New IgG/IgM Antibody Test for COVID-19

Brent Dorval PhD

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in collaboration with

KBMO Diagnostics

Professional Education with Dr. Kara Fitzgerald:

- Teach-Ins with expert colleagues
- A chance to build your Functional Medicine community
- Please use the Q&A Box to submit your questions.

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Brent Dorval, PhD

- Founder and Chief Scientific Officer –KBMO Diagnostics
- Invented first 60 second HIV Diagnostic
- Advisor to WHO Vaccines and Diagnostics Committee in Geneva

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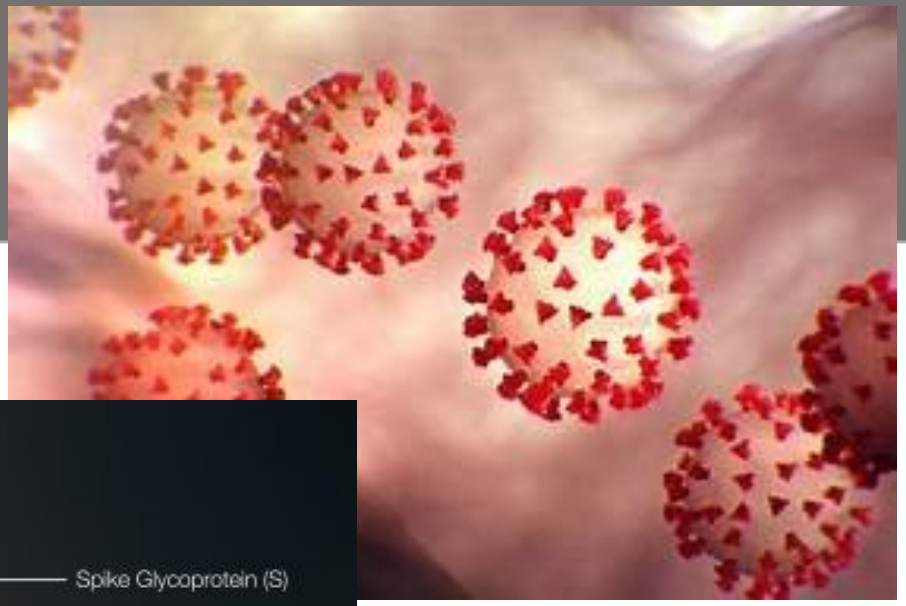
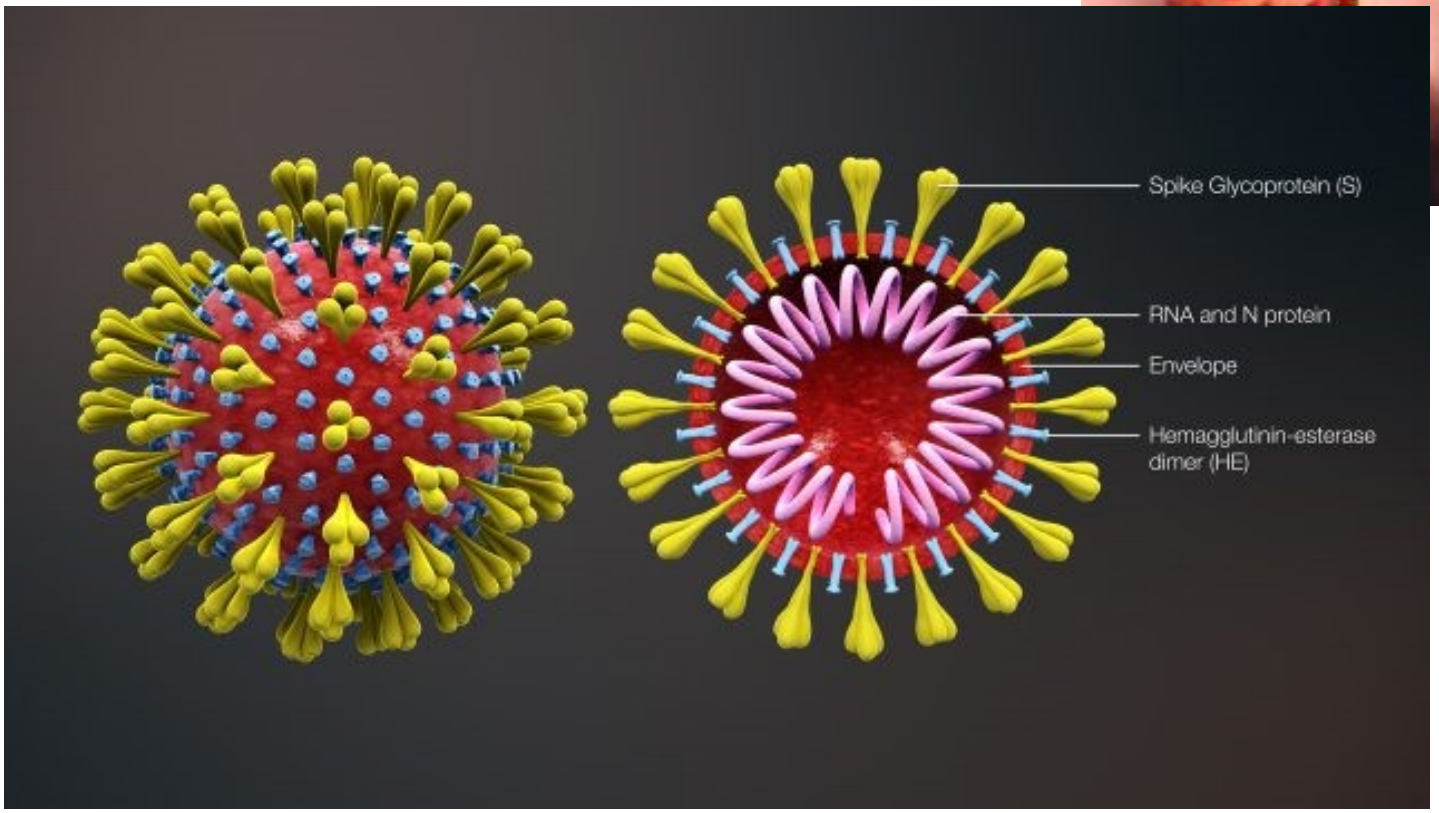
COVID-19 ASSAY





