SARS-CoV-2 and Influenza A/B Virus Multiplex Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing)

Product Identification

Product Name: SARS-CoV-2 and Influenza A/B Virus Multiplex Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing)
Reference Number:S3113E-24, S3113E-48, S3113E-24-P, S3113E-12-S
Package Specification:24 tests/kit, 48 tests/kit, Pre-packaged 24 tests/kit, Pre-packaged 12 tests/kit

Intended Use

The SARS-CoV-2 and Influenza A/B Virus Multiplex Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing) is intended for the qualitative detection of nucleic acids of the SARS-CoV-2, Influenza A and Influenza B in oropharyngeal swab and sputum from individuals meeting WHO SARS-CoV-2 clinical criteria (e.g., clinical signs and symptoms associated with SARS-CoV-2 infection) in conjunction with WHO SARS-CoV-2 epidemiological criteria (e.g., history of residence in or travel to a geographic region with active SARS-CoV-2 transmission at the time of travel, or other epidemiologic criteria for which SARS-CoV-2 testing may be indicated), suspected cases of influenza A virus and influenza B virus infection and other persons requiring the diagnosis or differential diagnosis of febrile respiratory infection.

For in vitro diagnostic use only. For professional use only.

Test principle summary and explanation

Summary

The SARS-CoV-2 (previously known as 2019-nCoV), is a RNA virus of the beta coronavirus family. The WHO has named the disease caused by SARS-CoV-2 as coronavirus disease 2019 (abbreviated “COVID-19”). It’s demonstrated that SARS-CoV-2 has the capability to spread rapidly, leads to significant impacts on healthcare systems and causing societal disruption. The potential public health threat posed by COVID-19 is globally high[1,2].

Influenza Virus is a RNA virus in the Orthomyxoviridae family which leads to human and animal influenza. It causes acute upper respiratory tract infection, spreads rapidly through the air and has periodic pandemics around the world. Human influenza virus are influenza pathogens which can be classified into three types, namely A , B and C. Among them, influenza A is the most harmful, while influenza B and influenza C have weak pathogenicity and are not easy to mutate. Influenza A Virus (Inf. A) has many subtypes. So far, there are 16 subtypes of HA and 9 subtypes of NA. Influenza B Virus (Inf. B) can be divided into two phylogenetic lineages: Yamagata family and Victoria family[3].

Test Principle

By applying real-time PCR (RT-PCR) technology on the fluorescence quantitative PCR instrument, this kit utilizes the conserved sequence of ORF 1ab and N gene of novel coronavirus (SARS-CoV-2), the conserved sequence of M gene of influenza A virus and the conserved sequence of NP gene of influenza B virus as multiplex RT-PCR amplification target regions to realize the detection of SARS-CoV-2 and influenza A/B virus via fluorescent signal changes.

The multiplex RT-PCR detection system contains primers and probes for internal control (IC) which can be used to monitor the sample collection, sample handling and RT-PCR process to avoid a false-negative result.

Materials provided

This kit is an amplification reaction reagent and contains the following components:

No.	Reagent Name	Spec. & Qty.				Main Ingredients
		24 T	48 T	Pre-packaged 24T	Pre-packaged 12T	
1	SARS-CoV-2/Inf A/B-PCR Mix	624 μL/tube x 1 tube	1248 μL/tube x 1 tube	26 μL/tube x 24 tubes	26 μL/tube x 12 tubes	Primers, Probes, dNTPs, $MgCl_2$, Rnasin, PCR buffer
2	SARS-CoV-2/Inf A/B-Enzyme Mix	96 μL/tube x 1 tube	192 μL/tube x 1 tube	4 μL/tube x 24 tubes	4 μL/tube x 12 tubes	RT Enzyme, Taq Polymerase
3	SARS-CoV-2/Inf A/B-Positive Control	1000 μL/tube x 1 tube	1000 μL/tube x 1 tube	1000 μL/tube x 1 tube	1000 μL/tube x 1 tube	Armored RNA containing the target genes (*ORF1ab, N, M*, *NP* gene) and internal control Gene fragments (Rnase P)
4	SARS-CoV-2/Inf A/B-Negative Control	1000 μL/tube x 1 tube	1000 μL/tube x 1 tube	1000 μL/tube x 1 tube	1000 μL/tube x 1 tube	Normal saline

