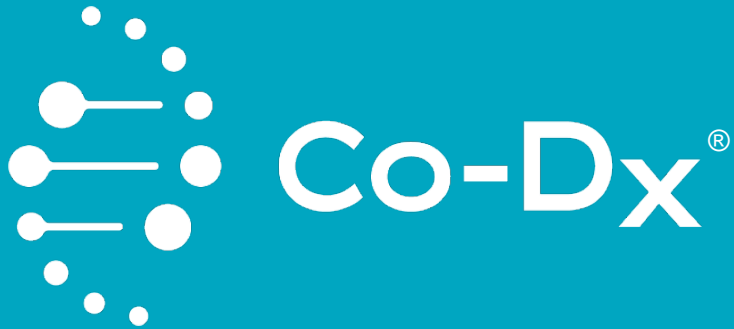


May
2024



Instructions for Use Co-Dx™ Logix Smart® Mycobacteria Tuberculosis (MTB) Kit

REF MTB-K-007

CE

IVD

Co-Dx™ Logix Smart® Mycobacteria
Tuberculosis (MTB) Kit
CO-DIAGNOSTICS, INC



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1 INTENDED USE

Real-time polymerase chain reaction (qPCR) is recommended for detection of the Mycobacteria Tuberculosis (MTB) complex during the acute stages of infection. The **Co-Dx™ Logix Smart® Mycobacteria Tuberculosis (MTB)** kit detects the bacteria within 40 cycles from respiratory tract fluid samples. Non-Tuberculosis mycobacteria are commonly present in the lungs and in the environment and can cause a Tuberculosis-like disease. Mycobacteria can also infect or spread to other parts of the body.

The marker *IS6110* has been used for decades to detect MTB-complex members, although more recent studies showed that the *IS6110* marker was not present in some isolates, and that *MPB64* was found as an additional conserved marker to increase the sensitivity of tests designed for detection of the MTB-complex.

The **Co-Dx Logix Smart MTB** kit is intended for molecular biology applications. This product is released for use as an *in vitro* diagnostic device, for export only and is not for sale in the United States.

The **Co-Dx Logix Smart MTB** kit was designed and validated for use in respiratory tract fluid specimen for detection of presence or absence of Mycobacteria Tuberculosis complex *M. Tuberculosis*, *M. bovis*, *M. africanum*, *M. canetti*, *M. microti* and *M. pinnipedii* through amplification of the bacterial DNA markers *IS6110* and *MPB64*.

2 PRODUCT DESCRIPTION AND TEST PRINCIPLE

The **Co-Dx Logix Smart MTB** kit is designed to detect the presence or absence of deoxyribonucleic acid (DNA) of mycobacteria Tuberculosis complex members.

The real-time polymerase chain reaction (qPCR) amplifies the *IS6110* and *MPB64* regions of the pathogen genome. The amplified product is then detected by fluorescent dyes (FAM, CF560, and CF610).

- Each **Co-Dx Logix Smart MTB** kit contains a complete, ready-to-use master mix (MM).
- A human RNaseP gene marker serves as an Internal Positive Control (IPC) to monitor the quality of each reaction and is also designed to detect inadequate samples.
- A Negative Control (NC) is also provided for use.

Each kit provides reagents sufficient for 100 reactions. See Table 1 for kit components.

Table 1
Kit Components

Cap Color	Component	Symbol	Description	Individual Catalog Number
Brown	Co-Dx Logix Smart MTB Master Mix	MM	Proprietary blend of Co-Primers [®] and PCR reagents	TUBE-MTB-0001 (for 1x500 µL [100 reactions])
Clear	Co-Dx Logix Smart MTB Negative Control	NC	Nuclease-free water	TUBE-MTB-0002 (for 1x500 µL [100 reactions])
Red	Co-Dx Logix Smart MTB Positive Control	PC	Proprietary blend of positive template	TUBE-MTB-0003 (for 1x500 µL [100 reactions])

The product code for this kit is MTB-K-007. Contact the Co-Diagnostics' Sales department at (801) 438-1036 ext. 1 or go to www.co-dx.com/contact/ to order.