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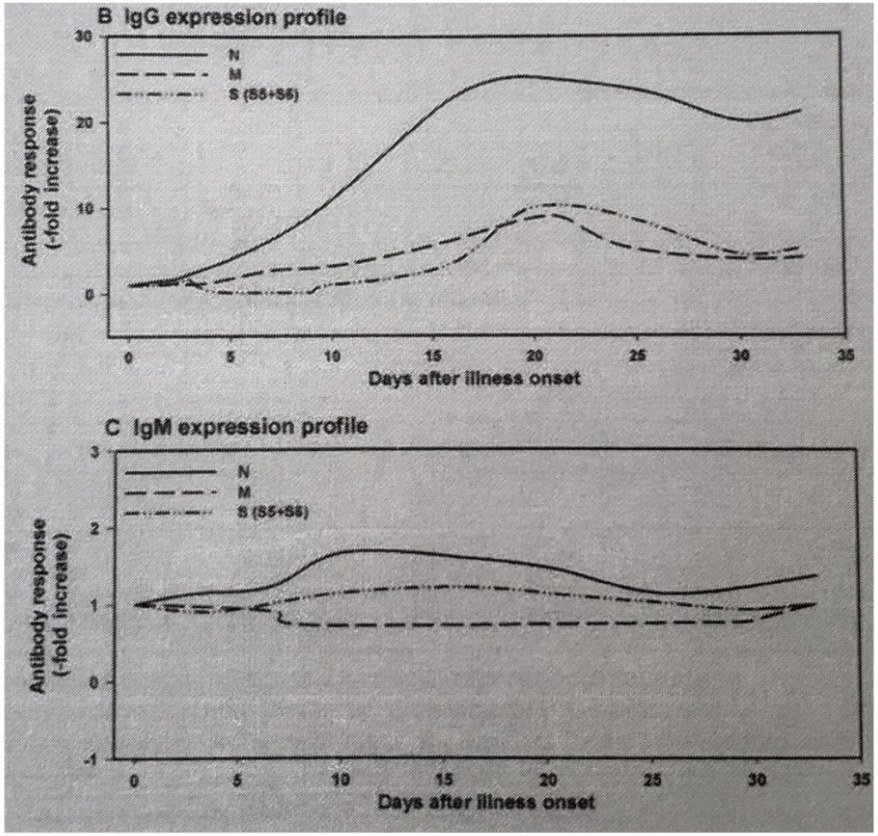
Why we test for IgG and IgM?

