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fluorecare®

PRODUCT NAME

SARS-CoV-2/RhV/PIV / Influenza A/B / RSV/ADV/hMPV/M.P Antigen Combo Test Kit (Colloidal Gold Chromatographic Immunoassay)

REF MF-139

Intended Use

The fluorecare® SARS-CoV-2 / RhV/ PIV / Influenza A/B / RSV/ADV/hMPV/M.P Antigen Combo Test Kit is applicable to the simultaneous qualitative detection and differentiation in vitro of novel Coronavirus (SARS-CoV-2) antigen, Influenza A virus antigen, Influenza B virus antigen, RSV antigen, Adenovirus(ADV) antigen, Human Metapneumovirus(hPMV) antigen , RhV antigen , PIV antigen , Mycoplasma Pneumoniae (M.P) in Oropharyngeal swab, Nasal swab or Nasopharyngeal swab samples.

It can be used as an aid in the diagnosis of disease caused by SARS-CoV-2 in symptomatic patients within 7 days of onset and in the diagnosis of diseases caused by RhV, PIV, Influenza A/B, RSV,ADV,hMPV,M.P.

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

BACKGROUND

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, and most often 3 to 7 days. The main manifestations include fever, fatigue, and dry cough. Nasal congestion, runny nose, sore throat, aches and pains, and diarrhea are found in a few cases.

Rhinovirus(Rhv) usually resides in the upper respiratory tract and mainly causes upper respiratory tract infections such as the common cold in adults. In infants, young children, and patients with chronic respiratory diseases, in addition to upper respiratory tract infections, it can also cause bronchitis and bronchopneumonia.

Human parainfluenza viruses (PIV) are a type of virus that often causes lower respiratory tract infections in children, the human parainfluenza virus can cause recurrent upper respiratory tract infections (such as colds and sore throat). It can also cause severe recurrent lower respiratory tract diseases (such as pneumonia, bronchitis, and bronchiolitis), especially in the elderly and immunocompromised population.

Influenza (flu) is a contagious respiratory illness caused by influenza viruses. Influenza viruses can cause mild to severe illness. Severe influenza may result in hospitalization or death. Some specific populations, such as the elderly, young children, and people with certain underlying health conditions, are at higher risk of developing serious flu complications. There are two main types of influenza viruses: type A and B. Both type A and B influenza viruses regularly spread in people, and are responsible for seasonal flu each year. Influenza viruses can be spread to others before and after a person shows signs and symptoms of being sick.

Respiratory syncytial virus (RSV) belongs to the genus Pneumovirus of the family Paramyxoviridae. It can be spread by coughing and air droplets, mainly causing lower respiratory tract infections, such as bronchiolitis and pneumonia, in infants under 6 months of age, and upper respiratory tract infections, such as rhinitis and the common cold, in older children and adults, and bronchitis or pneumonia in the elderly.

Adenovirus (ADV) is a non-enveloped icosahedral double-stranded DNA virus with a nucleocapsid. There are about 57 serotypes of adenovirus that can infect humans, and they can infect the respiratory tract, gastrointestinal tract, urinary tract and bladder, eye, liver, etc. About 1/3 of the known serotypes of human adenovirus are commonly associated with human diseases.

hMPV belongs to the family pneumonaviridae and the genus Metapneumovirus. It is a single-stranded negative strand RNA virus with an average diameter of about 200nm. hMPV infection is mostly a mild self-limited disease. Some patients require hospitalization due to complications such as bronchiolitis, pneumonia, acute exacerbation of chronic obstructive pulmonary disease (COPD), and acute exacerbation of bronchial asthma. It can even lead to death.

Mycoplasma Pneumoniae (M.P) is the pathogen of human mycoplasma pneumonia. The main pathological changes of mycoplasma pneumonia are interstitial pneumonia and bronchopneumonia, which is called primary atypical pneumonia. It is mainly transmitted by droplets, the incubation period is 2 ~ 3 weeks. The clinical symptoms are mild,there are headache, sore throat, fever, cough and other general respiratory symptoms.

