
EDI
EPITOPE DIAGNOSTICS, INC.
COVID-19
Diagnostic Immunoassay solutions
for Coronavirus detection

COMPANY PROFILE

Epitope Diagnostics, Inc.

*We provide the **highest quality products** and services to the healthcare community for detection and prevention of diseases.*

Company History

- Founded in 2003.
- Established in San Diego, CA.
- 100+ Products including ELISA, CLIA, rapid tests, and antibodies.

Certifications

- ISO 13485:2016 certified company.
- European CE and FDA certified.
- 3rd Party Validated Assays

ROBUSTNESS OF TECHNOLOGY

Enzyme Linked Immunoassay (ELISA)

A well-established plate-based assay technique designed for detecting and quantifying substances such as peptides, proteins, antibodies and hormones.

Coating

Antigen is adsorbed onto well in ELISA plate in coating buffer

Blocking

A buffer containing unrelated protein is used to block free sites in the wells

Detection

Enzyme conjugated detection antibody

binds antigen

Readout

Substrate is catalyzed by enzyme to generate colored readout

ROBUSTNESS OF TECHNOLOGY

PCR vs. Rapid Tests vs. ELISA

Polymerase Chain Reaction (PCR) is a diagnostic test designed to confirm a clinical disease through the amplification of DNA and RNA. However, PCR can only achieve a sensitivity of 50 to 79%, presents issues during the isolation of the virus from clinical specimen, and requires biosafety level 3 laboratory facilities.

Rapid Test Diagnostics (RTD) are lateral-flow assays, that use a dipstick or cassette format to perform a qualitative detection of a disease. However, due to the format of the assay, they can only achieve a sensitivity of 30%.

•ELISAs are more accessible and rely on a standardized technology.
• ELISA have a larger window of detection and can determine information about past infections.
• ELISA uses standardized serum sample.
• ELISA has higher levels of sensitivity and specificity.
• ELISA can be easily converted to quantitative to measure response.

Source: Wikipedia

Source: Pixabay

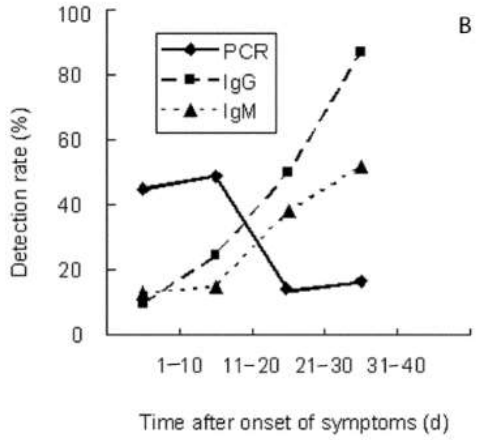
Source: Wikipedia

ROBUSTNESS OF TECHNOLOGY

ELISA Case Study: SARS 2003 Outbreak

•The specificities of the SARS ELISA for IgG and IgM detection were 98.6% and 93.9%, with corresponding sensitivities of 58.9% and 74.7%, respectively. [1]

•The median time to detection was 8 days (range, 5 to 17 days) after disease onset, and the rates after the onset of illness were 33% by the first week, 97% by the second week, and 100% by the third week. Compared with the results on the detection of IgG, the median time by IgM detection was 3 days earlier. [2]



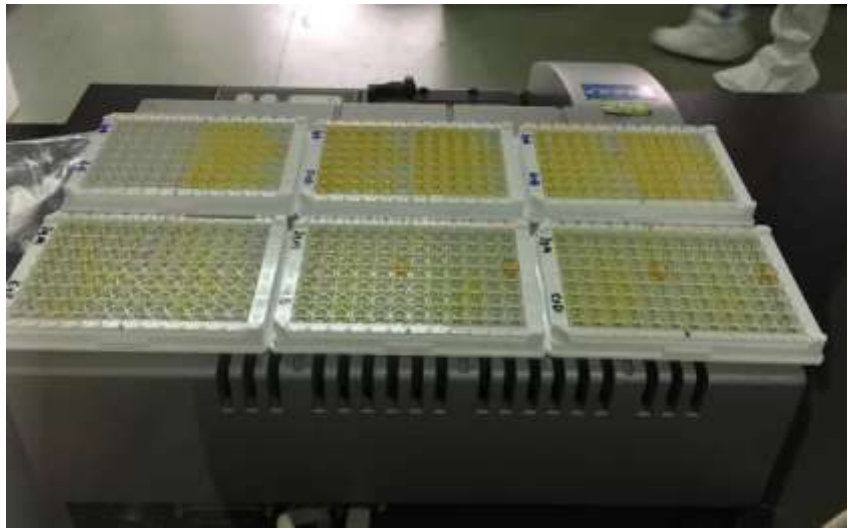
Fgiure1:Zhai, J., Briese, T., Dai, E., Wang, X., pang, X., Du, Z., Liu, H., Wang, J., Wang, H., Guo, Z., Chen, Z., Jiang, L., Zhou, D., Han, Y., Jabado, O., Palacios, G., Lipkin, W. I., & Tang, R. (2004). Real-time polymerase chain reaction for detecting SARS coronavirus, Beijing, 2003. Emerging infectious diseases, 10(2), 300–303. https://doi.org/10.3201/eid1002.030799

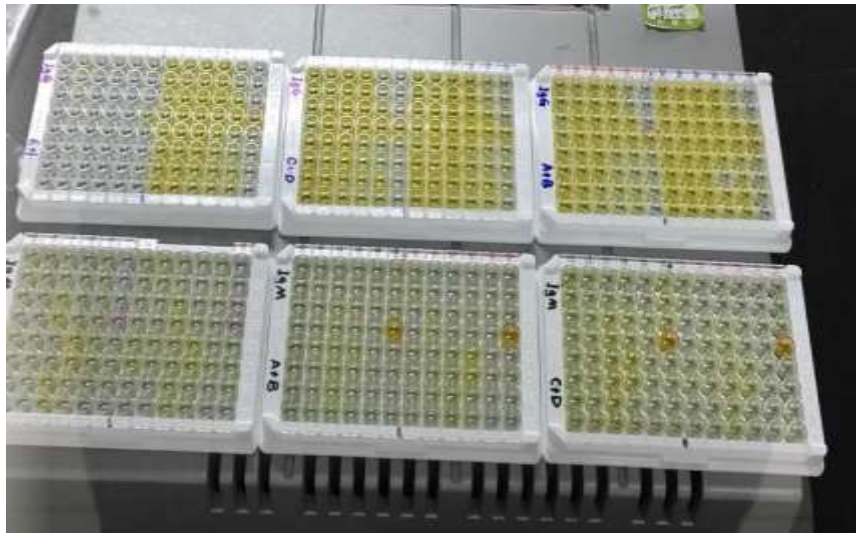
1. Yu, F., Le, M. Q., Inoue, S., Hasebe, F., Parquet, M. D. C., Morikawa, S., & Morita, K. (2007). Recombinant Truncated Nucleocapsid Protein as Antigen in a Novel Immunoglobulin M Capture Enzyme-Linked Immunosorbent Assay for Diagnosis of Severe Acute Respiratory Syndrome Coronavirus Infection. Clinical and Vaccine Immunology, 14(2), 146–149. doi: 10.1128/cvi.00360-06
2. Woo, P. C. Y., Lau, S. K. P., Wong, B. H. L., Tsoi, H.-W., Fung, A. M. Y., Kao, R. Y. T., … Yuen, K.-Y. (2005). Differential Sensitivities of Severe Acute Respiratory Syndrome (SARS) Coronavirus Spike Polypeptide Enzyme-Linked Immunosorbent Assay (ELISA) and SARS Coronavirus Nucleocapsid Protein ELISA for Serodiagnosis of SARS Coronavirus Pneumonia. Journal of Clinical Microbiology, 43(7), 3054–3058. doi: 10.1128/jcm.43.7.3054-3058.2005

