Basic introduction of IgG and IgM for COVID-19

International Marketing

EXCEED IN QUALITY AND MORE

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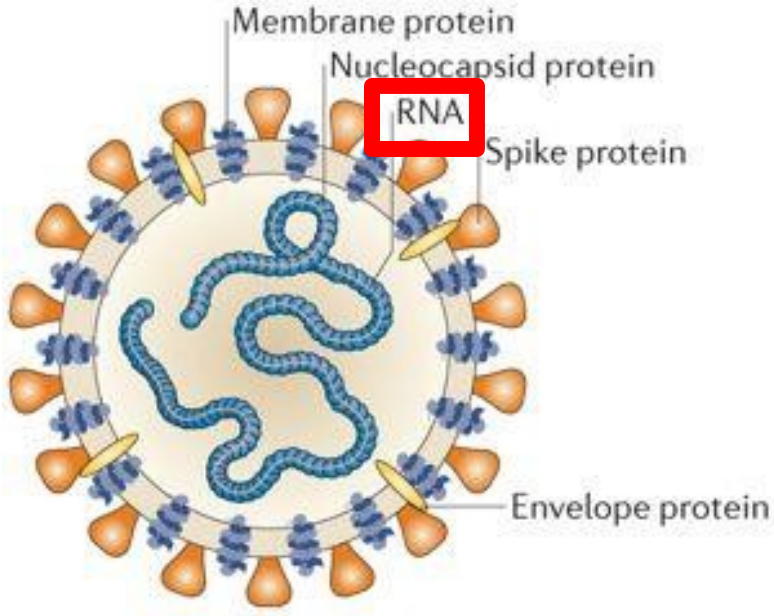
Compare with Nucleic Acid Test or PCR

1

Nucleic Acid Test or PCR

PCR (Polymerase chain reaction) tests measure the ribonucleic acid (RNA, nucleic acid) of the novel coronavirus.

- Nucleic acid (RNA) is inside the virus structure.
- PCR usually takes a long time to get results

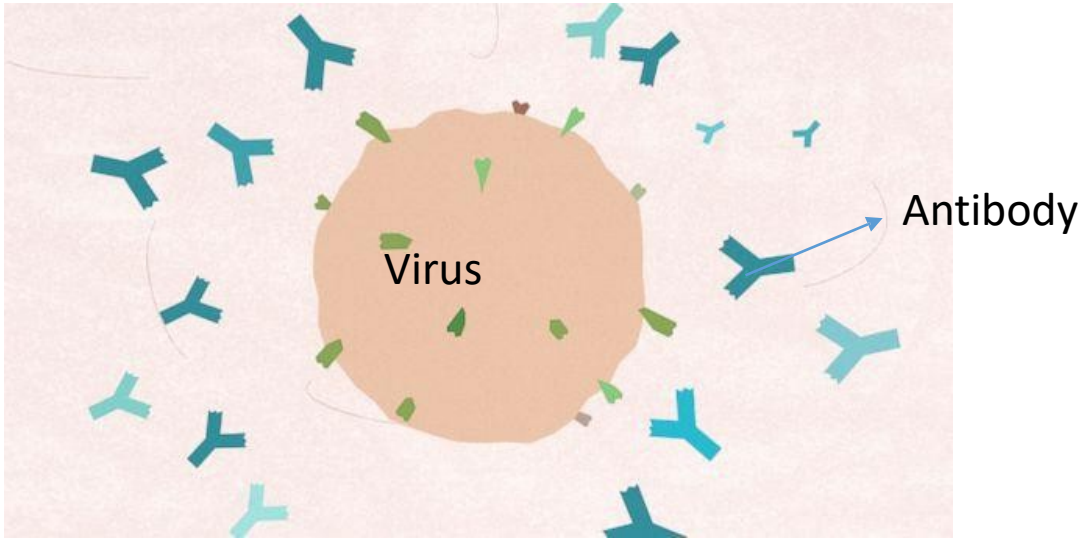


Nature Reviews | Microbiology

Antibody test

Antibody, also known as an immunoglobulin (Ig), has different types, such as IgG, IgM. Antibody is not inside virus.