Materials required but not provided

Materials required but not provided: 1.5 mL DNase-free and RNase-free centrifuge tubes, 0.2 mL PCR reaction tubes, pipette tips (10 μL, 200 μL and 1000 μL tips with filters are preferred), desktop centrifuge, desktop vortex mixer, various models of pipettes, Sample Release Reagent (Reference Number: S1014E Series) or Nucleic Acid Extraction-Purification Kit (Reference Number: S10016E/S50016E/S10018E Series) manufactured by Sansure Biotech Inc. for nucleic acid extraction, Sample Storage Reagent, such as Sample Storage Reagent (Reference Number: X1002E/X1003E/X1004E/X1010E/X1011E Series) manufactured by Sansure Biotech Inc.

Warnings and precautions

Warnings

1. Do not mix or exchange components from different kits.
2. Self-prepared materials: 4% NaOH for sputum liquefaction.
3. All biological materials in the kit have been inactivated.

Precautions

1. For in vitro diagnostic use only. Please read the product manual carefully before operation.
2. Please learn and be familiar with the operation procedures and precautions for each instrument before test. Please make sure quality control for each test.
3. Laboratory management shall strictly follow management practices of PCR gene amplification laboratory, laboratory personnel must receive professional training, test processes must be performed in separated rooms, all consumables should be for single use only after sterilization, special instruments and devices should be used for every process, all lab devices required in different processes and rooms should not be cross-used.
4. All specimens for detection should be handled as potentially infectious. Wear laboratory coats, protective disposable gloves and change the gloves often to avoid cross-contamination between samples. Handling of specimens and waste must meet relevant requirements outlined in local, state and national regulations.
5. Note: Improper operation during the storage, transportation and use of the reagent may affect the test results. For example, improper storage and transportation, sample collection, sample processing and test process are not standardized, please strictly follow the instructions.

Due to the characteristics of swab and other sample collection process and viral infection process itself, false negative results may be caused by insufficient sample volume, which should be combined with other clinical diagnosis and treatment information for comprehensive judgment, retest when necessary.

6.Due to the characteristics of swab and other sample collection process and viral infection process itself,false negative results may be caused by insufficient sample volume.which should be combined with other clinical diagnosis and treatment information for comprehensive judgment, retest when necessary.

7. After the addition of the sample in the tube the resulting solution is to be considered potentially biohazardous, handle the reagent with appropriate precautions and good laboratory practice.
8.The safe disposal of the reagents supplied must be carried out according to the instructioncontainedinthespecificSafetyDataSheetsand in compliance with the national regulations on disposal of potentially hazardous waste.
9. Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established: If you have any questions about the test or the results, please contact Sansure's customer service hotline +86-731-88883176-6116 or send an email to info@sansure.com.cn/ support@sansure.com.cn

IVD storage, operating conditions and stability

1. The shelf life of the kit is 12 months at -25° C to -15° C and protected from light.
2. Please refer to the date of manufacture and expiry date on the outer package.
3. The reagents keep valid and stable within the expiry date if not used. As long as the container of the reagent is opened, the freeze/thaw cycles should not exceed five.

Instrumentation

The diagnostic kit is compatible to Fluorescence Quantitative Analysis System containing FAM, HEX, ROX and CY5 channels, such as:

1. Angilent/AriaDx Real-Time PCR System
2. Applied Biosystems/7500 Real-Time PCR System
3. Bio-Rad/CFX96 Dx and CFX96 Deepwell Dx Systems
4. Hongshi/SLAN®-96P Real-Time PCR System
5. Molarray/Real-Time Quantitative Thermal Cycler (Model: MA-6000)
6.QuantGene 9600 Real-time quantitative PCR
7.Roche/LightCycler® 480 instrument II
8.Sansure/Portable Molecular Diagnostic System (S-Q37A/S-Q37B)
9. Sansure/Portable Molecular Workstation (Model: S-Q36A)
10.Sansure/Portable Molecule Workstation (Model: S-Q31A/S-Q31B)
11.Thermofisher/QuantStudio™ 5 Real-Time PCR System

Collecting and preparing specimens

1.Applicable specimen type: Oropharyngeal swab, sputum.
2.Collection of specimen: Collect sample in accordance with the relevant provisions of "Specimen Collection Method" in the "Pneumonia Laboratory Technical Guide for Novel Coronavirus Infection" from "Pneumonia Prevention and Control Plan for Novel Coronavirus Infection".