Antibody Response to SARS-CoV Proteins During Infection
NucleoProtein (N), Membrane (M), Spike (S)
Wu et.al. J Biomed Sci 2004, 11:117-126



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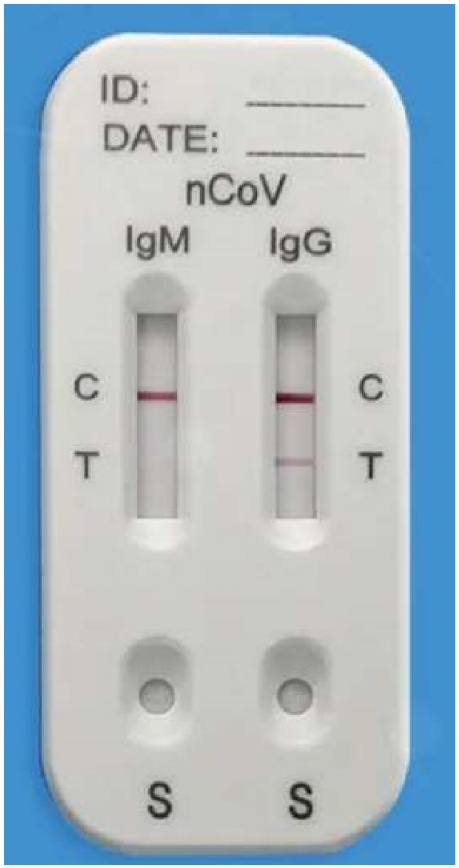
Current Laboratory Diagnostic Methods

	Advantages	Limitations
Isolation & Culture	Golden Standard	• Time-consuming (about 1 week) • Easily polluted
Nucleic Acid Detection	Early diagnosis with high sensitivity and specificity	• High requirements for lab condition • Expensive
Antigen Detection	Direct evidence of infection	• High skills required for operators • Specimen quality may affect the result easily.
IgM Antibody Detection	Earliest serum antibody with high sensitivity and specificity	• Individual differences and low immunity may delay antibody emergence.
IgG Antibody Detection	• Past/Secondary infection • Retrospective diagnosis reference	• Developed later

Principle

The kit detects 2019-nCoV IgM and IgG antibodies by immuno- capture method. The nitrocellulose membrane is coated by mouse-anti human monoclonal IgM antibodies, mouse-anti human monoclonal IgG antibodies, and goat-anti-mouse IgG antibodies. The recombinant 2019-nCoV antigen and mouse IgG antibodies are labeled with colloidal gold as a tracer. The antibodies will bind to colloidal gold-coated 2019- nCoV antigens to form compounds, which are further captured by pre-coated mouse-anti human IgM antibodies to form new compounds and generate purple line (T). The binding of colloidal gold-labeled mouse IgG antibodies with goat-anti-mouse IgG antibodies will present purple line, which is used as the control line(C).



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Clinical Data used for CFDA approval

The clinical trial of this product is based on the clear diagnosis / exclusion criteria of the disease identified in the “Novel Coronavirus Pneumonia Diagnosis and Treatment Program“ developed by the Chinese CDC.

Clinical research was conducted in 5 institutions and the total cases were 447.

Using this kit, 110 cases out of 126 clinically confirmed cases are positive, with the sensitivity of 87.3% (95% CI: 80.40% to 92.0%); 62 cases of clinically excluded cases are totally negative with the specificity of 100% (95% CI: 94.20% to 100%).