PRINCIPLE

The SARS-CoV-2/RhV/PIV / Influenza A/B / RSV/ADV/hMPV/M.P Antigen Combo Test Kit is a qualitative test to detect SARS-CoV-2 /RhV/PIV Antigen / Influenza A/B Antigen / RSV/ ADV/ hMPV/M.P Antigen in samples by the colloidal gold chromatographic immunoassay method. After the treated sample solution is applied to the test card, the SARS-CoV-2 Antigen (or RhV/PIV/Influenza A/B / RSV/ADV/hMPV/M.P) in the collected sample will be combined with the SARS-CoV-2 (or RhV/PIV/Influenza A/B / RSV/ADV/ hMPV/M.P) antibody labeled with colloidal gold on the conjugate pad to form a SARS-CoV-2 Antigen (or RhV/PIV/Influenza A/B / RSV/ADV/hMPV/M.P)-antibody-colloidal gold complex. Due to chromatography, the SARS-CoV-2 Antigen (or RhV/PIV/Influenza A/B / RSV/ADV/hMPV/M.P)-antibody-colloidal gold complex diffuses along the nitrocellulose membrane. Within the detection line (T) region, the SARS-CoV-2 Antigen (or RhV/PIV/Influenza A/B / RSV/ADV/hMPV/M.P) complex will be captured by the antibody enclosed within the detection line region, showing a purple band. When colloidal gold-labeled SARS-CoV-2 (or RhV/PIV/Influenza A/B / RSV/ADV/hMPV/M.P) complex diffuses to the quality control line (C) region, it will be captured by goat anti-mouse IgG to form a purple band. When the reaction is over, the results can be interpreted by visual observation.

Specifications

1 Test/box, 25 Tests/box

Components	REF MF-139-01	REF MF-139-25
	1 Test/box	25 Tests/box
Test Card (including the desiccant)	1 cassette	25cassettes
	Contains： Plastic shell and strips. The test strip contains: A Nitrocellulose membrane coated with SARS-CoV-2/ RhV/PIV/Influenza A/B / RSV/ADV/hMPV/M.P antibody, and the conjugate pad containing colloidal gold-labeled SARS-CoV-2/ RhV/PIV/Influenza A/B / RSV/ADV/hMPV/M.P antibody. Other components include PVC pad and absorbent paper.	
Instructions for Use	1 copy	1 copy
Sterile swab	1 piece	25 pieces
STS(Sample treatment solution)	1 tube	25 tubes
	Normal saline solution 0.5 mL per tube.	

MATERIALS REQUIRED BUT NOT PROVIDED

Timer.

STORAGE CONDITIONS AND EXPIRATION DATE

1.Store test kit at 2-30℃ in a dry place, protected from light. Test kit is valid for 24 months.

2.The Test Card must remain in the sealed pouch until use. Once the test card pouch is opened, the test should be performed within 1 hour.

TEST PROCEDURE

Use a disinfectant to disinfect your hands after hand washing.

Clean the surface on which the test will be performed.

Before testing, read the instructions for use carefully, and bring the testing kit and samples to room temperature (20-25℃). The test should be performed at 20~25℃. If the kit is removed from the refrigerator, allow it to stand at room temperature (20-25℃) for 5 minutes before testing.

1. Twist off the cap of the Sample treatment tube and remove the inner blue stopper. The blue stopper should be removed before use.Insert the treatment tube into the hole of the kit or use other items to hold the treatment tube upright.

2. Tear open the foil bag, take out the test card, and use it as soon as possible within 1 hour.

3. Sample collection

3.1Nasal swab collection method:

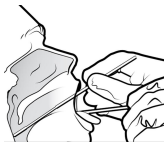
3.1.1 Carefully remove sterile nasal swab from the packaging. (Avoid touching the end with the cotton swab.)

Insert the nasal swab into the left nostril to a depth of 2.5 cm (1 inch) from the entrance of the nostril.

3.1.2Rotate the nasal swab on the nostril wall (mucous membrane) 5 times to ensure adequate sampling.

3.1.3Repeat the process in the right nostril with the same nasal swab, collecting from both nasal passages to ensure an adequate sample.

3.2 Oropharyngeal swab collection method:



3.2.1Tip the patient's head slightly.

3.2.2Instruct the patient to open mouth as wide as possible to reveal the pharyngeal tonsils on either side.

3.2.3Wipe the base of patient' s tongue with swab.

3.2.4Slightly rub the pharyngeal tonsils back and forth on both sides at least 3 times.

3.2.5Rub the posterior pharyngeal wall up and down at least 3 times.

