Clinical Validation Report

Product Name: Covid-19 IgG/IgM Rapid Test

Product Code: COVID-19/20

Model and Specifications: tests packed independently

Abstract of Research

To evaluate clinical applications of the COVID-19/20 manufactured by Assut Europe SpA, to in-vitro qualitative tests on the content of the Covid-19 antibody in clinical samples (serum/plasma/whole blood), a clinical research has been made for this test strip.

In total, 220 serum samples were selected as research object, of them, 93 cases were diagnosed as positive according to the novel coronavirus pneumonia treatment plan, 127 cases were diagnosed as negative according to the novel coronavirus pneumonia treatment plan.

The research objects were classified into the IgG and IgM of positive group and negative group by comparing test results of these products. Meanwhile, these samples were tested via a test card, to compare the test results of the tested product and those of the reference product, with statistical analysis being made. The coincidence rate of positive/negative and the total coincidence rate of both products were proven higher than 90% in comparison, indicating favorable consistency with the reference product. In the analysis results of Kappa inspection, Kappa was proven >0.8, indicating favorable and high consistency of both methods. Both systems were proven equivalent. The tested product is applicable to auxiliary clinical diagnosis.

As a large family of virus, coronavirus is a single plus strand RNA virus featured by envelopes. As known to us, such virus can trigger major diseases such as cold, Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS). COVID-19 was identified in the cases of viral pneumonia in Wuhan, 2019 and was named officially by WHO on January 12, 2020. As a core protein of COVID-19, N protein (Nucleocapsid) is a component inside the virus, and is relatively conservative among category-p coronaviruses and is a common tool for diagnosis on coronaviruses. As a key receptor for COVID-19's entry in the cell, ACE2 is of great significance for research on the virus infection mechanism.

To validate the applicability and accuracy of such test strip on clinical applications, a systematic research is required for its clinical properties. In total, 220 samples were involved in this clinical research.

The purpose of research of this clinical test is: calculate the consistency percentage of negative/positive and the total consistency percentage and the Kappa coefficient by making statistics of and analyzing test results through comparative experimental research for the followings for the same clinical sample: the COVID-19/20 produced by Assut Europe SpA, the tested product, and the 2019-nCoV antibody test kit (colloidal-gold). The equivalence between the tested product and the reference product is verified according to the results of statistical analysis, so as to validate the applicability and accuracy of the tested product in auxiliary clinical diagnosis.

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The results of this clinical test are important basis for evaluating the effectiveness and safety of the tested product.

A proper object of research shall be selected by reference to the Technical Guidelines for Clinical Research of IVD Kit. The Covid-19 antibody test kit whose marketing is approved, is adopted as the reference reagent for synchronous comparison through the blind method. The consistency percentage of positive/negative and the total consistency percentage and the Kappa coefficient of the product and the reference reagent shall be analyzed.

Test scheme: 220 cases of serum are selected as the objects of research from clinical cases. The sample is classified into the positive group and the negative group as per the test results of the reference product. Meanwhile, the sample shall be tested via the qualitative test strip tested and the reference one and then the test results of the tested product and the reference product shall be compared, with statistical analysis being made. The consistency percentage of negative/positive and the total consistency percentage and the Kappa coefficient shall be calculated and the applicability and accuracy of the tested product for clinical diagnosis shall be judged based on this. The consistency in diagnosis in test results of the product and the reference product shall be judged through Kappa inspection and analysis. Moreover, the consistency in test results of the serum sample shall be analyzed, and the Kappa coefficient shall be calculated.

All samples of the subjects shall be subject to determination by the reference test strip and the tested product synchronously and respectively, and then the determination results of both shall be compared. The test results of the tested product recorded shall be subject to statistical analysis with those of the reference product upon completion of determination of all clinical samples, to calculate the consistency percentage of negative/positive and the total consistency percentage. Afterwards, equivalence of both shall be evaluated as per these statistical indexes.

A Methods evaluating clinical performance

Whether various indexes can reach the standards of clinical evaluation shall be judged by calculating the consistency percentage of negative/positive and the total consistency percentage in the test results of the tested product and the reference product, to validate the accuracy and applicability of the product in clinical applications. The tested product shall be subject to tests through the sample of different types, with statistics on the results. Meanwhile, different types of sample of the subjects shall be subject to determination by the tested product synchronously, and then the determination results of both shall be compared. The test results recorded shall be subject to statistical analysis upon completion of determination of all clinical samples, to calculate the consistency percentage of negative/positive and the total consistency percentage. Afterwards, equivalence of both shall be evaluated as per these statistical indexes.