- Antibody can interact with certain antigen (such as virus).
- When body is infected by antigen (such as virus), the body immune system will secret the specific antibody to defend.
- By measuring the level of specific antibody, we can know if the body is or was infected.
- Rapid test



Comparison

The differences between PCR tests and antibody tests become obvious:

- PCR measures the substance inside the virus, take long time
- Antibody level reflects the infection of the virus and measures the infection indirectly, rapid test

Because of the difference:

- PCR can be used to confirm the infection
- Antibody tests can be used to screen sceptical patients or monitoring the recovery of confirmed infection
- They are both irreplaceable to each other

IgG and IgM

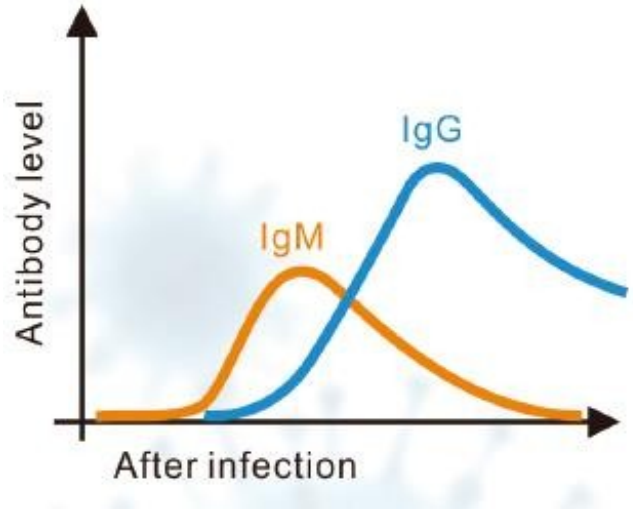
2

IgG and IgM

The measured IgG and IgM are specific to the novel coronavirus.

What's the difference between IgG and IgM

- After the virus infection, the antibody IgM appears and rises in the early stage, while antibody IgG appears and rises in the late stage.
- By combining IgG and IgM, we can know if the body is infected and which stage it is.



Colloidal Gold

3

- Colloidal gold is a kind of method to measure the antibody on a test card. Sometimes it’s also called lateral flow method or similar.
- This method doesn’t need any equipment to read results. Results can be read through eyes.
- Qualitative results

Test Kit and Operation

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Test Kit

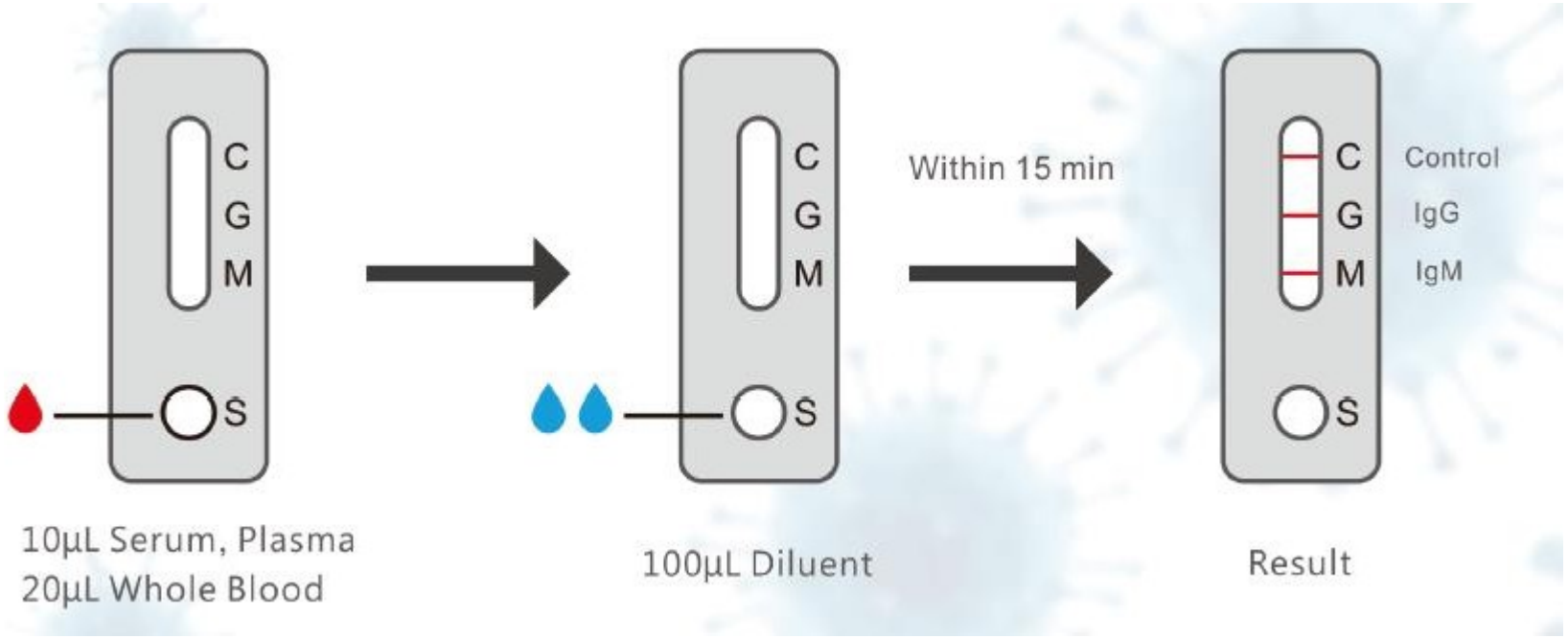
- 25 tests per kit
- Components
- Each card report both IgG and IgM results