3 REAGENT STORAGE AND HANDLING

- The **Co-Dx Logix Smart MTB** kit is shipped on dry ice and should arrive frozen. Contact your distributor if one or more of the components are not frozen upon arrival or are compromised during shipment.
- Store all components immediately upon arrival at a temperature between -40°C and -16°C to prevent degradation of reagents.
- Do not use expired products. The integrity of expired components cannot be guaranteed.
- Follow internal laboratory procedures for quality control when using this product.
- Protect the MM from light.
- If you will be using reagents intermittently, freeze the reagents in multiple aliquots to ensure that less than 10 freeze/thaw cycles occur. Excessive thawing and freezing of components (specifically the MM) could affect the performance of the assay.
- Avoid storing components at temperatures between +2°C and +8°C for more than 4 hours.
- If you work in an area prone to power outages, keep a back-up generator for your freezer as well as a temperature data log system to ensure that the product remains frozen at a temperature between -40°C and -16°C.
- Dispose of the product in accordance with applicable regional, national, and local laws and regulations. This product is not biological waste. The Safety Data Sheet (SDS) for this product can be viewed from Co-Diagnostics website at [Product Information - Co-Dx](#).

- Always follow the most recently recommended product stability data as it becomes available. This data can be found in our latest version of the Instructions for Use at [Product Information - Co-Dx](#).

4 MATERIAL REQUIRED BUT NOT INCLUDED WITH THE TEST

Extraction reagents, automation systems, and thermal cyclers required but not included with the test are displayed in Table 2 and Table 3.

Table 2

Extraction Reagents Validated but Not Included with the Test

Extraction Reagent Options	Catalog Number	Manufacturer
QIAamp DNA Mini Kit	51304 (50 preps), 51306 (250 preps)	Qiagen

Table 3

Thermocyclers Validated but Not Included with the Test

Thermocycler	Manufacturer
Co-Dx Box	BMS

4.1 Consumables Required but Not Provided

The following consumables are required but not provided with the kit:

- Heating block with temperature capabilities of 37-95°C
- Pipettes capable of transferring 5 µL, with appropriate tips and filters
- Ice or cooling block
- Vortex
- Real-time PCR System with FAM (green), Cal Fluor 560 (yellow), and Cal Fluor 610 (orange) dyes (or equivalent) and accompanying tubes/plates and caps/films
- Material needed for extraction, (e.g., a centrifuge with a rotor for 2 mL tubes and is capable of spinning at 12,000 rpm)
- Disposable powder-free gloves and lab coats
- DNA extraction kit
- A 10% bleach or other appropriate cleaning solution that degrades nucleic acids
- PCR plates or strip tubes for the thermocycler being used

4.2 Equipment Required but Not Provided

The following equipment is required but is not provided with the kit:

- Several micropipettes capable of pipetting volumes from 5 µL to 1,000 µL
- A cold block or ice
- A vortex and centrifuge
- A PCR workstation, for MM plating and setup

5 WARNINGS AND PRECAUTIONS



WARNING!

Before performing any testing or running any patient sample, verify that all instruments have been properly installed, calibrated, and are well maintained. Do **not** use instruments with outdated calibration.

As with any diagnostic or laboratory experiment, good laboratory practices for molecular biology are essential for the proper performance of the qPCR or any laboratory experiment. Attention should also be taken to the procedures specific to molecular diagnostics.

Due to the high sensitivity of the **Co-Dx Logix Smart MTB** kit and qPCR technology, handle samples and materials with care while performing the assay to keep reagents and amplification mixtures free of contamination.

Users should also do the following:

- Use sterile pipette tips with filters.
- Use standard precautions when handling any patient samples, as they may contain infectious agents.
- Store and extract positive materials (specimens, positive controls [PCs], and amplicons) separately from other reagents.
- Always use the NC provided with this kit.
- Consult appropriate Safety Data Sheets (SDS) for safety. The SDS for the **Co-Dx Logix Smart MTB** kit is provided with the shipment. If not provided with the shipment, the SDS can be retrieved from Co-Diagnostics website at the following link: [Product Information - Co-Dx](#).
- Use Good Laboratory Practices for Molecular Biology, which requires a unidirectional workflow and the separation of negative and positive materials, to prevent contamination.

- Since information in this document is periodically updated to reflect our latest study results, always use the most recent version that can be found at [Product Information - Co-Dx](#).