Oropharyngeal swab:

Use a sterile flocking swab (nylon sampling head and ABS sampling rod) to wipe the bilateral pharyngeal tonsils and posterior pharyngeal wall. After sampling, quickly place the sterile swab into the sample storage reagent (Reference Number: X1002E/X1003E/X1004E/X1010E/X1011E Series) manufactured by Sansure Biotech Inc. for storage.

It has been proved that storage solution, such as sterile virus sampling solution, physiological saline and 2-4 M Guanidine (such as Guanidine Hydrochloride) can also be used as Sample Storage Reagent for sample preservation. The sample storage reagent containing guanidine cannot be directly adapted to Sample Release Reagent (Reference Number: S1014E Series) manufactured by Sansure Biotech Inc. for nucleic acid extraction. If necessary, it is recommended to use Nucleic Acid Extraction-Purification Kit (Reference Number: S10016E/S50016E/ S10018E Series) manufactured by Sansure Biotech Inc. for nucleic acid extraction.

Sputum:

After rinsing the patient’s mouth with clean water, collect deep cough sputum into a sample collection cup that containing the sampling solution. The sampling solution is Physiological saline, PBS buffer and Sample Storage Reagent (Reference Number: X1002E/X1003E/X1004E/X1010E/X1011E Series) from Sansure Biotech Inc.

3. Storage and delivery of specimens:

The test specimens can be processed immediately and the specimens to be tested within 24 hours can be stored at 4 °C. Specimens that cannot be detected within 24 hours should be stored at -70 °C or below for long-term storage (in the absence of -70 °C storage conditions, the test specimens can be stored at -20 °C for 9 months, and nucleic acid can be stored at -25°C to -15°C for 9 months). Multiple freeze/thaw cycles should not exceed five times. Specimens should be transported in a sealed frozen pitcher with ice or in a sealed foam box with ice.

Test procedure

1. Please refer to the following procedures when using Angilent AriaDx, SLAN-96P, ABI7500, Life Technologies QuantStudio ™ 5, Roche 480, MA-6000, CFX96 and QuantGene 9600 PCR instrument:

1.1 Preparation of reagent (performed at “reagent preparation room”)

1.1.1 Take out all the components out off the kit and equilibrate them at room temperature, then vortex each of them respectively for later use.

1.1.2 According to the quantity of test specimens, SARS-CoV-2/Inf A/B-Positive Control and SARS-CoV-2/Inf A/B-Negative Control, pipette appropriate quantity of SARS-CoV-2/Inf A/B-PCR Mix and SARS-CoV-2/Inf A/B-Enzyme Mix (SARS-CoV-2/Inf A/B-PCR Mix 26 μL/test + SARS-CoV-2/Inf A/B-Enzyme Mix 4 μL/test), mix them thoroughly to make a PCR-Mastermix, centrifuge it instantaneously for later use.

Components	1 specimen	10 specimens	24 specimens	48 specimens
SARS-CoV-2/Inf A/B-PCR Mix (μL)	26	260	624	1248
SARS-CoV-2/Inf A/B-Enzyme Mix (μL)	4	40	96	192

Note: The above configuration is just for your reference and to ensure enough volume of the PCR-Mastermix, more volume of the actual pipetting may be required.

1.1.3 Transfer the above-prepared reagents to the “specimen processing room” for later use.

1.2. Processing and loading of specimens (performed at “specimen processing room”)

1.2.1 Processing of specimens

It is recommended to use the Sample Release Reagent (Reference number: S1014E Series) and Nucleic Acid Extraction-Purification Kit (Reference number: S10016E Series) manufactured by Sansure Biotech Inc. to extract the nucleic acid as per the product manual.

1.2.2 Add 30 μL PCR-Mastermix into the PCR reaction tube with 20 μL above processed specimens. Carry out fluorescence quantitative PCR detection on fluorescence PCR instrument.

1.3. PCR Amplification (performed at “amplification and analysis room”) (Refer to user manual of each instrument to adjust the settings.)