ASSAY DEVELOPMENT

Selecting the best COVID-19 antigen

- Verified 8 recombinant COVID-19 nucleocapsid protein and 5 peptides
- Built 6 IgG ELISA test models and 6 IgM ELISA test models for verification
- Data obtained with 20 serum samples of COVID-19 confirmed cases





ASSAY PERFORMANCE

IgG Clinical Testing in China

Serum samples from two cohorts of patients were tested using the IgG ELISA kit at the Jiaxing City Center for Disease Control and Prevention and the First University Hospital of Zhejiang University Medical School. The first cohort consisted of serum samples from normal healthy patients collected prior to the COVID-19 outbreak [December 3, 2019] (n = 54) and serum samples from RT-PCR confirmed positive patients after two weeks of the onset of the disease (n = 30). The results are as follows:

	Confirmed Positive	Confirmed Negative
IgG Test Positive	30	0
IgG Test Negative	0	54
IgG Test Borderline	0	0

Sensitivity = 100%
Specificity = 100%
PPV = 100%
NPV = 100%

ASSAY PERFORMANCE

IgM Clinical Testing in China

Serum samples from two cohorts of patients were tested using the IgG ELISA kit at the Jiaxing City Center for Disease Control and Prevention and the First University Hospital of Zhejiang University Medical School. The first cohort consisted of serum samples from normal healthy patients collected prior to the COVID-19 outbreak [December 3, 2019] (n = 54) and serum samples from RT-PCR confirmed positive patients after two weeks of the onset of the disease (n = 20). The results are as follows:

	Confirmed Positive	Confirmed Negative
IgM Test Positive	9	0
IgM Test Negative	10	54
IgM Test Borderline	1	0

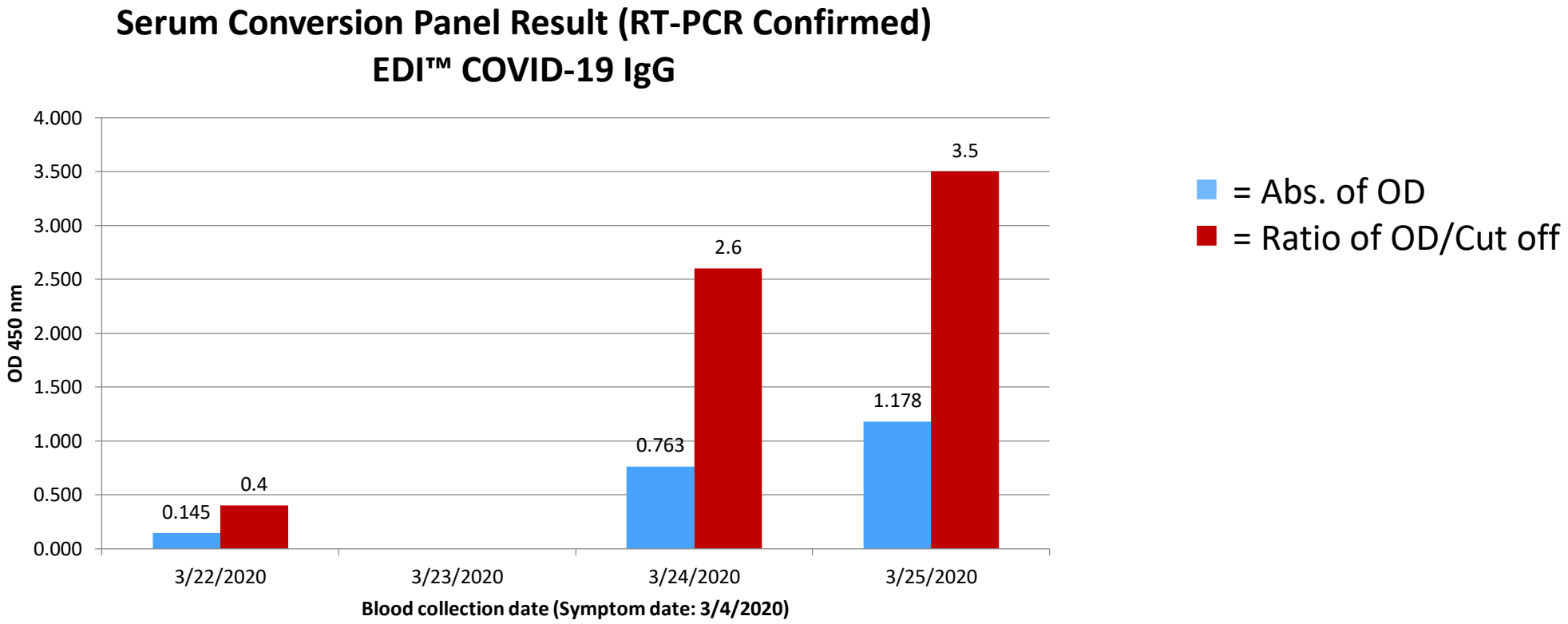
Sensitivity = 45.0%
Specificity = 100%
PPV = 100%
NPV = 83.1%

IgM is the first immunoglobulin to be produced in response to an antigen and will be primarily detectable during the early onset of the disease. The National Health Commission of the People's Republic of China states that IgM antibodies begin to show positive after 3-5 days of onset of COVID-19. Serum samples for the clinical test were from patients after two weeks of the onset of the disease Therefore, low levels of clinical sensitivity for IgM can be attributed to the collection date of the positive cohort where IgM levels are expected to be lower.

ASSAY CLINICAL PERFORMANCE

Double Blind Study of US COVID-19 Donor Sample

Serum samples from a RT-PCR confirmed positive patient was tested using the IgG ELISA kit at a University in the United States. The results are as follows:



ASSAY PERFORMANCE

Double Blind Study of Six US COVID-19 Patients

Serum samples from 6 RT-PCR confirmed positive patients and 7 RT-PCR negative samples were tested using the IgG and IgM ELISA kits . The results are as follows:

1. All 6 patients showed COVID-19 IgG positive result.

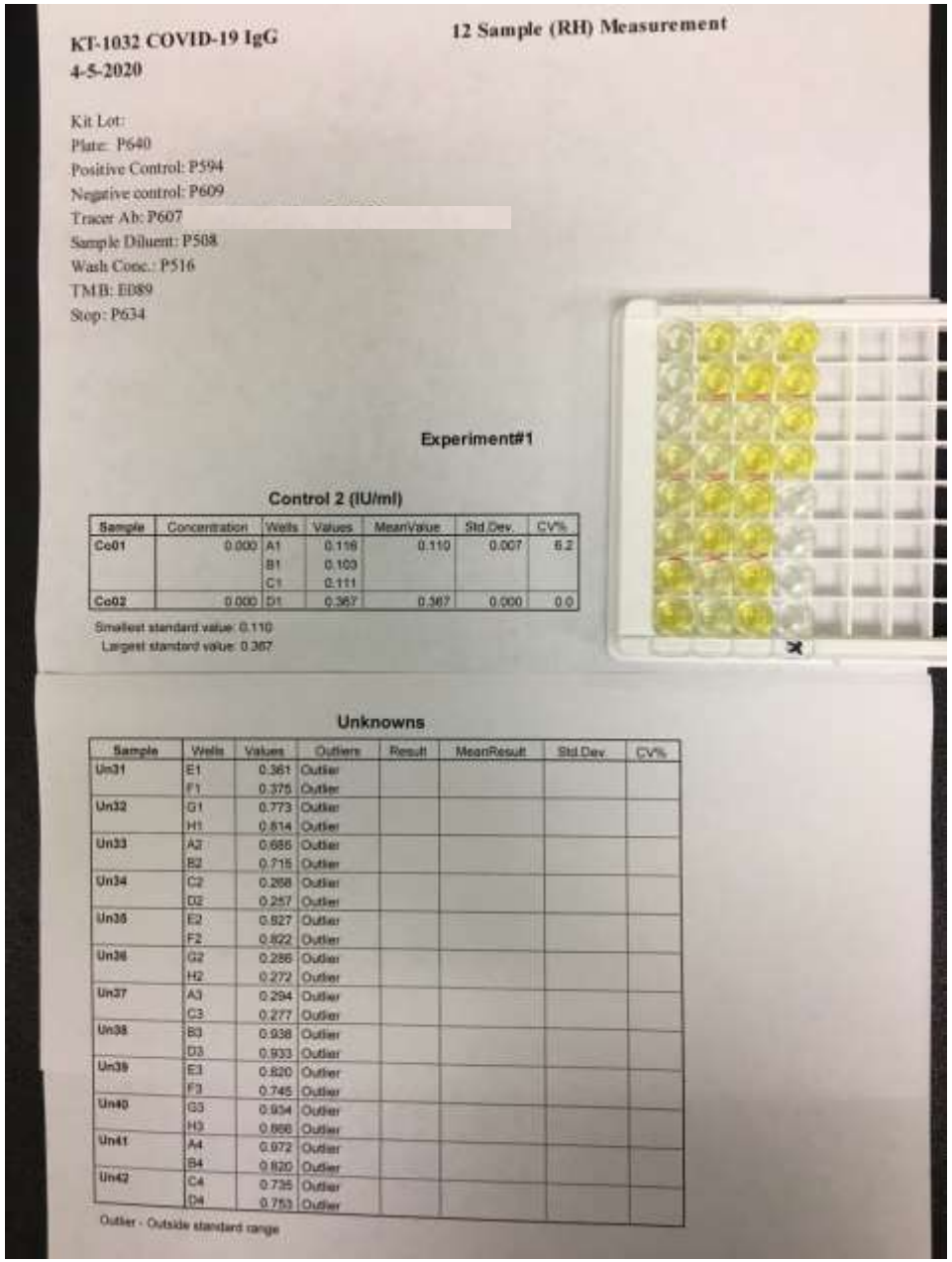
2. One patient showed COVID-19 IgM positive result (2.9 times above positive cut off)

3. All 7 RT-PCR negative samples showed negative of COVID-19 IgG and IgM

Note: all the samples are tested in duplicate.

ASSAY EXAMPLE

COVID-19 IgG Measurement in 12 Serum Samples in Duplicate



KT-1032 COVID-19 IgG
4-5-2020

12 Sample (RH) Measurement

Kit Lot:
Plate: P640
Positive Control: P594
Negative control: P609
Tracer Ab: P607
Sample Diluent: P508
Wash Conc.: P516
TMB: E089
Stop: P634

Experiment#1

Control 2 (IU/ml)

Sample	Concentration	Wells	Values	MeanValue	Std.Dev.	CV%
Co01	0.000	A1	0.116	0.110	0.007	6.2
		B1	0.103			
		C1	0.111			
Co02	0.000	D1	0.367	0.367	0.000	0.0