3.2.6Test the sample as soon as possible.

3.3Nasopharyngeal swab collection method:

3.3.1Tip the patient' s head back and collect sample from the nostril that has more mucus (head should be inclined from vertical for proper specimen collection).

3.3.2Insert the swab through the nostril entry and then slowly move along the bottom of the nasal cavity (Move gently to avoid traumatic bleeding).

3.3.3When the tip of the swab reaches the posterior wall of the nasopharyngeal cavity, gently rotate it several times. (Collect as much secretion as possible)

3.3.4To prevent reflex coughing, stop for one minute.

3.3.5Slowly remove the swab.

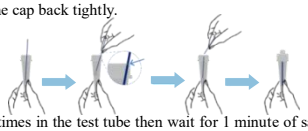
3.3.6Test the sample as soon as possible.

3.4 Prepare a sample treatment tube and open the treatment tube dropper.

Take 500μL sample (VTM) to the tube.

Load the dropper lid, shake the tube upside down, then wait for 1 minutes of reaction.

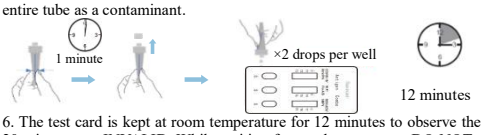
4. Place the swab sample into the tube, then break the swab at the break line and leave the lower half in the treatment tube. Secure the cap back tightly.



5. Squeeze the swab 10 times in the test tube then wait for 1 minute of sample reaction time. Unscrew the tip cover at the top of the cap. If the tip cover on the top of the cap is not unscrewed, and the blue stopper inside the cap is not removed, you will not be able to drip liquid from the tube.

Each sample well of the test card requires 2 drops (about 60 μL) of the treated sample solution. The oval wells marked with "S" at the bottom of the test card are the sample wells. You can squeeze sample solution into 3 sample wells at the same time to detect 8 different types of antigens or squeeze into only one sample well to detect one type of antigen. Only 2 drops of the treated sample solution can be squeezed into each sample well. Adding too much or too little of the treated sample solution may result in invalid test results.

After dripping the sample, place the blue stopper, cap and tip cover back onto the tube and dispose of the entire tube as a contaminant.



6. The test card is kept at room temperature for 12 minutes to observe the test results. Results observed after 20 minutes are INVALID. While waiting for results to appear, DO NOT touch the test card or move the test card from its location.

＞20min

INTERPRETATION OF RESULTS

1. COVID-19/RhV/PIV Positive: The presence of detection line T1 and quality control line (C) indicated positive COVID-19, the presence of detection line T2 and quality control line (C) indicated positive RhV, and the presence of detection line T3 and quality control line (C) indicated positive PIV.

2. M.P/Influenza A/B Positive: The presence of line T4 and quality control line (C) indicate positive for M.P.The presence of line T5 and quality control line (C) indicate positive for influenza A. The presence of line T6 and control line (C) indicate positive for influenza B.

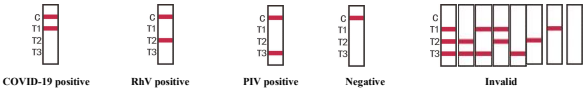
3.RSV/ADV/hMPV Positive:The presence of detection line T7 and quality control line (C) indicated positive RSV, the presence of detection line T8 and quality control line (C) indicated positive ADV, and the presence of detection line T9 and quality control line (C) indicated positive hMPV.

4.Negative: Only the quality control line (C) can be observed.

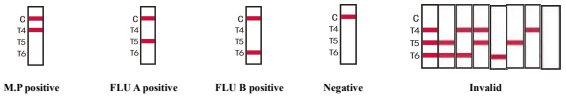
5. Invalid: If NO Control line (C) is present, the test did not work and is considered Invalid. This may be the result of an incorrect test procedure and the test should be repeated. If the retest result is still invalid, please contact us:

bio@microprofit.com.

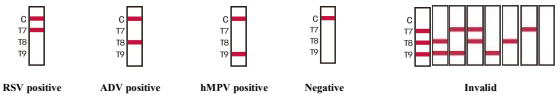
COVID-19 /RhV/PIV Antigen Results:



M.P /Influenza A/B Results:



RSV/ADV/hMPV Results:



Note: If there is a C line and more than one detection line, please refer to the position of the detection line to obtain the corresponding result. If there is no C line, the result is invalid.