6 SAMPLE COLLECTION, HANDLING, SHIPPING, AND STORAGE

6.1 Sample Collection

Adhere to the following guidelines when collecting samples:

- Collect sputum samples in the early morning.
- Use the N-acetyl-L-cysteine-sodium hydroxide (NALC-NaOH) decontamination followed by a DNA extraction method prior to real-time PCR set-up.

Sample collection is fundamental to produce a good result for any molecular diagnostic assay. Extreme exposure environments that could not only damage the microorganism but also its DNA can affect the efficiency of the test and its results. See the Center for Disease Control (CDC) TB education page on the CDC's manual Chapter 4: Diagnosis of TB Disease, page 88. See <https://www.cdc.gov/tb/education/corecurr/pdf/chapter4.pdf> for instructions on standard protocols for appropriate collection of sputum samples.

6.2 Sample Handling

Adhere to the following guidelines when handling samples:

- Refrigerate respiratory specimens at 2-8°C for up to 72 hours after collection.
- If a delay in testing or shipping is expected, freeze specimens at -70°C or below.
- Freeze extracted nucleic acid samples at -70°C or lower.

6.3 Sample Shipping

Adhere to the following guidelines when shipping samples:

- Store and ship all specimens cold (2-8°C) or frozen (-20°C) for molecular diagnostic testing.
- For cold specimens, package the sample in an insulated container with adequate ice packs to ensure specimen integrity.
- For frozen specimens, ship the sample in an insulated container with enough dry ice to ensure the specimens will remain frozen until received. See the CDC's information here: [Storing and Shipping Respiratory Specimens](#).

- Ship specimens known to contain or suspected of containing MTB virus that also require shipment by air, as a Biological Substance Category B, UN3373. Follow the international regulations, as described in the WHO Guidance on Regulations for the Transport of Infectious Substances 2021-2022: (<https://www.who.int/publications/i/item/9789240019720>).

6.4 Sample Storage

Adhere to the following guidelines when storing samples:

- Instruct patients to keep samples refrigerated (insulated boxes and ice packs could be provided) until samples are delivered to the laboratory or collect samples at the clinic and keep samples refrigerated until delivery to the laboratory.
- Keep specimens at a temperature between -30°C and -10°C (for up to 7 days). For storage longer than 7 days, freeze specimens below -70°C.
- Avoid repeated freezing and thawing of a specimen.
- If a specimen is kept for retesting, aliquot the specimen in different tubes to avoid freezing and thawing cycles.
- Monitor the temperature in the storage areas and record the temperature regularly to identify potential fluctuations.
- Do not use domestic refrigerators or freezers with wide temperature fluctuations. These appliances are not suitable for the storage of frozen specimens (CDC, 2020).

7 PROCEDURE

7.1 Recommendations

7.1.1 Extraction of Sample DNA

The **Co-Dx Logix Smart MTB** kit has been validated for use in respiratory tract fluid samples using the NALC-NaOH decontamination protocol followed by QIAamp DNA Mini Kit Extraction (Cat No. 51304/51306, Qiagen).

Any other commercial extraction kits that are capable of producing a trustworthy and good quality DNA yield can also be used with **Co-Dx Logix Smart MTB** kit.

7.2 Set Up the Reagent and Reaction

7.2.1 Set Up Reagent

Perform these steps to set up the reagent:

- 7.2.1.1 Clean all working surfaces with a fresh 10% bleach solution followed by molecular-grade alcohol or another equivalent method of cleaning that disinfects and degrades nucleic acids.
- 7.2.1.2 Vortex all **Co-Dx Logix Smart MTB** MM, PC, NC, and all sample tubes for about three seconds.
- 7.2.1.3 Briefly spin the MM, PC, NC down before using to ensure reagents are properly mixed and to ensure removal of any condensation or residue from the lids.
- 7.2.1.4 Thaw all reagents and samples on ice, or a cold block, before starting the setup.

7.2.2 Set Up the Reaction

Perform the steps below to set up the reaction.

- 7.2.2.1 Collect enough reaction wells for each of the following:
 - One for each NC,
 - One for each sample you want to test, and
 - One (or more) for each PC

Note: The example below displays the minimum number of wells needed for 5 samples.

PC	1
NC	1
Samples	5

Total wells required	7
-----------------------------	----------

- 7.2.2.2 Pipette 5 µL of MM into each well collected.
- 7.2.2.3 Pipette 5 µL of the NC into the appropriate wells (in addition to the 5 µL of MM already in the well).