Each test card is packed inside an individual pouch

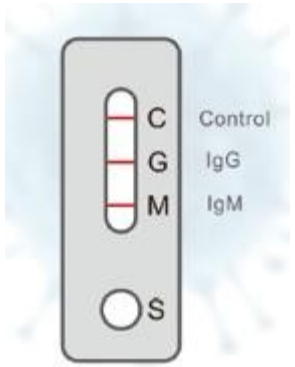
Operation

How to use:

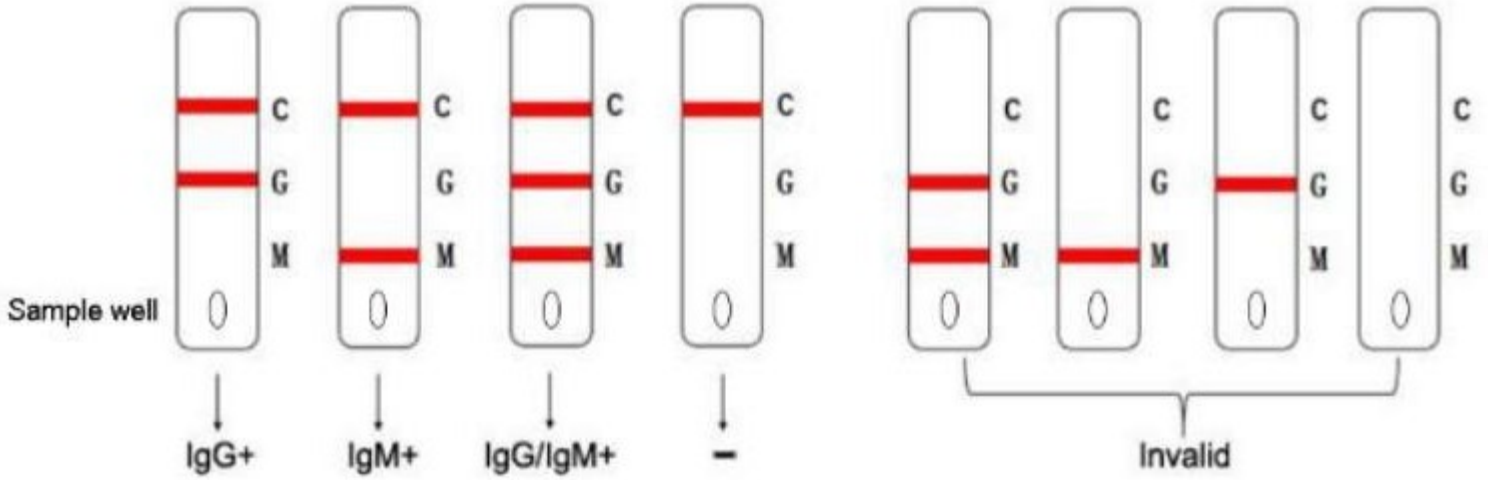
- Take one pouch from the kit, open the pouch, put the test card on the table.
- Add 20uL of whole blood (or 10uL of centrifuged serum/plasma) into the sample inlet by a pipette.
- Instantly add 4 drops of diluent into the sample inlet.
- Read the results within 15 minutes (no more than 15 minutes)