LIMITATION OF METHODOLOGY

1. This kit is a qualitative test and is only used for in vitro auxiliary diagnosis,a definitive diagnosis of viral infection can be made by a physician only after all clinical and laboratory test results have been evaluated.
2. Negative test results may occur if the level of antigen in the sample is below the limit of detection of the test or due to improper sample collection. A negative result does not mean that other infections are excluded, except COVID-19,Rhinovirus,Parainfluenza virus,influenzaA/B virus, RSV virus,Adenovirus,Human Metapneumovirus,Mycoplasma Pneumoniae.
3. Improper sampling, transportation, handling, and low virus content in the sample may lead to false negative results.
4. Reading the test results earlier than 12 minutes or later than 20 minutes may give incorrect results.
5. A negative test result for an antigen does not rule out the possibility of infection or serve as a basis for exemption from applicable transmission control rules (e.g., contact restrictions and protective measures).

INDEX OF CHARACTERISTICS

1. Positive reference coincidence rate: the positive reference coincidence rate of the enterprise is 100%.
2. Negative reference product conformity rate: the negative reference product conformity rate of the enterprise is 100%
3. Limit of detection (LoD)：
①The LoD of SARS-CoV-2 is 49 $TCID_{50}$/mL.
②The LoD of Rhinovirus:4ng/mL.
③The LoD of Parainfluenza1/2/3 virus:100ng/mL.
④The LoD of the Influenza A is: 2009H1N1 $1.96\times10^4TCID_{50}$/mL,Seasonal H1N1 $2\times10^4TCID_{50}$/mL,Type A H3N2 $5\times10^3TCID_{50}$/mL.
⑤The LoD the Influenza B is:B/Victoria $2.625\times10^3TCID_{50}$/mL,B/Yamagata $4\times10^4TCID_{50}$/mL.
⑥RSV type A is 1.15×10^4 TCID50/mL, RSV type B is 1.6×10^4 TCID50/mL.
⑦The LoD of Adenovirus:Adenovirus Type 3 is 200pg/mL,Adenovirus Type 7 is 200pg/mL,Adenovirus Type 40 is 100pg/mL,Adenovirus Type 41 is 150pg/mL,Adenovirus Type 55 is100pg/mL.
⑧The LoD of Human Metapneumovirus:0.9μg/mL.
⑨The LoD of Mycoplasma Pneumoniae:8.12×10^3 CFU/mL
4. Cross-reactivity:
The following viruses/bacteria have no cross reactivity with this kit:：
Human Coronavirus (OC43) ; Human Coronavirus(229E); Human Coronavirus MERS (Florida/USA-2_Saudi Arabia_2014) ; Human Coronavirus (NL63); Human Coronavirus (HKU1) (N-protein) , Adenovirus Type 01; Adenovirus Type 02 ; Adenovirus Type 11; Enterovirus Type 68 (2014 Isolate) l; Human Metapneumovirus (Excluding hMPV) ; Parainfluenza Virus (Type 1)(Excluding PIV); Parainfluenza Virus (Type 2)(Excluding PIV) , Parainfluenza Virus (Type 3)(Excluding PIV), Parainfluenza Virus (Type 4B) , Respiratory Syncytial Virus Type A (Isolate: 2006) l(Excluding RSV); Rhinovirus (Type 1A)(Excluding Rhv), Influenza Type A, H3N2 (HK/8/68)(Excluding Influenza A); Influenza Type A, H1N1(Excluding