B Statistical methods

The products launched on the market shall be subject to comparative study and evaluation: Kappa inspection: each sample shall be tested with the tested product and the reference product respectively, and then the consistency in statistical results of these two inspection methods shall be compared through Kappa inspection.

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The data shall be subject to Kappa inspection and analysis and the Kappa coefficient shall be calculated. Favorable consistency can be proven if Kappa is >0.8. The consistency in test results of the tested product and the reference product is evaluated as per the evaluation standards.

Standards of clinical evaluation

The coincidence rate shall be calculated by comparing with the reference product whose marketing is approved. The product performance shall meet the following requirements:

1) Coincidence rate of negative: the sample whose test results are negative for both the tested product and the reference product and the proportion in the sample whose test results are negative for the reference product shall be more than 90%.

2) Coincidence rate of positive: the sample whose test results are positive for both the tested product and the reference product and the proportion in the sample whose test results

are positive for the reference product shall be more than 90%.

3) Total coincidence rate: the sample whose test results are the same for the tested product and the reference product and its proportion in the total number of sample shall be more than 90%.

		Reference system		Total
		Positive	Negative	
Test system	Positive	a	b	a+b
	Negative	c	d	c+d
Total		a+c	b+d	a+b+c+d

In general, the formula calculating the coincidence rate of positive/negative is:

Coincidence rate of positive =a/(a+c)*100%

Coincidence rate of negative =d/(b+d)*1 00%

Total coincidence rate =(a+d)/(a+c+b+d)*100%

If the coincidence rate of positive/negative can meet clinical requirements, two methods or products are considered as equivalent; if the coincidence rate of positive/negative is greatly different, the clinical scheme shall be re-designed.

4) Kappa consistency analysis shall be adopted for statistical analysis of similar reference kits

The results of the tested product are statistical materials and can be analyzed as per the table below:

		Reference system		Total
		Positive	Negative	
Test system	Positive	a	b	a+b
	Negative	c	d	c+d
Total		a+c	b+d	a+b+c+d

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If conducting Kappa consistency analysis for the base data above, high consistency can be judged if the Kappa coefficient is >0.8; and both systems are considered as equivalent. Consistency is considered if 0.4<Kappa coefficient <0.8; and the coincidence rate of positive/negative shall be compared; with statistical analysis being made. Two such systems are considered as inconsistent and no-equivalent if the Kappa coefficient is <0.4.

In total; 220 test samples (125 for male and 95 for female) are included for the unit and all test samples included are tested.

The statistical results of test device were list as follows

Table 1: Statistics on Serum IgG Test Results of the Tested product and the Reference Product

	Positive Reference Product	Negative Reference Product	Total
Positive tested product	92	1	93
Negative tested product	0	127	127
Total	92	128	220

Item	Formula	Results
Coincidence rate of negative (%)	a/(a+c)*100%	100.00%
Coincidence rate of positive (%)	d/(b+d)*100%	99.22%
Total coincidence rate (%)	(a+d)/(a+b+c+d)*100	99.55%
Theoretical coincidence rate Pe	[(a+b)(a+c)+(c+d)(b+d)]/(a+b+c+d)^2	0.513
Kappa	(PA-Pe)/(1-Pe)	0.991

According to Table 1; among the 93 samples of the positive group; 92 are proven positive in the test results of the tested product; and 1 is proven negative. Among the 127 samples of the negative group; 127 are proven negative in the test results of the tested product and 0 is proven positive. Both the coincidence rate of positive/negative and the total coincidence rate are more than 90%, indicating favorable consistency with the reference product. According to the table, the Kappa coefficient = 0.991 (>0.8) in the results of Kappa inspection and analysis, indicating favorable and high consistency of two methods and equivalence of two such systems.