Smallest standard value: 0.110
Largest standard value: 0.367

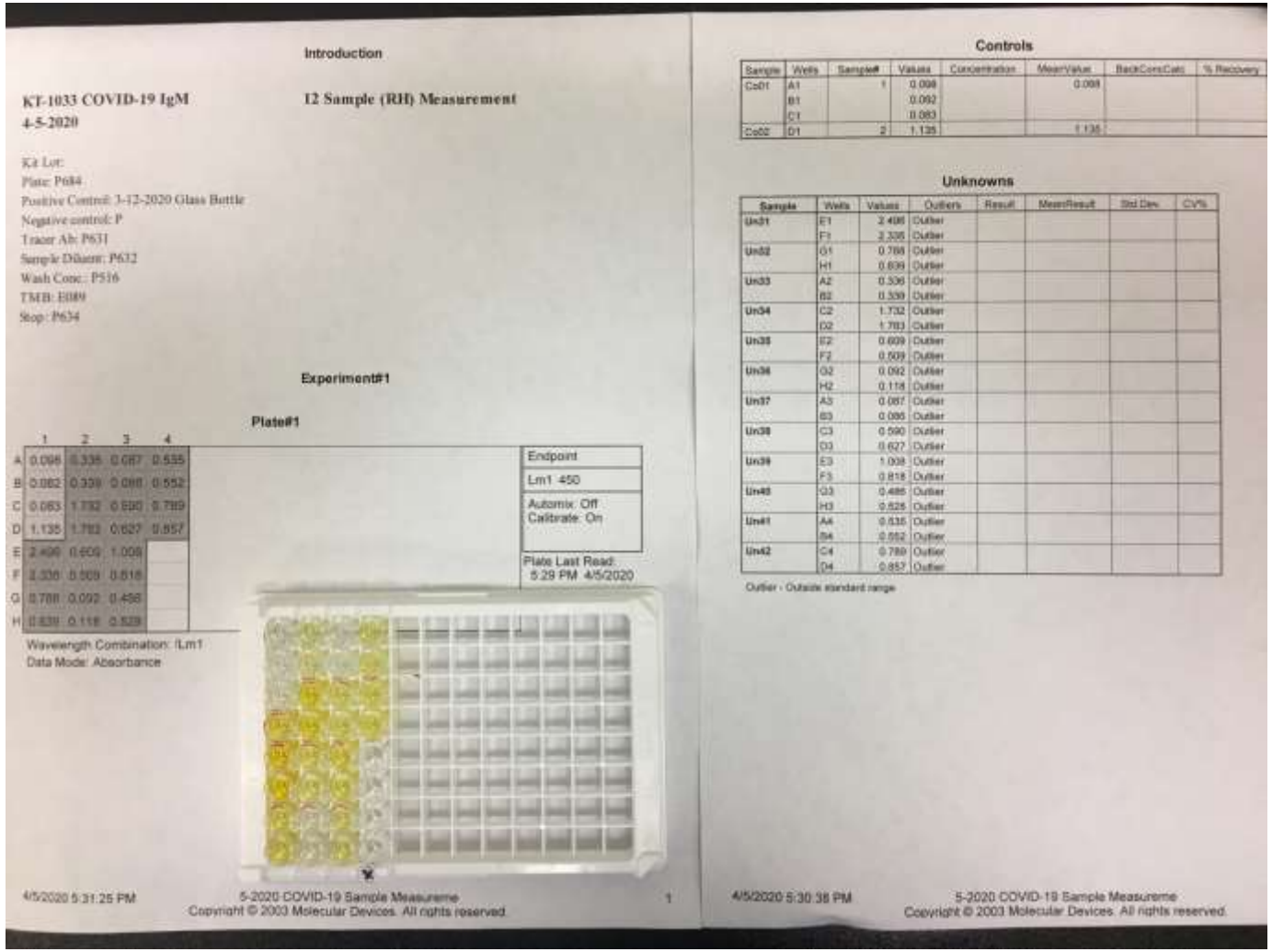
Unknowns

Sample	Wells	Values	Outliers	Result	MeanResult	Std.Dev.	CV%
Un31	E1	0.361	Outlier				
	F1	0.375	Outlier				
Un32	G1	0.773	Outlier				
	H1	0.814	Outlier				
Un33	A2	0.685	Outlier				
	B2	0.715	Outlier				
Un34	C2	0.268	Outlier				
	D2	0.257	Outlier				
Un35	E2	0.827	Outlier				
	F2	0.822	Outlier				
Un36	G2	0.286	Outlier				
	H2	0.272	Outlier				
Un37	A3	0.294	Outlier				
	C3	0.277	Outlier				
Un38	B3	0.938	Outlier				
	D3	0.933	Outlier				
Un39	E3	0.820	Outlier				
	F3	0.745	Outlier				
Un40	G3	0.934	Outlier				
	H3	0.866	Outlier				
Un41	A4	0.972	Outlier				
	B4	0.820	Outlier				
Un42	C4	0.735	Outlier				
	D4	0.753	Outlier				

Outlier - Outside standard range

ASSAY EXAMPLE

COVID-19 IgM Measurement in 12 Serum Samples in Duplicate



Introduction

KT-1033 COVID-19 IgM
4-5-2020

12 Sample (RH) Measurement

Kit Lot:
Plate: P684
Positive Control: 3-12-2020 Glass Bottle
Negative control: P
Tracer Ab: P631
Sample Diluent: P632
Wash Conc.: P516
TMB: E089
Stop: P634

Experiment#1

Plate#1

	1	2	3	4
A	0.096	0.335	0.087	0.535
B	0.092	0.339	0.098	0.552
C	0.083	1.732	0.590	0.789
D	1.135	1.783	0.627	0.857
E	2.406	0.609	1.008	
F	2.335	0.509	0.818	
G	0.788	0.092	0.486	
H	0.839	0.118	0.529	

Endpoint
Lm1 450
Automix: Off
Calibrate: On
Plate Last Read:
5:29 PM 4/5/2020

Wavelength Combination: !Lm1
Data Mode: Absorbance

4/5/2020 5:31:25 PM 5-2020 COVID-19 Sample Measureme 1
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Controls

Sample	Wells	Sample#	Values	Concentration	MeanValue	BackConcCalc	% Recovery
Co01	A1	1	0.088		0.088		
	B1		0.092				
	C1		0.083				
Co02	D1	2	1.135		1.135		

Unknowns

Sample	Wells	Values	Outliers	Result	MeanResult	Std Dev.	CV%
Un31	E1	2.406	Outlier				
	F1	2.335	Outlier				
Un32	G1	0.788	Outlier				
	H1	0.839	Outlier				
Un33	A2	0.336	Outlier				
	B2	0.339	Outlier				
Un34	C2	1.732	Outlier				
	D2	1.783	Outlier				
Un35	E2	0.609	Outlier				
	F2	0.509	Outlier				
Un36	G2	0.092	Outlier				
	H2	0.118	Outlier				
Un37	A3	0.087	Outlier				
	B3	0.098	Outlier				
Un38	C3	0.590	Outlier				
	D3	0.627	Outlier				
Un39	E3	1.008	Outlier				
	F3	0.818	Outlier				
Un40	G3	0.486	Outlier				
	H3	0.529	Outlier				
Un41	A4	0.535	Outlier				
	B4	0.552	Outlier				
Un42	C4	0.789	Outlier				
	D4	0.857	Outlier				

Outlier - Outside standard range

4/5/2020 5:30:38 PM 5-2020 COVID-19 Sample Measureme
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ASSAY CLINICAL PERFORMANCE

COVID-19 IgM/IgG Measurement in 4 Patients (All results are average from two replicates)

Donor#	Lot#	Age	Gender	Location	Symptoms Date	Date Swab Collected	Positive Result Date	Test Type	Blood Draw Dates	ELISA Ab Tested	IgG OD	IgG S/CO	IgM OD	IgM S/CO
PCR17	190629	48	M	CA	3/13/2020	3/21/2020	3/23/2020	Nasopharangeal Swab	4/4/2020	4/5/2020	0.825	2.6	0.559	2.7
PCR17	190633	48	M	CA	3/13/2020	3/21/2020	3/23/2020	Nasopharangeal Swab	4/5/2020	4/5/2020	0.896	2.8	0.544	2.6
PCR18	190628	53	F	CA	3/20/2020	3/27/2020	3/28/2020	Nasopharangeal Swab	4/4/2020	4/5/2020	0.936	2.9	0.609	2.9
PCR18	190632	53	F	CA	3/20/2020	3/27/2020	3/28/2020	Nasopharangeal Swab	4/5/2020	4/5/2020	0.900	2.8	0.507	2.5
PCR19	190630	44	F	CA	3/16/2020	3/21/2020	3/22/2020	Nasopharangeal Swab	4/4/2020	4/5/2020	0.263	2.6	1.758	8.5
PCR19	190634	44	F	CA	3/16/2020	3/21/2020	3/22/2020	Nasopharangeal Swab	4/5/2020	4/5/2020	0.744	2.3	0.823	4
tbd	190631	51	M	CA	3/28/2020	pending	pending	pending	4/4/2020	4/5/2020	0.794	2.5	0.814	3.9
tbd	190635	51	M	CA	3/28/2020	pending	pending	pending	4/5/2020	4/5/2020	0.368	1.2	2.416	11.7

IgG
Positive Cut Off: 0.319
Negative Cut Off: 0.261

IgM
Positive Cut Off: 0.207
Negative Cut Off: 0.169

COVID-19 IgM/IgG Measurement in PCT Confirmed Patient Sera (All results are average from two replicates)