1.3.1 Place PCR reaction tubes into the specimen wells of the amplification equipment. Set up the SARS-CoV-2/Inf A/B-Positive Control, SARS-CoV-2/Inf A/B-Negative Control and the test specimens in the corresponding sequence and input specimen names.

1.3.2 Select PCR test channel:

a) Select FAM channel to test SARS-CoV-2 nucleic acids, HEX channel to test Influenza A nucleic acids, and ROX channel to test Influenza B nucleic acids.

b) Select CY5 channel to test internal control.

1.3.3 Set cycle parameters

No.	Steps	Temperature	Time	Cycle No.
1	Reverse transcription	50 °C	5 min	1
2	Predenaturation	95 °C	1 min	1
3	Denaturation	95 °C	10 sec	41
	Annealing, extension and fluorescence detection	60 °C	20 sec*	

(*Note: It cannot be set to 20 seconds due to ABI 7500 instruments, but can be set to 31 seconds.)

When the settings are completed, save the settings and carry out the reaction procedure.

2. Please process according to the following steps for Portable Molecule Workstation (Model: S-Q31A&B):

2.1 Preparation of consumables and reagents

2.1.1 Take out the reaction tube carrier, PCR reaction tube and Tip;

2.1.2 Put the Tip into **Well H**,and PCR reaction tube into **Well** PCR(The well location information has been marked on the reaction tube carrier);

2.1.3 Put Sample Release Reagent (Reference Number : S1014E Series) into the **Well B**; Put SARS-CoV-2/Inf A/B-PCR Mix into the **Well C**; Put SARS-CoV-2/Inf A/B-Enzyme Mix into the **Well D**;

2.1.4 Add 20μL sample to be tested or SARS-CoV-2/Inf A/B-Positive Control or SARS-CoV-2/Inf A/B-Negative Control into the **Well B** (To avoid bubbles during operation, it is recommended to pipet deeply and release slowly).

2.2 Test Procedure (Refer to user manual of each instrument to adjust the settings.)

2.2.1 Gently press the front door to open it.

2.2.2 Place the **Well A** of reagent strip into the instrument towards the outside of the instrument,and close the front door of the instrument.

2.2.3 Click the**"Lab task"** on the instrument display screen to enter the interface of setting new experimental task.

2.2.4 Select the required experimental project in the drop-down menu of **Lab project**, enter the corresponding task name in the **Task Name** bar, and input and select other items that should be input or selected.

2.2.5 Click **"Submit"** to submit the experimental task and **"OK"** to run the instrument and start the experimental task successively.

2.2.6 When the Portable Molecule Workstation (Model: S-Q31B) shows **"Please transfer the PCR tube to the 1/2/3/4"**(The S-Q31A shows "Please transfer the PCR tube”) on the interface, take out the PCR tube and cover it well, then centrifuge it instantaneously.

2.2.7 Insert the PCR tube into the PCR amplification module (the "PCR 1/2/3/4" cover has been automatically opened at this time), close the PCR lid of the amplification module, then click **"OK"** for amplification detection.

3. Please process according to the following steps for Portable Molecular Workstation (Model: S-Q36A):

3.1 Preparation of consumables and reagents

3.1.1 Take out the Consumables kits and reagents.

3.1.2 Put Sample Release Reagent (Reference Number : S1014E Series) into the **Well B**; Put SARS-CoV-2/Inf A/B-PCR Mix into the **Well C**; Put SARS-CoV-2/Inf A/B-Enzyme Mix into the **Well D**,(The well location information has been marked on the carrier set)

3.1.3 Add 20μL sample to be tested or SARS-CoV-2/Inf A/B-Positive Control or SARS-CoV-2/Inf A/B-Negative Control into the **Well B** (To avoid bubbles during operation, it is recommended to

pipet deeply and release slowly).

3.2 Test Procedure (Refer to user manual of each instrument to adjust the settings.)

3.2.1 Click the ""and "" button on the instrument display screen to open the door of the instrument and put the prepared consumables into the designated position of the instrument.

3.2.2 Click the "New" on the instrument display screen to enter the new experiment task setting interface.

3.2.3 Select the required experimental project in the drop-down menu of lab project, enter the corresponding task name in the Task Name bar, and input and select other items that should be input or selected.