Table 2: Statistics on Serum IgM Test Results of the Tested product and the Reference Product

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	Positive Reference Product	Negative Reference Product	Total
Positive tested product	71	0	71
Negative tested product	2	147	149
Total	73	147	220

Item	Formula	Results
Coincidence rate of negative (%)	a/(a+c)*100%	97.26%
Coincidence rate of positive (%)	d/(b+d)*100%	100.00%
Total coincidence rate (%)	(a+d)/(a+b+c+d)*100	99.09%
Theoretical coincidence rate Pe	[(a+b)(a+c)+(c+d)(b+d)]/(a+b+c+d)^2	0.560
Kappa	(PA-Pe)/(1-Pe)	0.979

According to Table 2, among the 71 samples of the positive group, 71 are proven positive in the test results of the tested product, and 0 is proven negative. Among the 149 samples of the negative group, 147 are proven negative in the test results of the tested product and 2 are proven positive. Both the coincidence rate of positive/negative and the total coincidence rate are more than 90%, indicating favorable consistency with the reference product. According to the table; the Kappa coefficient = 0.979 (>0.8) in the results of Kappa inspection and analysis, indicating favorable and high consistency of two methods and equivalence of two such systems.

Analysis on Inconsistency in Test Results

Sample number	Gender	Age	Tested product	Reference Product	Clinical Diagnosis
46	Male	57	IgG(+) IgM(-)	IgG(+) IgM(+)	Subsequent visit of pneumonia triggered by COVID-19
62	Male	81	IgG(+) IgM(-)	IgG(+) IgM(+)	Subsequent visit of pneumonia triggered by COVID-19

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114	Female	70	IgG(+) IgM(-)	IgG(+) IgM(-)	Non-pneumonia triggered by COVID-19

For those subjected to subsequent visit, IgM in the blood may be degraded and IgG definite diagnosis is more effective.

The consistency analysis was performed between diagnostic results of test product and the diagnostic results of nucleic acid detection method, in order to calculate the diagnostic sensitivity and specificity of test product. The statistic result was listed in the tables.

	Nucleic acid testing result		Total
Test device	Positive	Negative	
IgM Positive	True Positive (A1)	False Positive (B1)	A1+B1
IgG Positive	True Positive (A2)	False Positive (B2)	A2+B2
IgM & IgG Positive	True Positive (A3)	False Positive (B3)	A3+B3
IgM & IgG Negative	False negative (C)	True negative (D)	C+D
Total	A1+A2+A3+C	B1+B2+B3+D	A1+B1+A2+B2+A3+B3+C+D

In general, the calculation formula of diagnostic sensitivity and diagnostic specificity was as follows: Diagnostic sensitivity= (Al+A2+A3) 1 (Al+A2+A3+C) X 100%

Diagnostic specificity= D/ (B1+ B2+B3+D) X 100%

Table 3 The comparison result of test device and Nucleic acid method

	Nucleic acid testing result		Total
Test device	Positive	Negative	
IgM Positive	2	0	2
IgG Positive	20	3	23
IgM & IgG Positive	70	0	70
IgM & IgG Negative	1	124	125
Total	93	127	220

Item	Calculation formula	Results	95%-L	95%-H
Diagnostic sensitivity (%)	(A1+A2+A3)/(A1+A2+A3+C) x 100%	98.90%	94.16%	99.81%
Diagnostic specificity	D/(B1+B2+B3+D) x 100%	97.60%	93.29%	99.19%

It can be seen from table 3 that in the 93 positive sample group, the detection results of the test device are 2 IgM Positive, 20 IgG Positive, 70 IgM Positive & IgG Positive and 1 IgM & IgG Negtative; in the 127 negative sample group, the detection results of the test device are 0 IgM Positive, 3 IgG Positive, 0 IgM Positive & IgG Positive and 124 1gM & lgG Negative. The sensitivity and specificity of the diagnosis were more than 90%, which indicated that it was consistent with the contrast product.

(I) Discussion

The COVID-19/20 test card manufactured by Assut Europe SpA, contains the COVID-19 recombinant protein (colloidal-gold signs) enveloped on the gold-labeled pad in advance as well as the mouse-anti-human IgG antibody fixed into the test zone G and the mouse-anti-human IgM

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antibody fixed into the test zone M and corresponding antibody in the quality control area (C). It can be used for rapid tests on the COVID-19 antibody in the serum/plasma specimen as well as auxiliary clinical screening of those suffering from pneumonia triggered by Covid-19. This clinical test aims at evaluating the clinical properties of such product. The test conditions are concluded as follows:

Test results of the serum sample of the tested product and the reference product: both the coincidence rate of negative/positive and the total coincidence rate are larger than 90%, indicating favorable consistency with the reference product. In the analysis results of Kappa inspection, Kappa was proven >0.8, indicating favorable and high consistency of both methods. Both systems were proven equivalent.