Donor#	Lot#	Age	Gender	Location	Symptoms Date	Date Swab Collected	Positive Result Date	PCR Test Type	Blood Draw Dates	IgG OD	Ratio of IgG OD/Cut Off	IgM OD	Ratio of IgM OD/Cut Off
PCR10	190679	50	F	CO	3/20/2020	3/24/2020	3/28/2020	SARS CORONAVIRUS W/CoV 2 RNA,QL REAL TIME RT PCR	4/7/2020	1.474	4.1	0.253	1.3
PCR15	190791	38	M	CA	3/17/2020	3/24/2020	3/28/2020	Real Time RT-PCR	4/11/2020	0.702	2.0	0.095	0.5
PCR17	190790	48	M	CA	3/13/2020	3/21/2020	3/23/2020	Nasopharangeal Swab	4/11/2020	1.618	4.5	0.297	1.5
PCR23	190774	34	F	MA	3/14/2020	3/16/2020	3/18/2020	cobas (R) SARS-CoV-2	4/8/2020	0.696	1.9	0.131	0.6
PCR24	190776	57	M	CA	3/12/2020	3/13/2020	3/17/2020	SARS CORONAVIRUS W/CoV 2 RNA, REAL TIME RT PCR	4/9/2020	1.243	3.5	0.175	0.9
PCR25	190680	49	M	PA	3/13/2020	3/20/2020	3/27/2020	cobas (R) SARS-CoV-2	4/6/2020	1.764	4.9	0.129	0.6
PCR25	190773	49	M	PA	3/13/2020	3/20/2020	3/27/2020	cobas (R) SARS-CoV-2	4/7/2020	1.773	5.0	0.105	0.5
PCR25	190778	49	M	PA	3/13/2020	3/20/2020	3/27/2020	cobas (R) SARS-CoV-2	4/8/2020	1.846	5.2	0.101	0.5
PCR26	190681	36	F	PA	3/16/2020	3/20/2020	3/26/2020	cobas (R) SARS-CoV-2	4/6/2020	1.490	4.2	0.311	1.5
PCR26	190772	36	F	PA	3/16/2020	3/20/2020	3/26/2020	cobas (R) SARS-CoV-2	4/7/2020	1.699	4.7	0.230	1.1
PCR26	190779	36	F	PA	3/16/2020	3/20/2020	3/26/2020	cobas (R) SARS-CoV-2	4/8/2020	1.681	4.7	0.304	1.5
PCR27	190685	33	M	PA	3/11/2020	3/12/2020	3/15/2020	Labtest SARS-CoV-2, NAA	4/7/2020	0.666	1.9	0.059	0.3
PCR28	190684	40	F	PA	3/24/2020	3/26/2020	3/27/2020	cobas (R) SARS-CoV-2	4/6/2020	0.571	1.6	0.082	0.4
PCR28	190785	40	F	PA	3/24/2020	3/26/2020	3/27/2020	cobas (R) SARS-CoV-2	4/8/2020	0.540	1.5	0.087	0.4
PCR29	190683	25	F	PA	3/17/2020	3/26/2020	3/27/2020	cobas (R) SARS-CoV-2	4/6/2020	1.844	5.2	0.607	3.0
PCR29	190784	25	F	PA	3/17/2020	3/26/2020	3/27/2020	cobas (R) SARS-CoV-2	4/8/2020	1.699	4.7	0.639	3.2
PCR30	190682	25	M	PA	3/16/2020	3/28/2020	4/2/2020	cobas (R) SARS-CoV-2	4/6/2020	1.869	5.2	1.896	9.4
PCR30	190781	25	M	PA	3/16/2020	3/28/2020	4/2/2020	cobas (R) SARS-CoV-2	4/8/2020	1.676	4.7	1.918	9.5
PCR31	190775	46	M	CA	3/11/2020	3/14/2020	3/19/2020	Real Time RT-PCR	4/8/2020	1.091	3.0	0.138	0.7
PCR31	190777	46	M	CA	3/11/2020	3/14/2020	3/19/2020	Real Time RT-PCR	4/9/2020	1.559	4.4	0.106	0.5
PCR32	190780	33	M	KS	3/16/2020	3/18/2020	3/20/2020	Nasopharangeal Swab	4/8/2020	0.949	2.7	0.879	4.4
PCR33	190786	51	F	CA	3/23/2020	3/25/2020	3/26/2020	Labtest SARS-CoV-2, NAA	4/11/2020	1.569	4.4	0.143	0.7
PCR34	190787	31	M	CA	3/11/2020	3/18/2020	3/26/2020	Real Time RT-PCR	4/11/2020	0.268	0.7	0.086	0.4
PCR35	190788	45	F	CA	3/25/2020	3/30/2020	3/30/2020	Nasopharangeal Swab	4/11/2020	1.862	5.2	0.137	0.7
PCR36	190789	32	F	CA	3/25/2020	3/31/2020	4/1/2020	Labtest SARS-CoV-2, NAA	4/11/2020	0.174	0.5	0.068	0.3

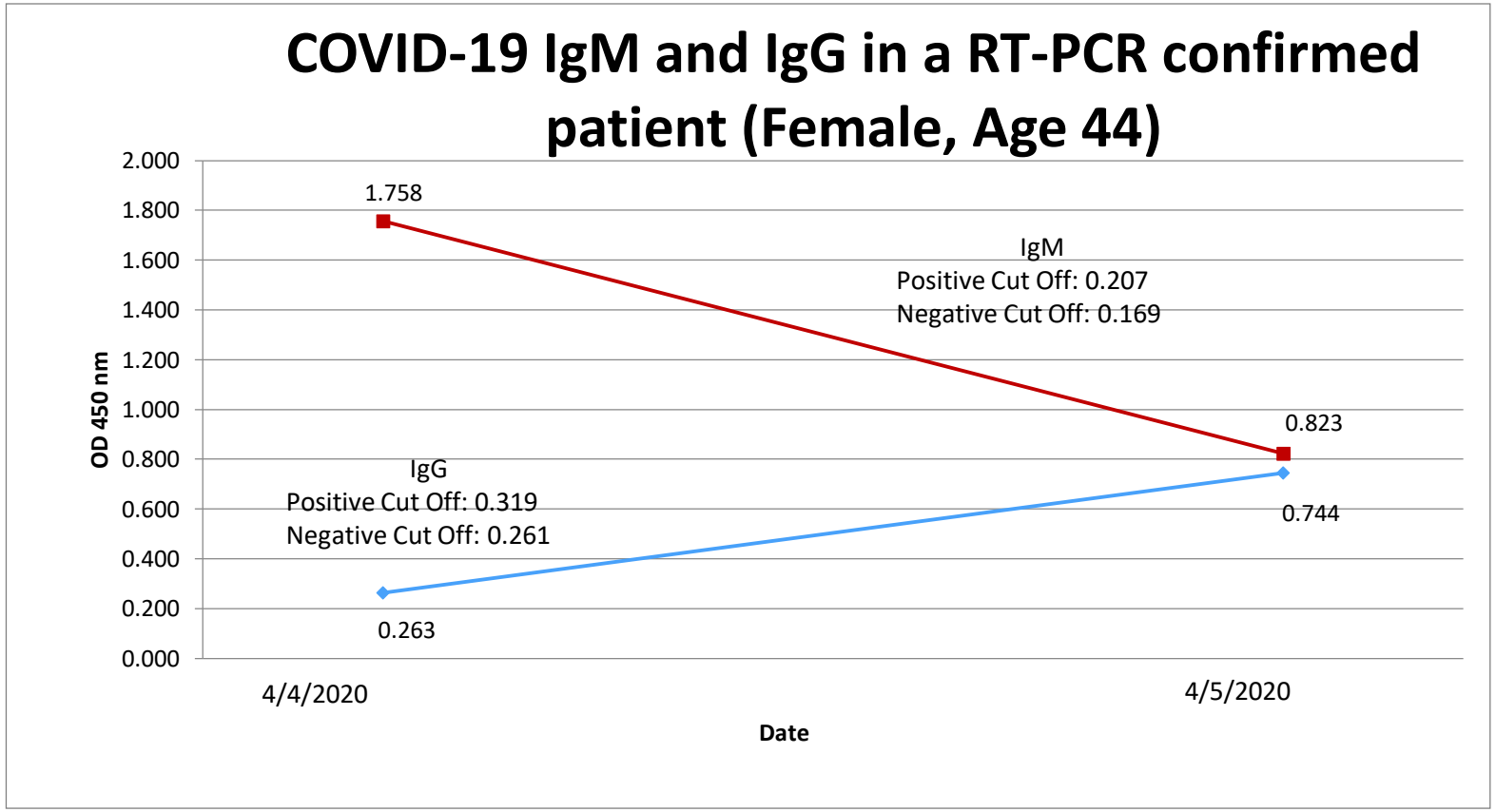
IgG
Positive Cut Off: 0.358
Negative Cut Off: 0.293