Note: Ensure that at least one NC is included in each run and that enough space remains for at least one PC.

Important:

- Pipette on ice, if possible.
- Perform PC pipetting and sample setup in a separate area, or at a separate time from the MM and NC.
- Change pipette tips between samples and change pipette tips after pipetting each component.
- Pipette the PC last, if possible, to avoid contamination events.

- 7.2.2.4 Pipette 5 µL of sample or PC into the appropriate well.
- 7.2.2.5 Seal the reaction plate with an optical adhesive film or seal each reaction tube with its appropriate lid.
- 7.2.2.6 Place the plate or tubes into the rRT-PCR instrument in the correct orientation and start the run.

7.3 PCR Instrument Setup for the Co-Dx Box or MIC

- 7.3.1 Contact the Laboratory at (801) 438-1036 ext. 3 or at www.co-dx.com/contact/ for the downloadable template file. The template file comes pre-programmed with the PCR instrument setup described in this section. When not using a template, use the settings outlined in Table 4 to program the Co-Dx Box PCR instrument.

Table 4

Co-Dx Box or MIC PCR Instrument Settings

Item	Setting
Reaction Volume	10 µL
Ramp Rate	Default
Passive Reference	None

7.3.2 Program the thermocycler according to the conditions displayed in Table 5.

Table 5

Thermocycler Conditions

Stage	Cycles	Temperature	Time
Initial Denature	1	95°C	2 minutes
Amplification	45	95°C	3 seconds
		55°C	32 seconds

7.3.3 Define the fluorescence detectors (dyes) displayed in Table 6.

Table 6

Fluorescence Detector Definitions

Target	Detector Name	Reporter	Quencher
MTB specific DNA	IS6110	FAM	BHQ-1
MTB specific DNA	MPB64	CF560	BHQ-1
RNaseP specific DNA (IPC)	RNaseP	CF610 (ROX/Texas Red)	BHQ-2

7.3.4 When the run is finished, ensure that the run file is saved.

7.3.5 Check to see that both the positive control (PC) and NC passed.

7.3.6 If controls pass, interpret the sample results. If controls fail, the run is invalid, and you must document the run and initiate troubleshooting.

8 DATA ANALYSIS

Verification and validation studies for **Co-Dx Logix Smart MTB** kit were performed by following Good Laboratory Practices for Molecular Biology assays (Viana & Wallis, 2011). If these conditions are not met, the performance will display higher variability, due to user errors while experimenting.

8.1 Validity of Diagnostic Test Runs

8.1.1 Valid Diagnostic Test Run

8.1.1.1 Verify that both the PC and the NC pass.

8.1.1.2 The control conditions outlined in Table 7 must be met. If controls pass, interpret the sample results.

Table 7

Required Control Conditions

Control Type	Control Name	Purpose of Control	IS6110	MPB64	RNaseP (IPC)
MTB Positive Control (PC)	IS6110 (FAM™)	Verifies the performance of the master mix	+	+	+
	MPB64 (CF®560)				
	RNaseP (CF®610)				
No Template Control (NC)	Nuclease-free water	Verifies the reagents are free of contamination	-	-	-

8.1.2 Invalid Diagnostic Test Run

8.1.2.1 If any of the controls fail, the run is invalid. Document the run and initiate troubleshooting.

8.2 Interpretation of Results

Once the controls have passed, the patient samples can be interpreted based on three possible outcomes:

- Positive
- Negative
- Inconclusive

A positive result will show an amplification curve or cycle threshold value for IS6110 or MPB64 below 40 cycles. Amplification curves greater than 40 cycles for MTB are in the uncertainty zone. The amplification of the RNaseP shows that the extraction was successful.

A negative result will show no amplification for IS6110 and MPB64; however, occasionally amplification greater than 40 cycles can occur. Any amplification curves greater than 40 cycles for MTB are outside of the detection limits for the assay. The absence of amplification curves for MTB targets indicates a negative result only when the RNaseP (IPC) marker is positive.

An inconclusive result will occur if any of the controls fail. See the troubleshooting section of this document.

The interpretation of results can be translated to Table 8.