- Read results

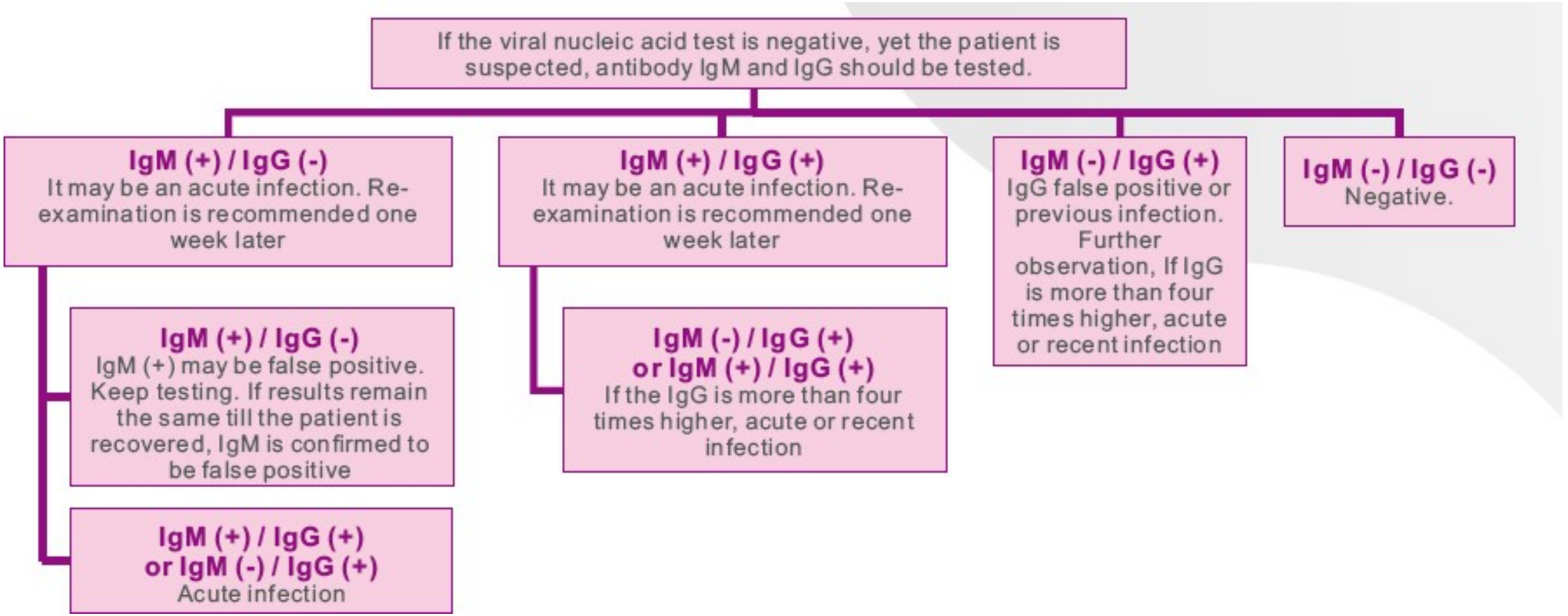


The result may be one of the following possibility



Interpretation of results

- Diagnosis of COVID-19 can be made based on the following chart



Performance

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Performance

- Clinical evaluation-Whole blood

IgG

		Comparison method		Sum
		Positive	Negative	
AIT	Positive	33	2	35
	Negative	1	70	71
Sum		34	72	106

Positive predictive value (Sensitivity)	33/35	94.29% (80.84%～99.30%)
Negative predictive value (Specificity)	70/71	98.59% (92.40%～99.96%)
Total coincidence rate	103/106	97.17% (91.95%～99.41%)

Performance

- Clinical evaluation-Whole blood

IgM

		Comparison method		Sum
		Positive	Negative	
AIT	Positive	34	1	35
	Negative	1	76	77
Sum		35	77	112

Positive predictive value (Sensitivity)	34/35	97.14% (85.08%～99.93%)
Negative predictive value (Specificity)	76/77	98.70% (92.98%～99.97%)
Total coincidence rate	110/112	98.21% (93.70%～99.78%)