IgM
Positive Cut Off: 0.202
Negative Cut Off: 0.166

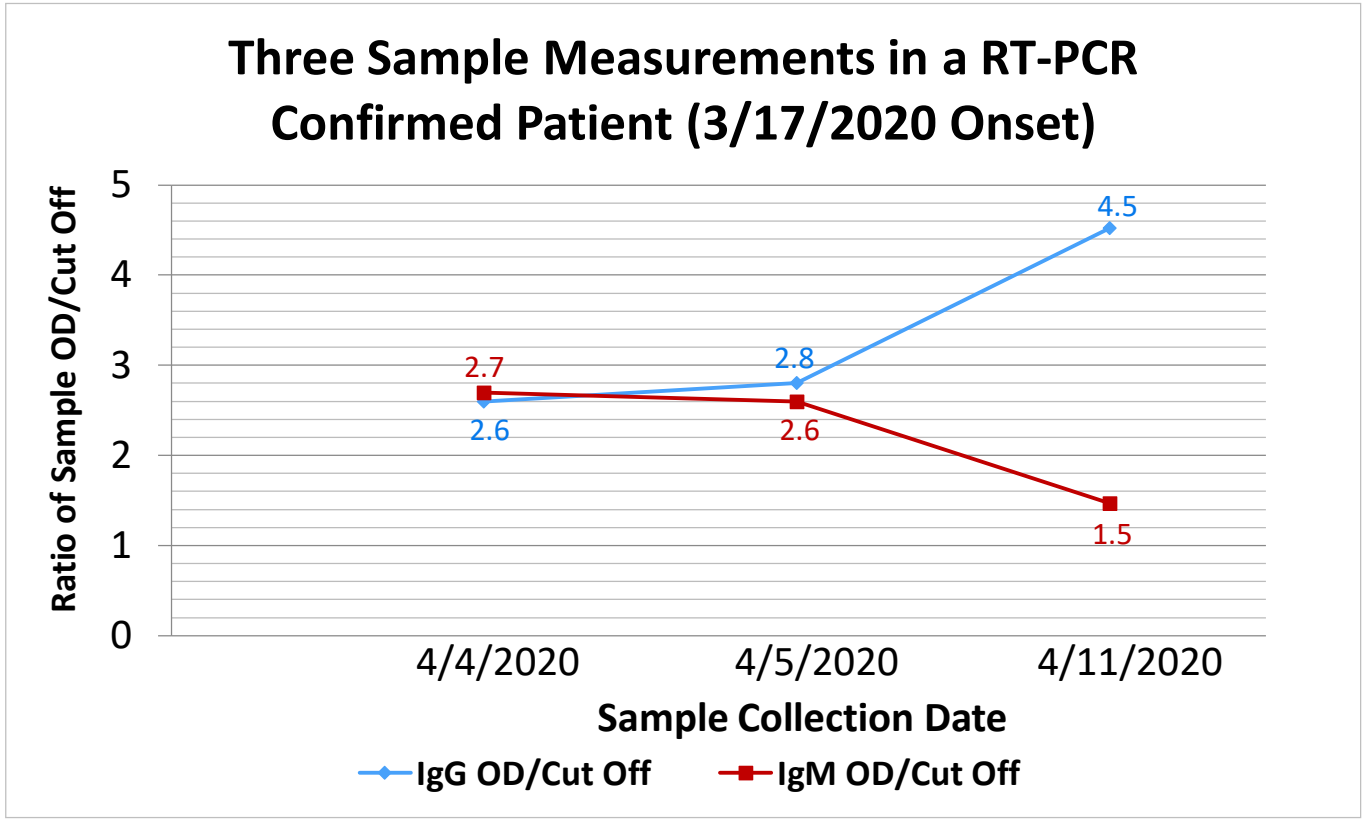
Ratio of Sample OD/Cut Off:
Positive: ≥ 1.0
Negative: < 1.0

ASSAY CLINICAL PERFORMANCE

Two Serum Samples from One US COVID-19 Patient (PCR 19)



Three Serum Samples Collected and Measured in Different days from One US COVID-19 Patient (PCR 17)



Note: The results are presented in a ratio of sample OD/assay cut off. The Positive result should have the ratio equal and greater than 1.0.

Study of Two Clinically Cured COVID-19 Patients

Test Class	IgG	IgM
	Positive Cut Off: 0.349 Negative Cut Off: 0.286	Positive Cut Off: 0.226 Negative Cut Off: 0.185
Patient 1	**1.621**	**0.142**
Patient 2	**1.389**	**0.127**

Summary:

- IgG remains highly positive
- IgM is negative
- Multiple RT-PCR tests were negative
- No clinical symptom

UTILIZATION FOR THE CORONAVIRUS RESPONSE

KT-1032 *EDI™* Novel Coronavirus COVID-19 IgG ELISA Kit

IgG is the most abundantly found immunoglobulin to be produced in response to an antigen and will be maintained in the body after initial exposure for long term response *

Principle	Indirect Method
Sample Type	Serum
Sample Volume	10 µL
Assay Incubation	80 minutes, RT
Total Wash Steps	2
Limit of Detection	5IU/mL
Repeatability	CV < 15%
Reproducibility	CV < 20%

- Utilizes an immunocomplex of "COVID-19 recombinant antigen – human anti-COVID-19 IgG antibody - HRP labeled anti-human IgG tracer antibody" is formed if there is coronavirus IgG antibody present in the tested materials.

- Can easily be converted to quantitative to aid in the development of IgG-based treatments for COVID-19

*Wu, L.-P., Wang, N.-C., Chang, Y.-H., Tian, X.-Y., Na, D.-Y., Zhang, L.-Y., … Liang, G.-D. (2007). Duration of Antibody Responses after Severe Acute Respiratory Syndrome. Emerging Infectious Diseases, 13(10), 1562–1564. doi: 10.3201/eid1310.070576

UTILIZATION FOR THE CORONAVIRUS RESPONSE

KT-1033 *EDI™* Novel Coronavirus COVID-19 IgM ELISA Kit

IgM is the first immunoglobulin to be produced in response to an antigen and will be primarily detectable during the early onset of the disease*

Principle	Capture Method
Sample Type	Serum
Sample Volume	20 µL
Assay Incubation	80 minutes, 37 ºC
Total Wash Steps	2
Limit of Detection	5IU/mL
Repeatability	CV < 15%
Reproducibility	CV < 20%

- Utilizes an immunocomplex of “Anti-hIgM antibody - human COVID-19 IgM antibody - HRP labeled COVID-19 antigen" if there is novel coronavirus IgM antibody present in the tested materials.