Table 8

Interpretation of Results

Marker	IS6110	MPB64	Patient Internal Positive Control (RNaseP)	Co-Dx Logix Smart MTB Positive Control (PC)	Co-Dx Logix Smart MTB Negative Control (NC)	Result
Instrument Reading	+	+	Pass			MTB DNA+
	+	-				MTB DNA +
	-	+				MTB DNA +
	-	-				MTB DNA -
Any Result			Fail	Pass		Inconclusive: See Troubleshooting
			Pass	Fail	Pass	
				Pass	Fail	

An analyte result will be considered positive (+) if a Cq value of < 45, or negative (-) if a Cq value of ≥ 45 cycles. When possible, always check that the medical history and/or symptoms match with the result prior to treatment.

9 TROUBLESHOOTING

9.1 Stability

Real-time and Accelerated Shelf-life, and In-use Stability Studies are currently being tested. Results will be communicated as soon as they are released. A new version of this Instructions for Use will be issued to replace this one. Always use the latest version of this document.

Without the stability studies results it is imperative that the storage conditions are followed as best possible to ensure the product's performance is maintained.

The expiration date of this product has been established as 12 months and it does not exceed the expiration date of any of its reagents used in manufacturing.

9.2 User Errors

The PCR assay method is a technique that uses Molecular Biology technology to amplify a single copy or a few copies of a segment of a particular DNA sequence.

In order to ensure the Good Laboratory Practices for molecular biology assays, it is essential that the user has good skills on pipetting to prevent errors such as splashes, cross-over contamination, and errors on volume selection. Pipette tips must be replaced for every pipetting. Gloves must be replaced often. Equipment must have calibration up to date for the pipettes and thermocyclers.

Verification and validation studies performed for MTB-K-007 have been conducted following the current Good laboratory Practices for Molecular Biology Assays. If these conditions are not met, the performance will show higher variability due to user errors while conducting the experiment.

9.3 Inconclusive Results

PCs and NCs are validated, manufactured, and tested along with the MM. The purpose of these controls is to validate the performance of the MM, and the technique adopted by the user during the experiment. If the user has a poor use of the techniques required to perform a molecular biology assay, it is more likely that either the PC will not amplify or that the NC will amplify.

9.3.1 Positive Control (PC) Not Amplifying

If the PC does not amplify, this means that an error occurred while conducting the experiment (e.g., poor conservation, break of stability, use of expired reagent, volume errors, pipetting error, or incorrect reagent used). Because this occurred, it is likely that the same error occurred with the sample, the results cannot be trusted, and the test must be invalidated. Investigate to identify possible causes for error, reprocess the test from extraction (or not, depending on the investigation results) and identify risks in the process.

9.3.2 Negative Control (NC) Amplifying

If the NC amplifies, this means that an error caused the NC to be contaminated with the PC or the sample (e.g., contamination occurred from pipetting, splashes occurred on the PCR plate, or the test was otherwise contaminated by the user). Because this occurred, it is more likely that the same error occurred to the sample, the results cannot be trusted, and the test must be invalidated. Investigate to identify possible causes for error and reprocess the test from extraction (or not, depending on the investigation results) and identify risks in the process.

10 LIMITATIONS

Limitations to this test include the following:

- Strict compliance with this document is required for optimal results. Always use the most recent version of this document. This can be downloaded for free at [Product Information - Co-Dx](#).
- The use of this product is to be limited to trained and instructed personnel in real-time PCR techniques and IVD procedures.
- Good laboratory practices are essential for the proper performance of this assay. It is also recommended that upon receipt of reagents, a test run be performed to check the performance of the reagents before testing on patient samples.
- Appropriate specimen collection, transport, storage, and processing procedures are required for optimal results.
- Do not use the **Co-Dx Logix Smart MTB** kit components directly on the specimens collected. Perform an appropriate nucleic acid extraction before using this assay.
- The presence of PCR inhibitors may cause false negatives or invalid results.
- Potential mutations of the target regions of the MTB genome covered by this test kit may fail to detect the presence of the pathogens.
- As with any diagnostic test, results of the **Co-Dx Logix Smart MTB** kit are to be interpreted with consideration of all clinical and laboratory findings.

11 ANALYTICAL EVALUATION

11.1 Limit of Detection (LoD) – Analytical Sensitivity

The limit of detection of a molecular diagnostic test is the lowest concentration of analyte that was consistently detected (95% or higher) during performance evaluation studies. Because some isolates may not have the DNA markers for *IS6110* AND *MPB64*, the non-amplification of one or the other does not preclude a positive result. Having a sample showing positive for *IS6110* and negative for *MPB64* indicates that the strain may have only one of the markers, and the result in this case is still positive for Tuberculosis.