B Statistical analysis results of the tested product and nucleic acid detection method

The comparison result of test device and nucleic acid detection method: diagnostic sensitivity and specificity are both more than 90%, indicating good consistency with the nucleic acid test results.

(II) Test conclusions

By analyzing the test results of the tested product and the reference, the consistency percentage of negative/positive and the total consistency percentage are proven high. Moreover, according to the results of statistical analysis, there is no remarkable difference in test results of both, indicating favorable consistency in diagnosis and equivalence of two such systems. Meanwhile, the diagnostic sensitivity and specificity of test device are both more than 90% compared with the detection results of nucleic acid method, indicating good consistency with the nucleic acid test results.

Annex I: Data of Clinical Tests

Sample No.	Gender	Age	Tested product	Reference Product	Nucleic acid test results
			Results	Results	
1	F	45	IgG (+)	IgG (+)	Positive
			IgM (+)	IgM (+)	
2	M	66	IgG (+)	IgG (+)	Positive
			IgM (-)	IgM (-)	
3	M	36	IgG (+)	IgG (+)	Positive
			IgM (+)	IgM (+)	
4	F	44	IgG (-)	IgG (-)	Negative
			IgM (-)	IgM (-)	
5	F	54	IgG (+)	IgG (+)	Positive
			IgM (+)	IgM (+)	
6	M	65	IgG (+)	IgG (+)	Positive
			IgM (-)	IgM (-)	

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7	M	69	IgG (+) IgM (+)	IgG (+) IgM (+)	Positive
8	M	74	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
9	F	25	IgG (+) IgM (-)	IgG (+) IgM (-)	Positive
10	M	53	IgG (+) IgM (+)	IgG (+) IgM (+)	Positive
11	F	33	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
12	M	28	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
13	M	42	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
14	F	77	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
15	M	82	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
16	F	36	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative

Sample No.	**Gender**	**Age**	**Tested product** **Results**	**Reference Product** **Results**	**Nucleic acid test results**
17	M	64	IgG (+) IgM (-)	IgG (+) IgM (-)	Positive
18	M	26	IgG (+) IgM (+)	IgG (+) IgM (+)	Positive
19	F	35	IgG (+) IgM (+)	IgG (+) IgM (+)	Positive
20	M	62	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
21	F	83	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
22	F	52	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
23	F	46	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
24	M	91	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
25	M	46	IgG (+) IgM (+)	IgG (+) IgM (+)	Positive
26	F	32	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
27	F	30	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
28	M	29	IgG (+)	IgG (+)	Positive

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			IgM (+)	IgM (+)	
29	F	66	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
30	F	31	IgG (+) IgM (+)	IgG (+) IgM (+)	Positive
31	M	95	IgG (+) IgM (+)	IgG (+) IgM (+)	Positive
32	M	34	IgG (+) IgM (+)	IgG (+) IgM (+)	Positive
33	F	55	IgG (+) IgM (+)	IgG (+) IgM (+)	Positive
34	F	82	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
35	M	40	IgG (+) IgM (+)	IgG (+) IgM (+)	Positive
36	M	57	IgG (+) IgM (+)	IgG (+) IgM (+)	Positive
37	M	37	IgG (+) IgM (-)	IgG (+) IgM (-)	Positive
38	F	27	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
39	M	56	IgG (+) IgM (+)	IgG (+) IgM (+)	Positive

Sample No.	**Gender**	**Age**	**Tested product** **Results**	**Reference Product** **Results**	**Nucleic acid test results**
40	F	87	IgG (+) IgM (+)	IgG (+) IgM (+)	Positive
41	M	73	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
42	M	59	IgG (+) IgM (+)	IgG (+) IgM (+)	Positive
43	F	25	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
44	F	43	IgG (+) IgM (+)	IgG (+) IgM (+)	Positive
45	M	31	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
46	M	57	IgG (+) IgM (+)	IgG (+) IgM (+)	Positive
47	M	66	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
48	M	72	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
49	M	51	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative

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50	F	54	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
51	F	49	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
52	M	68	IgG (+) IgM (+)	IgG (+) IgM (+)	Positive
53	F	29	IgG (+) IgM (-)	IgG (+) IgM (-)	Positive
54	F	58	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
55	F	55	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
56	F	42	IgG (+) IgM (+)	IgG (+) IgM (+)	Positive
57	M	39	IgG (+) IgM (+)	IgG (+) IgM (+)	Positive
58	M	51	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
59	F	33	IgG (-) IgM (+)	IgG (-) IgM (+)	Positive
60	F	46	IgG (+) IgM (+)	IgG (+) IgM (+)	Positive
61	M	54	IgG (-) IgM (+)	IgG (-) IgM (+)	Positive
62	M	81	IgG (+) IgM (+)	IgG (+) IgM (+)	Positive

Sample No.	**Gender**	**Age**	**Tested product** **Results**	**Reference Product** **Results**	**Nucleic acid test results**
63	F	19	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
64	M	37	IgG (+) IgM (+)	IgG (+) IgM (+)	Positive
65	M	48	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
66	F	72	IgG (+) IgM (+)	IgG (+) IgM (+)	Positive
67	F	66	IgG (+) IgM (-)	IgG (+) IgM (-)	Positive
68	M	47	IgG (+) IgM (+)	IgG (+) IgM (+)	Positive
69	M	62	IgG (+) IgM (+)	IgG (+) IgM (+)	Positive
70	M	58	IgG (+) IgM (+)	IgG (+) IgM (+)	Positive
71	F	83	IgG (+)	IgG (+)	Positive

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			IgM (+)	IgM (+)	
72	M	65	IgG (-)	IgG (-)	Negative
			IgM (-)	IgM (-)	
73	F	37	IgG (-)	IgG (-)	Negative
			IgM (-)	IgM (-)	
74	M	55	IgG (-)	IgG (-)	Negative
			IgM (-)	IgM (-)	
75	F	38	IgG (-)	IgG (-)	Negative
			IgM (-)	IgM (-)	
76	M	47	IgG (+)	IgG (+)	Positive
			IgM (+)	IgM (+)	
77	M	81	IgG (-)	IgG (-)	Negative
			IgM (-)	IgM (-)	
78	F	37	IgG (-)	IgG (-)	Negative
			IgM (-)	IgM (-)	
79	F	35	IgG (-)	IgG (-)	Negative
			IgM (-)	IgM (-)	
80	M	42	IgG (-)	IgG (-)	Negative
			IgM (-)	IgM (-)	
81	M	77	IgG (-)	IgG (-)	Negative
			IgM (-)	IgM (-)	
82	M	30	IgG (+)	IgG (+)	Positive
			IgM (+)	IgM (+)	
83	F	36	IgG (-)	IgG (-)	Negative
			IgM (-)	IgM (-)	
84	M	58	IgG (+)	IgG (+)	Positive
			IgM (+)	IgM (+)	
85	F	71	IgG (+)	IgG (+)	Positive
			IgM (+)	IgM (+)	

Sample No.	**Gender**	**Age**	**Tested product**	**Reference Product**	**Nucleic acid test results**
			Results	**Results**	
86	M	64	IgG (+)	IgG (+)	Positive
			IgM (-)	IgM (-)	
87	M	57	IgG (-)	IgG (-)	Negative
			IgM (-)	IgM (-)	
88	F	86	IgG (-)	IgG (-)	Negative
			IgM (-)	IgM (-)	
89	M	42	IgG (+)	IgG (+)	Positive
			IgM (-)	IgM (-)	
90	F	83	IgG (-)	IgG (-)	Negative
			IgM (-)	IgM (-)	
91	M	52	IgG (+)	IgG (+)	Positive
			IgM (+)	IgM (+)	
92	M	79	IgG (-)	IgG (-)	Negative
			IgM (-)	IgM (-)	

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93	F	45	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
94	M	40	IgG (+) IgM (+)	IgG (+) IgM (+)	Positive
95	F	88	IgG (+) IgM (+)	IgG (+) IgM (+)	Positive
96	M	64	IgG (+) IgM (-)	IgG (+) IgM (-)	Positive
97	M	17	IgG (+) IgM (-)	IgG (+) IgM (-)	Positive
98	F	62	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
99	F	42	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
100	M	53	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
101	M	62	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
102	F	38	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
103	F	78	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
104	M	56	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
105	M	36	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
106	M	48	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
107	F	70	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
108	M	84	IgG (+) IgM (+)	IgG (+) IgM (+)	Positive