3.2.4 Click "Submit" to submit the labl task and "OK" to run the instrument.

4. Please process according to the following steps for Portable Molecular Diagnostic System (S-Q37A/S-Q37B):

4.1 Pre-run preparation

4.1.1 Load the amplification reagent component assembly into the extraction reagent component (Nucleic Acid Extraction-Purification Kit, Reference Number: S50016E-12A) to compose the test reagent cartridge;

4.1.2 Open the seal plug of the sample loading hole, add 350 μL sample or SARS-CoV-2/Inf A/B-Positive Control or SARS-CoV-2/Inf A/B-Negative Control into the sample loading hole (To ensure Diagnostic System have 300 μL samples for nucleic acid extraction); or use transfer pipet from the extraction reagent kit to pipette sample into the sample loading hole (When sample enter the lower bubble of transfer pipet indicating enough sample has been taken). Then close the seal plug.

4.2 Test Procedure

4.2.1 Click the "Specimen" button on the instrument display screen to open the door of the instrument and enter the new experiment task setting interface.

4.2.2 Put the prepared consumables into the designated position of the instrument.

4.2.3 Enter specimen information, select the required experimental project in the drop-down menu of Experimental project, enter the corresponding task name in the Task Name bar, and input and select other items that should be input or selected.

4.2.4 Click "Submit" to submit the experimental task and "OK" to run the instrument.

Reading test results

1. Result Analysis (Refer to user manual of instrument to adjust the settings.)

Results will be saved automatically when reactions are completed. Analyze amplification curves of the target and the internal control. Adjust Start, End and Threshold values of Baseline of the graph according to the analysis result (Users can adjust the values according to the actual situation. Start value can be set between 3-15, and End value can be set between 5-20. Adjust the amplification curve of negative control to be flat or below threshold). Click “Analysis” to implement the analysis, and make sure that each parameter satisfies the requirements given in "5. Quality Control". Go to "Plate" window to record qualitative results.

2. Quality Control

	SARS-CoV-2/Inf A/B-Negative Control	SARS-CoV-2/Inf A/B-Positive Control
Ct value	No Ct or Ct > 40 at channels FAM, HEX, ROX and CY5 (internal control)	Ct ≤ 35 at channels FAM, HEX, ROX and CY5 (internal control)

The test result is treated as valid if all the above-mentioned conditions are met for the same test. Otherwise the test result is treated as invalid and it needs to be re-tested.

Reference Range

Through the research on reference values, the Ct reference Value of target gene and the internal control are both determined to be 40.

Interpretation of test results

Conclusion	Amplification results
SARS-CoV-2 Positive	There is typical S-shape amplification curve detected at FAM channel, and Ct ≤ 40.
Influenza A Positive	There is typical S-shape amplification curve detected at HEX channel, and Ct ≤ 40.
Influenza B Positive	There is typical S-shape amplification curve detected at ROX channel, and Ct ≤ 40.
SARS-CoV-2, Influenza A and Influenza B Negative	There is no typical S-shape amplification curve (No Ct) or Ct > 40 is detected at channels FAM, HEX and ROX, but the amplification curve is detected at CY5 channel and Ct ≤ 40.

If there is no typical S-shape amplification curve detected at FAM, HEX, ROX and CY5 channel (No Ct), or Ct > 40, it indicates that the specimen’s concentration is too low or there are interfering substances that inhibit the reaction. Then the test result is treated as invalid. An investigation should be performed to find out and exclude the reasons, please collect specimen again and retest the specimens. (If repeated tests results are still invalid, please contact info@sansure.com.cn)

Note: For virus cultures, there is no requirements for internal control test results.

Limitations of the procedure

1. Test results of the kit can be used only for clinical reference. The symptoms and physical signs, disease history, other laboratory examinations and therapeutic reactions of the patients should be comprehensively considered during their clinical diagnosis and treatment.
2. The possibility analysis of false negative results:

2.1 The inappropriate specimen collection, delivery, processing and specimen in low concentrations may lead to false negative results.

2.2 The mutation in the target sequence of virus to be measured or the changes in the sequence due to other causes may lead to false negative results.

2.3 The inappropriate reagent storage may lead to false negative results.

2.4 Unverified interferences or PCR inhibitors may lead to false negative results.

2.5 Cross-contamination occurring in the specimen processing may lead to false positive results.

2.6 The clinical laboratory should be equipped with instruments and operators in strict accordance with relevant requirements outlined in local, state and national regulations. Operate in strict accordance with the product manual.