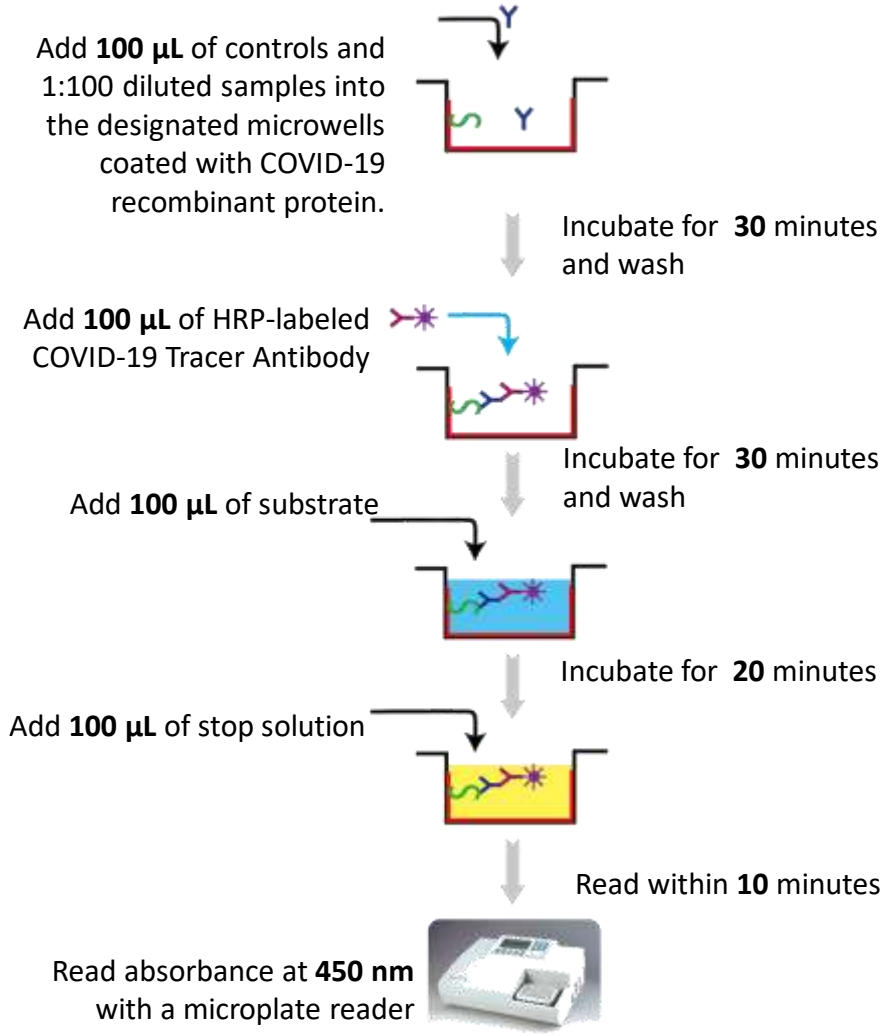
- National Health Commission of the People's Republic of China states that IgM antibodies begin to show positive after 3-5 days of onset of COVID-19.

*Wu, L.-P., Wang, N.-C., Chang, Y.-H., Tian, X.-Y., Na, D.-Y., Zhang, L.-Y., … Liang, G.-D. (2007). Duration of Antibody Responses after Severe Acute Respiratory Syndrome. Emerging Infectious Diseases, 13(10), 1562–1564. doi: 10.3201/eid1310.070576

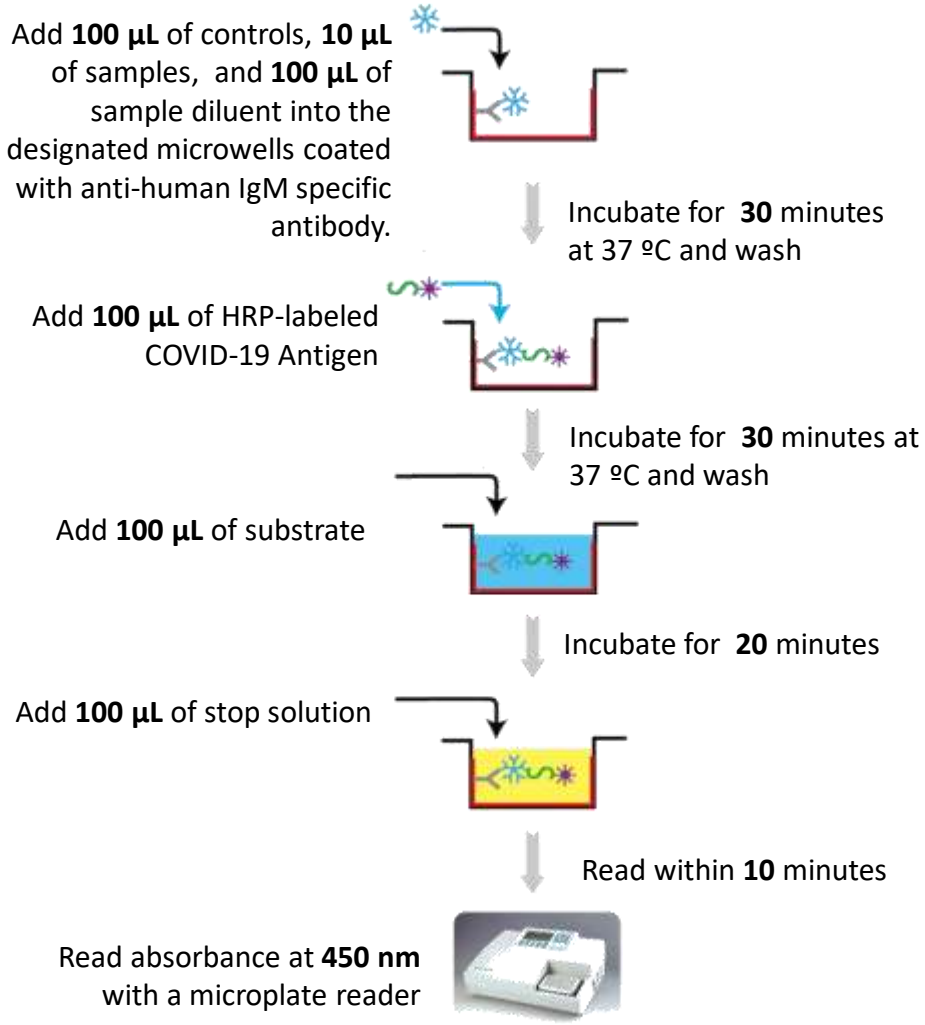
UTILIZATION FOR THE CORONAVIRUS RESPONSE

