratory. For negative control use the pipette for DNA samples.

Reference material:

To monitor all the examination processes covering DNA isolation and RealTime PCR detection is possible to use sample positive for *Mycoplasma hominis, Mycoplasma genitalium, Ureaplasma urealyticum, Ureaplasma parvum* and *Gardnerella vaginalis* DNA. The commercial positive material is not available.

Troubleshooting:

1. If there is no amplification of Internal Control (IAC DNA), there is some problem in the isolation of DNA or the kit is after the expiration date or there is RealTime instrument breakdown.
2. If there is no amplification of Positive Control, the kit is after the expiration date or there is RealTime instrument breakdown.

Performance characteristics

Analytical performance characteristics:

Kit EliGene® STD GAR/URE/MYC RT has a very high sensitivity – detects 10 genomic or plasmid DNA added to the amplification mix. Analytical sensitivity of the kit was verified as follows. The insert with specific DNA concentration was prepared by cloning and subsequently diluted to desired concentration of target sequence. The addition of human DNA to sample in common concentration has no effect to sensitivity of the method. Simultaneous analysis of multiple pathogens in one reaction mixture did not affect the assay result.

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Analytical sensitivity is 10 copies of *Mycoplasma hominis, Mycoplasma genitalium*, *Ureaplasma urealyticum, Ureaplasma parvum* and *Gardnerella vaginalis* DNA in reaction mix.

Analytical specificity of method was verified by searching the DNA database NCBI (GenBank, http://www.ncbi.nlm.nih.gov/) for the sequences of primers and probes and by addition of human DNA to MasterMix. 50 different samples of human DNA did not give false positive result. False positive result was not observed after the addition of DNA from these organisms *B. burgdorferi sensu lato*, *M. tuberculosis*, *M. bovis*, *M. cansasii*, *M. xenopii*, *M. avium*, *M. marinum*, *Lactobacillus sp.*, *Enterococcus faecalis*, *Pseudomonas sp.*, *E. coli*, *A. niger*, *C. albicans*, *S. aureus*, *S. agalactiae*, *Ch. trachomatis*, HBV, EBV, CMV, HSV1, HSV2, VZV.

Clinical specificity was tested on clinical urine samples and swab samples from men and women urogenital tract. A total of 40 clinical samples (urine samples and swabs from men and women urogenital tract) were collected in the Laboratory Diagnostic Center ELISABETH PHARMACON, spol. s r.o., Rokycanova 4437/5, Brno. These were selected samples of mixed infections of mentioned pathogens. Of these, 29 were positive for *Ureaplasma urealyticum/ Ureaplasma parvum*, 13 were positive for *Mycoplasma hominis/ Mycoplasma genitalium* and 31 were positive for *Gardnerella vaginalis*. Compared to the reference methods, 100 % agreement was achieved in results.

Diagnostic performance characteristics:

The clinical sensitivity and specificity of EliGene® STD GAR/URE/MYC RT kit is 100%.

Measuring interval

The kit enables the detection of 10^1–10^8 DNA molecules of *Mycoplasma hominis, Mycoplasma genitalium, Ureaplasma urealyticum, Ureaplasma parvum* and *Gardnerella vaginalis* in reaction mix.

Internal control of quality

As an internal control of quality the Internal Control (IAC DNA) for checking the process of DNA isolation and amplification together with Positive Control for functional control of MasterMix is used.

Limitation of the examination procedure

The sensitivity of kit depends on handling with sample (isolation of DNA). It is strictly recommended to use isolation kits and procedures mentioned above.

The sensitivity of DNA detection depends on sample collection, storage (store at 4 °C) and processing methods (DNA isolation, sample collection date, detection immediately after isolation).

Biological reference intervals

Not applicable information for this kit.

Warning

After mixing, MasterMix is stable at -20 °C. Do not freeze tubes with MasterMix more than 5 times! Do not mix components of the kits of different lots.

Warnings and general precautions

- Handle and dispose of all biological samples as if they were capable of transmitting infective agents. Avoid direct contact with the biological samples. Avoid splashing or spraying. The materials that come into contact with biological samples must be autoclaved at 121 °C for one hour before disposal.
- Handle and dispose of all reagents and all assay materials as if they were capable of transmitting infective agents. Avoid direct contact with the reagents. Avoid splashing or spraying. Waste must be treated and disposed of in compliance with the appropriate safety standards. Disposable combustible materials must be incinerated. Liquid waste containing acids or bases must be neutralized before disposal.
- Wear suitable protective clothing and gloves and protect eyes/face.
- Never pipette solutions by mouth.
- Do not eat, drink, smoke or apply cosmetic products in the work areas.
- Wash hands carefully after handling samples and reagents.
- Dispose of leftover reagents and waste in compliance with regulations in force.
- Read all the instructions provided with the kit before running the assay.
- Follow the instructions provided with the kit while running the assay.
- Do not use the kit after the expiry date.
- Only use the reagents provided in the kit and those recommended by the manufacturer.
- Do not mix reagents from different batches.
- Do not use reagents from other manufacturer´s kit.

Warnings and precautions for molecular biology

- Molecular biology procedures, such as extraction, reverse transcription, amplification and detection of nucleic acids, require qualified staff to prevent the risk of erroneous results, especially due to degradation of the nucleic acids contained in the samples or due to sample contamination by amplification products.
- It is necessary to have separate areas for the extraction/preparation of amplification reactions and for the amplification/detection of amplification products. Never introduce an amplification product in the area designed for extraction/preparation of amplification reactions.
- It is necessary to have lab coats, gloves and tools which are exclusively employed in the extraction/preparation of amplification reactions and for the amplification/detection of amplification products. Never transfer lab coats, gloves or tools from the area designed for the amplification/detection of amplification products to the area designed for the extraction/preparation of the amplification reactions.
- The samples must be exclusively employed for this type of analysis. Samples must be handled under a laminar safety box. Tubes containing different samples must be never opened at the same time. Pipettes used to handle samples must be exclusively employed for this specific purpose. The pipettes must be of the positive displacement type or be used with aerosol filter tips. The tips employed must be sterile, free from DNases and RNases, free from DNA and RNA.
- Reagents must be handled under PCR box (not in laminar flow box). The pipettes employed to handle the reagents must be used exclusively for this purpose. The pipettes must be of the positive displacement type or be used with aerosol filter tips. The tips employed must be sterile, free from DNases and RNases, free from DNA and RNA.

- Amplification products must be handled in such way as to reduce dispersion into the environment as much as possible, in order to avoid the possibility of contamination. Pipettes used to handle amplification products must be employed exclusively for this specific purpose.

Warnings and precautions specific to components of the kit

- The tubes containing mix (STD 1 Mix) are disposable and therefore must be used once only in the preparation of the reaction mixture.
- The tubes containing IAC DNA and PC DNA STD 1 are disposable and therefore must be used once only in the preparation of the reaction mixture.
- These mixes carry the following safety warnings (P):

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P281 Use personal protective equipment as required.

In the case of any problems, contact the customer center of ELISABEHT PHARMACON, spo. s r.o.

Literature

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Symbols

	Catalog number
	Upper limit of temperature
	Batch code
	Use by (last day of month)
	*in vitro* diagnostic medical device
	Fulfilling the requirements of European Directive 98\79\EC for *in vitro* diagnostic medical device.
	Contains sufficient for "N" tests
	Attention, consult instructions for use
	Manufacturer

Manufacturer

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