Performance characteristics

1. Accuracy

Test enterprise positive references and the results are all positive.

2. Specificity

For SARS-CoV-2 and Influenza A/B Virus Multiplex Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing), there are also no cross-reaction with positive samples of coronavirus (NL63, HKU1, 229E,OC43), SARS coronavirus, MERS coronavirus, respiratory syncytial virus type A and Type B, nasal virus Type A, Type B and Type C, adenovirus Type 1, 2, 3, 4, 5, 7 and 55, parainfluenza virus Type 1, 2 and 3, intestinal virus Type A, B, C (EV-C95) and D(EV-D70), partial pulmonary virus, Human metapneumoviru, cryptococcus neoformans, pyogenic streptococcus, acinetobacter baumannii, pneumocystis yersinensis, klebsiella pneumoniae, streptococcus pneumoniae, haemophilus influenzae, pseudomonas aeruginosa, legionella pneumophilia, bordetella pertussis, staphylococcus aureus, mycoplasma pneumoniae, chlamydia pneumonia, EB virus, human cytomegalo virus, aspergillus fumigatus, candida albicans, candida glabrata, mycobacterium tuberculosis, non-tuberculous mycobacterium, norovirus, rotavirus, varicella zoster virus, measles virus, mumps virus, human genome DNA and etc. Test the enterprise negative references, and the results are all negative.

3. Limit of detection: The limit of detection of this kit is 200 copies/mL.

4. Precision: The coefficient of variation (CV%) of Ct value of the inter/inner batch, inter/inner day precision is ≤ 5%.

5. Possible interfering substances in specimens: 100 ug/mL hydroxymezoline hydrochloride, 50 ug/mL dexamethasone, 50 ug/mL cefmenoxime hydrochloride, 100 ug/mL oseltamivir, 100 ug/mL zanamivir, 100 ug/mL ribavirin, 100 ug/mL azithromycin, 300U/mL α-interferon, 320 ug/mL budesonide, 125 ug/mL beniferin, 100 ug/mL tobramycin, 50 ug/mL beclometrasone, 100 ug/mL flunicasone, 100 ug/mL momethasone, 200 ug/mL fluticasone, 200 ug/mL histamine dihydrochloride, 100 ug/mL peramivir, 100 ug/mL lopenavir, 100 ug/mL mupiroxacin, 100 ug/mL triamcinolone, 100 ug/mL litonavir, 100 ug/mL abidor, 60 ug/mL sodium chloride, 100 ug/mL urea, 10 ug/mL heme, 20 ug/mL purified mucin, 2%(v/v) anhydrous ethanol, and 5%(v/v) human whole blood have no significant interference with the detection results of the kit.

List of references

1. A selective sweep in the Spike gene has driven SARS-CoV-2 human adaptation. Cell, 2021.
2. The Architecture of 2019-nCoV Transcriptome. Cell, 2020.
3. Influenza virus genotype to phenotype predictions through machine learning: a systematic review. Emerging microbes & infections, 1896–1907.

Symbol key

Symbols	Meanings	Symbols	Meanings
IVD	*In Vitro* Diagnostic Medical Device	LOT	Batch Code
	Use-by date	REF	Reference Number
	Manufacturer		Date of Manufacture
	Contains sufficient for <n> tests		Temperature Limit
	Caution		Consult Instructions for Use
21 PAP	PAP21: Not corrugated cardboard		Do not re-use
PCR MIX	PCR Mix	ENZYME MIX	Enzyme Mix
CONTROL -	Negative Control	CONTROL +	Positive Control
REFERENCE + A	Positive Reference A	REFERENCE + C	Positive Reference C
REFERENCE + B	Positive Reference B	REFERENCE + D	Positive Reference D
LYSIS BUFFER	Lysis Buffer	INTER CONTROL	Internal Control
CONCENTRATE	Concentrate	VERSION	Version
PRE	Prepackaging		Keep away from light
EC REP	Authorized representative in the European Community	CE	This product fulfills the requirements of the European Directive 98/79/EC for *in vitro* diagnostic medical devices.
UDI	Unique device identifier		

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