Sample No.	**Gender**	**Age**	**Tested product** **Results**	**Reference Product** **Results**	**Nucleic acid test results**
109	F	64	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
110	M	58	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
111	M	55	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
112	F	51	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
113	F	33	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
114	F	70	IgG (+)	IgG (-)	Negative

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			IgM (-)	IgM (-)	
115	M	45	IgG (+)	IgG (+)	Positive
			IgM (+)	IgM (+)	
116	M	49	IgG (+)	IgG (+)	Positive
			IgM (+)	IgM (+)	
117	F	36	IgG (-)	IgG (-)	Negative
			IgM (-)	IgM (-)	
118	F	34	IgG (+)	IgG (+)	Positive
			IgM (-)	IgM (-)	
119	F	43	IgG (-)	IgG (-)	Negative
			IgM (-)	IgM (-)	
120	M	74	IgG (+)	IgG (+)	Positive
			IgM (+)	IgM (+)	
121	M	38	IgG (-)	IgG (-)	Negative
			IgM (-)	IgM (-)	
122	F	48	IgG (+)	IgG (+)	Positive
			IgM (+)	IgM (+)	
123	F	36	IgG (-)	IgG (-)	Negative
			IgM (-)	IgM (-)	
124	M	54	IgG (-)	IgG (-)	Negative
			IgM (-)	IgM (-)	
125	M	71	IgG (+)	IgG (+)	Positive
			IgM (+)	IgM (+)	
126	M	55	IgG (+)	IgG (+)	Negative
			IgM (-)	IgM (-)	
127	F	19	IgG (+)	IgG (+)	Positive
			IgM (+)	IgM (+)	
128	M	65	IgG (-)	IgG (-)	Negative
			IgM (-)	IgM (-)	
129	F	40	IgG (-)	IgG (-)	Negative
			IgM (-)	IgM (-)	
130	M	71	IgG (+)	IgG (+)	Positive
			IgM (+)	IgM (+)	
131	M	33	IgG (+)	IgG (+)	Positive
			IgM (+)	IgM (+)	

Sample No.	**Gender**	**Age**	**Tested product**	**Reference Product**	**Nucleic acid test results**
			Results	**Results**	
132	M	38	IgG (-)	IgG (-)	Negative
			IgM (-)	IgM (-)	
133	F	54	IgG (-)	IgG (-)	Negative
			IgM (-)	IgM (-)	
134	F	35	IgG (-)	IgG (-)	Negative
			IgM (-)	IgM (-)	
135	M	86	IgG (+)	IgG (+)	Positive
			IgM (+)	IgM (+)	

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136	M	48	IgG (+) IgM (-)	IgG (+) IgM (-)	Positive
137	F	39	IgG (+) IgM (+)	IgG (+) IgM (+)	Positive
138	M	56	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
139	M	89	IgG (+) IgM (-)	IgG (+) IgM (-)	Positive
140	F	44	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
141	F	77	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
142	M	76	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
143	M	62	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
144	M	49	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
145	F	84	IgG (+) IgM (+)	IgG (+) IgM (+)	Positive
146	M	40	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
147	F	36	IgG (+) IgM (+)	IgG (+) IgM (+)	Positive
148	M	80	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
149	M	72	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
150	M	37	IgG (+) IgM (+)	IgG (+) IgM (+)	Positive
151	F	16	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
152	M	85	IgG (+) IgM (+)	IgG (+) IgM (+)	Positive
153	F	53	IgG (+) IgM (-)	IgG (+) IgM (-)	Positive
154	M	22	IgG (+) IgM (-)	IgG (+) IgM (-)	Positive

Sample No.	**Gender**	**Age**	**Tested product Results**	**Reference Product Results**	**Nucleic acid test results**
155	M	16	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
156	F	51	IgG (+) IgM (-)	IgG (+) IgM (-)	Negative
157	F	78	IgG (-)	IgG (-)	Negative