Assay Protocols

KT-1032 *EDI™* Novel Coronavirus COVID-19 IgG ELISA Kit



KT-1033 *EDI™* Novel Coronavirus COVID-19 IgM ELISA Kit



UTILIZATION FOR THE CORONAVIRUS RESPONSE

Interpretation of Assay Results

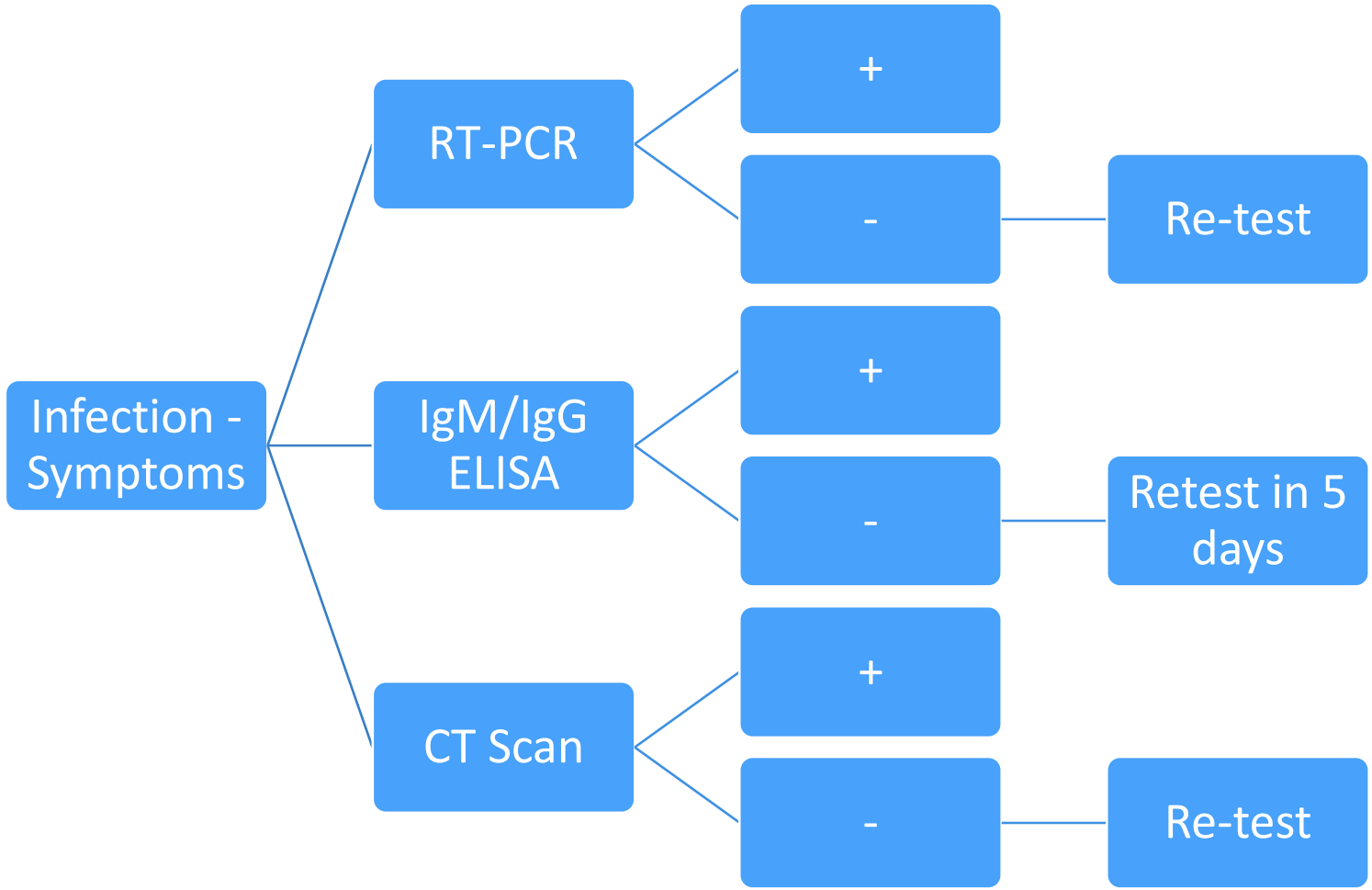
Defined assay cut-off to minimize inter-assay and inter-lab OD differences.

1. Calculate the average value of the absorbance of the negative control (xNC).
2. Calculate the cutoffs using the following formulas:
   - IgG Positive Cutoff = 1.1 X (xNC + 0.18)
   - IgG Negative Cutoff = 0.9 X (xNC +0.18);
   - IgM Positive Cutoff = 1.1 X (xNC + 0.1)
   - IgM Negative Cutoff = 0.9 X (xNC +0.1)
3. Determine the interpretation of the sample by comparing the OD to the following table:

Interpretation	Interval	Results
Negative	Measured value ≤ negative cutoff	The sample does not contain the new coronavirus (COVID-19) related antibody
Positive	Measured value ≥ positive cutoff	The sample contains novel coronavirus (COVID-19) associated antibodies.
Borderline	negative cutoff ‹ Measured value ‹ positive cutoff	Retest the sample in conjunction with other clinical tests.

UTILIZATION FOR THE CORONAVIRUS RESPONSE

Clinical Algorithm



UTILIZATION FOR THE CORONAVIRUS RESPONSE

Recognized by Government Agencies

"Suspected cases with one of the following etiology or serological evidence:

1. Real-time fluorescent RT-PCR detection of new coronavirus nucleic acid positive;
2. Viral gene sequencing, highly homologous to known new coronaviruses;
3. Serological Antibody Test:

- Serum new coronavirus-specific IgM antibodies and IgG antibodies were positive;
- Serum new coronavirus-specific IgG antibodies turned positive from negative or
- The positive IgG value turned 4 times or higher in the recover phase than acute phase."

National Health Commission of the People's Republic of China

New Coronavirus Pneumonia Diagnosis and Treatment Program (Trial Version 7)

UTILIZATION FOR THE CORONAVIRUS RESPONSE

Recognized by Government Agencies

Rule Out **Suspect Patients** to be Negative for COVID-19, the following two laboratory results should be satisfied.

1. Two times 2019-nCOV RT-PCR negative with specimen collected minimum 24 hours apart.
2. The COVID-19 IgM and IgG must be negative after 7 days of disease onset.

National Health Commission of the People's Republic of China

New Coronavirus Pneumonia Diagnosis and Treatment Program (Trial Version 7)

UTILIZATION FOR THE CORONAVIRUS RESPONSE

Recognized by Government Agencies

FDA has allowed for distribution under Section D of Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency.

Our kits are registered under product code QKO, our submission number is D376537. Our establishment registration number is 2032839.

Per the aforementioned guidance, the following statements are required:
•This test has not been reviewed by the FDA.
•Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus.
•Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
•Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
•Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.

This kit is only provided for use by clinical laboratories or to healthcare workers for point-of-care testing, and **not** for at home testing.

UTILIZATION FOR THE CORONAVIRUS RESPONSE

Benefits of ELISA Testing

- IgM and IgG tests can be combined for efficient clinical diagnosis at multiple stages.
- Established industry technology.
- Easy-to-use and cost efficient product.
- Minimal error in sample handling.
- Low risk and low incidence of cross-contamination.

MANUFACTURING CAPABILITY AND TIMELINE

Easily and continuously scalable.

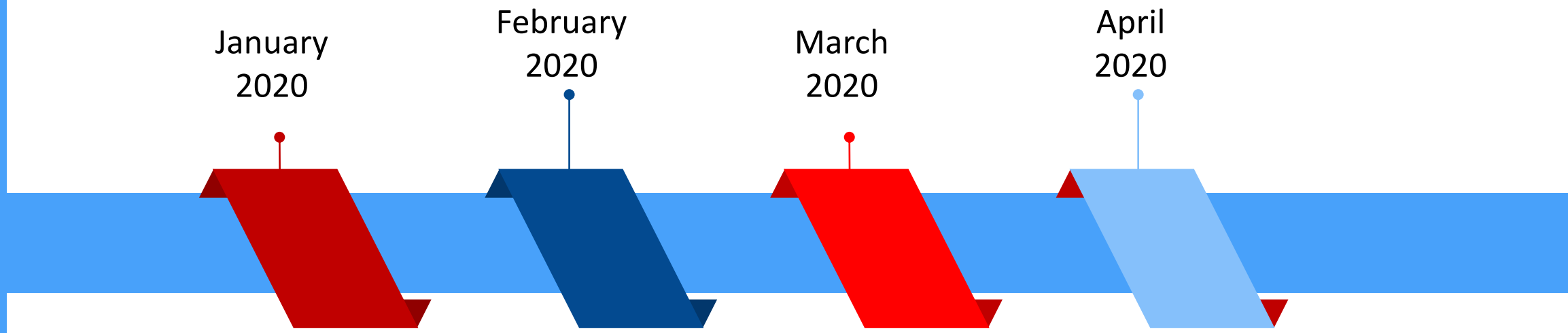
500,000 Tests/Week

With potential up to 1,000,000 Tests/Week

- ***US-Based Manufacturing***
- ***Materials sourced from the US***
- ***ISO 13485 certified facility***
- ***cGMP manufacturing***

REGULATORY STRATEGY

United States, Europe, and Beyond



January 2020

- Product Development

February 2020

- Product Finalized
- Clinical Testing (China CDC, Hangzhou University)
- European CE Mark
- ANVISA

March 2020

- FDA EUA Submission
- Clinical Testing

April 2020

- Post Market Surveillance