Influenza A); Influenza Type A, H1N1pdm (Canada/6294/09) (Excluding Influenza A); Influenza Type B (Texas/6/11) (Excluding Influenza B); Influenza Type B (Alabama/2/17) (Excluding Influenza B); Staphylococus aureus (Protein A) DSM 21705 (E. Domann) , Staphylococus aureus (Protein A) DSM 21979 (E. Domann, Univ.), Staphylococus aureus (Protein A) DSM 46320 (E. Domann) , Staphylococcus epidermidis DSM 1798 (PCI 1200) ,Staphylococcus epidermidis DSM 20044 (Fussel) , Bordetella pertussis DSM 4923 (Walker), Bordetella pertussis DSM 4926 (Sato and Arai) ,Bordetella pertussis DSM 5571,Legionalle pneumophila DSM 7513 (Philadelphia-1) ,Legionalle pneumophila DSM 7514 (Los Angeles-1) , Streptococcus pyogenes DSM 20565 (SF130, T1),Streptococcus pyogenes DSM 2071 (S. Koshimura, Sv) ,Haemophilus influenzae DSM 24049 (TD-4),Haemophilus influenzae DSM 4690 (Maryland),Haemophilus influenzae DSM 23393 (Pittman 576) ,Mycobacterium tuberculosis DSM 43990 (BCGT, tice) ,Streptococcus pneumoniae (Protein G) DSM 20566 (SV1) , Streptococcus pneumoniae (Protein G) DSM 11967 (Jorgensen262) , Streptococcus pneumoniae (Protein G) DSM 25971 (Gyeonggi) ,Mycoplasma pneumoniae DSM 23978 (Eaton Agent, FH) , Mycoplasma pneumoniae DSM 23979 (M129-B7) ,Candida albicans DSM 1386 (NIH 3147) , Candida albicans DSM 1665 (132),Candida albicans DSM 5817 (806M) , Pseudomonas aeruginosa DSM 1117 (Boston 41501) , Pseudomonas aeruginosa DSM 3227 (Schutze),Streptococcus salivarius DSM 20560 (275) ,Streptococcus salivarius DSM 20067 (21367) ,SARS-CoV-2 (Excluding SARS-CoV-2); New coronavirus variant strain B.1.1.7 (Alpha) (Excluding SARS-CoV-2); New coronavirus variant strain B.1.351 (Beta) (Excluding SARS-CoV-2); New coronavirus variant strain P.1 (Gamma)(Excluding SARS-CoV-2); New coronavirus variant strain B.1.617.2 (Delta)(Excluding SARS-CoV-2); New coronavirus variant strain B.1.1.529 (Omicron)(Excluding SARS-CoV-2).
5. Endogenous Interfering Substances
Substances listed below are confirmed not to have interference response with fluorecare® SARS-CoV-2 / RhV/ PIV / Influenza A/B / RSV/ADV/hMPV/M.P Antigen Combo Test Kit:
Benzocaine, Blood (human), Mucin,Naso GEL (NeilMed) , CVS Nasal Drops (phenylephrine) ,Afrin (Oxymetazoline), CVS Nasal Spray (Cromolyn) , Zicam Cold Remedy , Homeopathic (Alkalol) , Sore Throat Phenol Spray , Tobramycin,Mupirocin , Fluticasone, Tamiflu (Oseltamivir phosphate) , Budenoside , Biotin , Methanol,Acetylsalicylic Acid ,Diphenhydramine, Dextromethorphan, Dexamethasone, Mucinex.
6. High-dose Hook Effect
When the Virus strains in the sample do not exceed the concentration in the following table, the high concentration of Virus strains in the sample has no effect on the detection results of the fluorecare® SARS-CoV-2/RhV/PIV / Influenza A/B / RSV/ADV/hMPV/M.P Antigen Combo Test Kit.