The limit of detection validated with **Co-Dx Logix Smart MTB** kit is 50 copies per reaction in a 5 µL sample. This value considers the lowest concentration for the detection of the two markers, *IS6110* and *MPB64*, for Mycobacteria Tuberculosis complex.

11.2 Inclusivity – Analytical Sensitivity

11.2.1 Date Performed

This test was performed on October 20, 2021.

11.2.2 Oligos Analyzed

The following oligos were analyzed during the test:

- TB.IS6110.F2.FAM
- TB.IS6110.R2
- MPB64.L1.F14.CF560
- MPB64.L1.R1

11.2.3 Analysis Methods

Target sequences were run under Blastn using default parameters, with the exception of the following:

- Optimized for somewhat similar sequences
- Max target sequences = 5000

https://blast.ncbi.nlm.nih.gov/Blast.cgi?PROGRAM=blastn&BLAST_PR OGRAMS=megaBlast&PAGE_TYPE=BlastSearch

All targets were compared against the entire NCBI, GenBank, and associated databases.

11.2.4 Results

Inclusivity analysis results are listed relative to the Mycobacterium Tuberculosis Complex (MTBC).

- TB.IS6110.F2.FAM
 - MTBC
 - 543 hits with 0 mismatches
 - 7 hits with 1 mismatch
 - 2 hits with 2 mismatches
 - 1 hit with 3+ mismatches

- TB.IS6110.R2
 - MTBC
 - 548 hits with 0 mismatches
 - 5 hits with 1 mismatch
 - 2 hits with 2 mismatches
 - 1 hit with 3+ mismatches
- MPB64.L1.F14.CF560
 - MTBC
 - 565 hits with 0 mismatches
- MPB64.L1.R1
 - MTBC
 - 565 hits with 0 mismatches

11.3 Exclusivity Analysis

11.3.1 Date Performed

This test was performed on October 20, 2021.

11.3.2 Oligos Analyzed

The following oligos were analyzed during the test:

- TB.IS6110.F2.FAM
- TB.IS6110.R2
- MPB64.L1.F14.CF560
- MPB64.L1.R1

11.3.3 Analysis Methods

Target sequences were run under Blastn using default parameters, with the exception of the following:

- Optimized for somewhat similar sequences
- Max target sequences = 5000

https://blast.ncbi.nlm.nih.gov/Blast.cgi?PROGRAM=blastn&BLAST_PR OGRAMS=megaBlast&PAGE_TYPE=BlastSearch

All targets were compared against the entire NCBI, GenBank, and associated databases.

11.3.4 Results

Exclusivity analysis results are listed with predicted cross-reactivity of each oligo relative to all organisms in the NCBI, GenBank, and associated databases except the Mycobacterium Tuberculosis Complex (MTBC). Predicted Cross Reactivity for a single oligo is defined as <3 Mismatches on the binding target of that oligo. A marker is expected to be cross-reactive if both the Forward and the Reverse have <3 mismatches combined.

- TB.IS6110.F2.FAM
 - No Predicted Cross Reactivity
- TB.IS6110.R2
 - No Predicted Cross Reactivity
- MPB64.L1.F14.CF560
 - No Predicted Cross Reactivity
- MPB64.L1.R1
 - No Predicted Cross Reactivity

12 MANUFACTURER AND AUTHORIZED REPRESENTATIVE

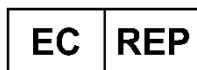
**Manufacturer:**

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13 REFERENCES











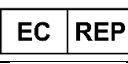

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14 LEGEND OF PACKAGE SYMBOLS

A legend of the package symbols is displayed in Table 9.

Table 9

Legend of Package Symbols

Icon	Description
	<i>In vitro</i> diagnostic medical device
	Catalog number
	Batch code
	Use-by-date
	Contains sufficient for x tests/reactions
	Protect from light
	Temperature limit
	Consult Instructions for Use document
	Non-sterile product - Do not sterilize.
	Manufacturer
	Authorized representative in the European Community
	CE-Marking for IVD in compliance to EU Directive 98/79/EC