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			IgM (-)	IgM (-)	
158	M	73	IgG (-)	IgG (-)	Negative
			IgM (-)	IgM (-)	
159	M	38	IgG (+)	IgG (+)	Positive
			IgM (+)	IgM (+)	
160	M	56	IgG (-)	IgG (-)	Negative
			IgM (-)	IgM (-)	
161	F	37	IgG (-)	IgG (-)	Negative
			IgM (-)	IgM (-)	
162	M	46	IgG (+)	IgG (+)	Positive
			IgM (+)	IgM (+)	
163	F	57	IgG (-)	IgG (-)	Negative
			IgM (-)	IgM (-)	
164	M	59	IgG (-)	IgG (-)	Negative
			IgM (-)	IgM (-)	
165	M	41	IgG (-)	IgG (-)	Negative
			IgM (-)	IgM (-)	
166	M	63	IgG (-)	IgG (-)	Negative
			IgM (-)	IgM (-)	
167	M	34	IgG (-)	IgG (-)	Negative
			IgM (-)	IgM (-)	
168	F	48	IgG (+)	IgG (+)	Positive
			IgM (+)	IgM (+)	
169	F	36	IgG (+)	IgG (+)	Positive
			IgM (+)	IgM (+)	
170	F	58	IgG (-)	IgG (-)	Negative
			IgM (-)	IgM (-)	
171	M	40	IgG (-)	IgG (-)	Negative
			IgM (-)	IgM (-)	
172	M	27	IgG (-)	IgG (-)	Negative
			IgM (-)	IgM (-)	
173	M	64	IgG (+)	IgG (+)	Positive
			IgM (+)	IgM (+)	
174	M	38	IgG (-)	IgG (-)	Negative
			IgM (-)	IgM (-)	
175	F	47	IgG (+)	IgG (+)	Positive
			IgM (+)	IgM (+)	
176	F	40	IgG (-)	IgG (-)	Negative
			IgM (-)	IgM (-)	
177	M	82	IgG (+)	IgG (+)	Positive
			IgM (+)	IgM (+)	

Sample No.	Gender	Age	Tested product Results	Reference Product Results	Nucleic acid test results
178	M	25	IgG (+)	IgG (+)	Positive
			IgM (-)	IgM (-)	

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179	F	71	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
180	F	46	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
181	M	57	IgG (-) IgM (-)	IgG (-) IgM (-)	Positive
182	M	30	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
183	M	52	IgG (+) IgM (+)	IgG (+) IgM (+)	Positive
184	F	67	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
185	M	33	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
186	F	53	IgG (+) IgM (+)	IgG (+) IgM (+)	Positive
187	M	38	IgG (+) IgM (-)	IgG (+) IgM (-)	Positive
188	M	52	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
189	F	46	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
190	M	44	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
191	M	78	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
192	F	87	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
193	F	74	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
194	M	69	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
195	M	46	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
196	F	55	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
197	F	38	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
198	M	53	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
199	M	36	IgG (+) IgM (+)	IgG (+) IgM (+)	Positive
200	M	33	IgG (+) IgM (+)	IgG (+) IgM (+)	Positive

Sample No.	Gender	Age	Tested product	Reference Product	Nucleic acid test results

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			Results	**Results**	
201	F	28	IgG (+) IgM (+)	IgG (+) IgM (+)	Positive
202	M	81	IgG (+) IgM (+)	IgG (+) IgM (+)	Positive
203	F	42	IgG (+) IgM (+)	IgG (+) IgM (+)	Positive
204	M	70	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
205	M	52	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
206	M	55	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
207	M	28	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
208	F	49	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
209	M	25	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
210	F	53	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
211	F	59	IgG (+) IgM (+)	IgG (+) IgM (+)	Positive
212	F	31	IgG (+) IgM (+)	IgG (+) IgM (+)	Positive
213	F	48	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
214	M	37	IgG (+) IgM (+)	IgG (+) IgM (+)	Positive
215	M	42	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
216	M	56	IgG (+) IgM (-)	IgG (+) IgM (-)	Positive
217	M	34	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
218	F	79	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
219	F	67	IgG (-) IgM (-)	IgG (-) IgM (-)	Negative
220	M	58	IgG (+) IgM (+)	IgG (+) IgM (+)	Positive

Note: "—" – negative sample; "+"- positive sample.

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