Virus strains	Limit value
SARS-CoV-2	1.8×10^5 $TCID_{50}$/mL
Rhv	4.8mg/mL
PIV 1/2/3	4.6mg/mL / 3.3mg/mL / 4.1mg/mL
2009H1N1	$9.8\times10^6TCID_{50}$/mL
Seasonal H1N1	1.3×10^7 $TCID_{50}$/mL
Type A H3N2	$2.1\times10^8TCID_{50}$/mL
B/Victoria	$1\times10^6TCID_{50}$/mL
B/Yamagata	1×10^6 $TCID_{50}$/mL
RSV type A	4.6×10^8 $TCID_{50}$/mL
RSV type B	3.2×10^7 $TCID_{50}$/mL
Adenovirus 3/7/40/41/55	20μg/mL/2μg/mL/10μg/mL/15μg/mL/10μg/mL
Human Metapneumovirus	1.8mg/mL
Mycoplasma Pneumoniae	8.12×10^6 CFU/mL

7. Clinical Accuracy
Clinical performance characteristics of the fluorecare® SARS-CoV-2/RhV/PIV / Influenza A/B / RSV/ADV/hMPV/M.P Antigen Combo Test Kit was evaluated in the clinical studies. 668 subjects participated in the clinical study of COVID-19 antigen, 310 subjects participated in the clinical study of rhinovirus antigen, 316 subjects participated in the clinical study of parainfluenza virus antigen, 134 subjects participated in the clinical study of influenza A virus antigen, 134 subjects participated in the clinical study of influenza B virus antigen, 357 subjects participated in the clinical study of RSV, 309 subjects participated in the clinical study of adenovirus, 315 subjects participated Clinical study of human metapneumovirus antigens, and 122 subjects participated Clinical study of Mycoplasma Pneumoniae antigens.
The test results are as follows:
For COVID-19 antigen detection, the positive coincidence rate is 92.93%,the negative coincidence rate is 100.00%, the total coincidence rate is 96.11%.
For RhV antigen detection, the positive coincidence rate is 97.48%, the negative coincidence rate is 98.68%, the total coincidence rate is 98.06%.
For PIV antigen detection, the positive coincidence rate is 98.08%, the negative coincidence rate is 98.75%, the total coincidence rate is 98.42%.
For FLU A antigen detection, the positive coincidence rate is 95.71%, the negative coincidence rate is 96.88%, the total coincidence rate is 96.27%.
For FLU B antigen detection, the positive coincidence rate is 92.86%, the negative coincidence rate is 96.88%, the total coincidence rate is 94.78%.
For RSV antigen detection, the positive coincidence rate is 98.72%, the negative coincidence rate is 100.00%, the total coincidence rate is 99.44%.
For ADV antigen detection, the positive coincidence rate is 98.06%, the negative coincidence rate is 100.00%, the total coincidence rate is 99.03%.
For hMPV antigen detection, the positive coincidence rate is 98.04%, the negative coincidence rate is 100.00%, the total coincidence rate is 99.05%.
For M.P antigen detection, the positive coincidence rate is 97.01%, the negative coincidence rate is 96.36%, the total coincidence rate is 96.72%.
8. Repeatability: The repeatability reference products of the enterprise were tested, repeated for 10 times, and the positive coincidence rate is 100%.
9. The fluorecare® SARS-CoV-2/RhV/PIV / Influenza A/B / RSV/ADV/hMPV/M.P Antigen Combo Test Kit is used for SARS-CoV-2 nucleocapsid protein detection, the mutants of SARS-CoV-2 Alpha, Beta, Gamma, Delta, and Omicron can be identified by the fluorecare® SARS-CoV-2/RhV/PIV / Influenza A/B / RSV/ADV/hMPV/M.P Antigen Combo Test Kit.

WARNING AND PRECAUTION

1. Read the Instructions for use completely before using the product. Follow the instructions carefully. Failure to do so may result in an inaccurate result.
2. The kit is only used for in vitro diagnosis; it cannot be used repeatedly. Do not swallow.
3. Avoid getting the buffer solution into the eyes or on skin.
4. Keep out of reach children.
5. The test kit is for single use only, do not reuse any component of the test kit.
6. Do not use this test beyond the expiration date printed on the outer package. Always check expiration date prior to testing.
7. Do not touch the reaction area of the test cassette.
8. Do not use the kit if the pouch is punctured or not well sealed.
9. DIPOSAL: All specimens and the used kit pose an infectious risk. The process of disposing the diagnostic kit must follow the local, state, and federal infectious disposal laws/regulations.
10. During the time of interpretation, no matter the shade of the color band, it can be found to be positive as long as two lines appear: one in the quality control area and another in the detection area, respectively.
11. Please ensure that an appropriate amount of sample is used for testing, too much or too little of sample amount will cause an inaccurate result.
12. The result should be read in 12 minutes. Please do not read the result after 20 minutes.
13. Various components of different batches of reagents cannot be used interchangeably in order to avoid incorrect results.

INTERPRETATION OF SYMBOLS

	Do not re-use	30°C 2°C	Temperature limit
IVD	*In vitro* diagnostic medical device		Consult instructions for use
Σn	Contains sufficient for <n> tests	EC REP	Authorized representative in the European Community
	Keep away from sunlight		Caution
	Manufacturer	CE	CE Marking
REF	Catalogue number	LOT	Batch code
	Date of manufacture		Use-by date
	Do no use if package is damaged		

GENERAL INFORMATION

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