Performance

- Clinical evaluation-Serum

IgG

		Comparison method		Sum
		Positive	Negative	
AIT	Positive	33	1	34
	Negative	1	71	72
Sum		34	72	106

Positive predictive value (Sensitivity)	33/34	97.06% (84.67%～99.93%)
Negative predictive value (Specificity)	71/72	98.61% (92.50%～99.97%)
Total coincidence rate	104/106	98.11% (93.35%～99.77%)

Performance

- Clinical evaluation-Serum

IgM

		Comparison method		Sum
		Positive	Negative	
AIT	Positive	33	2	35
	Negative	1	76	77
Sum		34	78	112

Positive predictive value (Sensitivity)	33/35	94.29% (80.84%～99.30%)
Negative predictive value (Specificity)	76/77	98.70% (92.98%～99.97%)
Total coincidence rate	109/112	97.32% (92.37%～99.44%)

Performance

- Clinical evaluation-Plasma

IgG

		Comparison method		Sum
		Positive	Negative	
AIT	Positive	33	2	35
	Negative	1	70	71
Sum		34	72	106

Positive predictive value (Sensitivity)	33/35	94.29% (80.84%～99.30%)
Negative predictive value (Specificity)	70/71	98.59% (92.40%～99.96%)
Total coincidence rate	103/106	97.17% (91.95%～99.41%)

Performance

- Clinical evaluation-Plasma

IgM

		Comparison method		Sum
		Positive	Negative	
AIT	Positive	34	3	37
	Negative	1	74	75
Sum		35	77	112

Positive predictive value (Sensitivity)	34/37	91.89% (78.09%～98.30%)
Negative predictive value (Specificity)	74/75	98.67% (92.79%～99.97%)
Total coincidence rate	108/112	96.43% (91.11%～99.02%)

Transportation, Storage, Packaging

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Transportation and storage

Novel Coronavirus (2019-nCoV) IgG/IgM Test Kit (Colloidal Gold)

- Transport or store at room temperature from 2 to 30°C
- If individual pouch unopened, the kit can be stored for 12 months.
- Once the individual pouch is opened, this test card should be used within 1 hour.

Packaging

Carton				Kit			Individual Pouch
Quantity (kits)	Gross weight (KG)	Net weight (KG)	Size (CM)	Quantity (tests)	Weight (KG)	Size (CM)	Size (CM)
30 kits	11.20	9.90	56*40*36cm	25	0.33	18*14*8	14*7
14 kits	5.40	4.62	37*32*32cm				

Certification

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CE

Certificate No.: EU2020006

Standards Applied:

EN ISO 13485: 2016	Medical devices. Quality management systems. Requirements for regulatory purposes
EN ISO 15223-1: 2016	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements
EN ISO 14971: 2012	Medical devices. Application of risk management to medical devices
EN ISO 18113-1: 2011	In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). Terms, definitions and general requirements
EN 13957: 2003	Sampling procedures used for acceptance testing of in vitro diagnostic medical devices. Statistical aspects
EN 14136: 2004	Use of external quality assessment schemes in the assessment of the performance of in vitro diagnostic examination procedures
EN ISO 17511:2003	In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control material
EN ISO 18113-2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use
EN ISO 23640:2015	In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents

CE

Place, Date of Issue: Shenzhen, Mar. 19th, 2020
Signature:
Name of Authorized Signatory: Ms. Yiping Li
Position Held in Company: Management Representative

Declaration of Conformity

Certificate No.:EU2020006

Product Name:
Novel Coronavirus（2019-nCoV）IgG/IgM Test Kit (Colloidal gold)

Model:
25T/kit, 50T/kit

Classification:
Others device, not in annex II and not for self-testing, not for performance evaluation.

Conformity Assessment Route:
IVDD 98/79/EC Annex III (excludes section 6)
We herewith declare under sole responsibility that the above mentioned products meet the provisions of the Council Directive 98/79/EC on in vitro diagnostic medical devices.

General Applicable Directive:
Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

Standards Applied:

EN ISO13485:2016	EN ISO 23640:2015	EN ISO 14971:2012	EN ISO 18113-1:2011
EN ISO 15223-1:2016	EN 13975:2003	EN 14136:2004	EN ISO 18113-2:2011
EN ISO 17511:2003			

THANK YOU

If need any support, please contact :

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