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Recent Peer Reviewed Data

The COVID-19 IgM/IgG Rapid Test was used in a cohort of 304 clinically diagnosed patients

ZHANG Wenjian et al.: http://www.nhc.gov.cn/yzygj/s7652m/202003/a31191442e29474b98bfed5579d5af95.shtml

Group I.	**PCR Positive and Antibody Positive:**	34.5% (105/304)
IgM only:	76.2%	early infection
IgG only:	86.6%	late infection/convalescent phase
IgM and IgG:	96.1%	transition phase
Group II.	**PCR Negative but Antibody Positive:**	41.4% (126/304)
IgM only:	69.2%	early infection
IgG only:	98.3%	late infection/convalescent phase
IgM and IgG:	100%	transition phase
Group III.	**PCR and IgG Negative:**	24.0% (73/304)

FUO: fever of unknown origin but not as a result of COVID-19

Conclusion: the COVID-19 rapid test is clinically useful and more predictive than PCR

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Our Test could be used in the absence of PCR?

The COVID-19 IgM/IgG Rapid Test was used in a cohort of 202 healthy or fever patients

ZHANG Wenjian et al.: http://www.nhc.gov.cn/yzygj/s7652m/202003/a31191442e29474b98bfed5579d5af95.shtml

PCR testing was not used or not available in this cohort of patients

IgM only:	99.0%	early infection
IgG only:	98.0%	late infection/convalescent phase
IgM and IgG:	99.0%	transition phase

Conclusion: the COVID-19 rapid test is clinically useful in the absence of PCR testing

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Chinese Regulatory Approvals

中华人民共和国
PEOPLE'S REPUBLIC OF CHINA
医疗器械产品出口销售证明
CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS

证书编号：冀唐药监械出 20200007
Certificate NO.: Certificate of medical device exports made in Tangshan issued by Hebei Drug Supervision Administration No. 20200007

产品名称：详见附表
Product(s): Details as per attached list.

规格型号：详见附表
Model: Details as per attached list.

产品注册或备案凭证号：详见附表
Registration certificate(s): Details as per attached list.

生产企业：英诺特（唐山）生物技术有限公司
Manufacturer: Innovita (Tangshan) Biological Technology Co., Ltd.

生产企业住所：河北省迁安市高新技术产业开发区聚鑫街 699 号
Address of manufacturer: No. 699, Juxin Street, High-tech Industrial Development Zone, Qian'an, Hebei.

生产许可或备案凭证号：冀食药监械生产许 20150033 号
Manufacturing License(s): Hebei Province Food And Drug Supervision Administration of Medical Device Manufacturing License No. 20150033

兹证明上述产品已准许在中国生产和销售。 This is to certify that the above products have been registered to be manufactured and sold in China.

证明有效日期至： 2021 年 02 月 21 日
This certification valid until: Feb. 21, 2021

备注：
Remark:

2020 年 02 月 27 日
（出具单位盖章）

附表

序号	产品名称 中文 /Chinese	产品名称英文 /English	规格型号 中文 /Chinese	规格型号 英文 /English	注册证号 中文 /Chinese	注册证号英文 /English
1	新型冠状病毒（2019-nCoV）抗体检测试剂盒（胶体法）	2019-nCov Ab Test (Colloidal Gold)	20 人份/盒，40 人份/盒	20T/box, 40T/box	国械注准 20203400177	Registration of Medical Devices approved by China Food and Drug Supervision Administration No. 20203400177

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2m tests run in Wuhan to date…

Peking University Third Hospital	Hubei Provincial Hospital of Integrated Traditional Chinese and Western Medicine
Beijing Friendship Hospital	Wuhan Xiehe Hospital
Beijing Youan Hospital	Hubei Provincial Hospital of Traditional Chinese Medicine
Beijing Chaoyang Hospital	Wuhan Children's Hospital
Beijing Armed Police General Hospital	Wuhan Fangcai Hospital
Children's Hospital of Fudan University	Beijing Children's Hospital
Shanghai Xinhua Hospital	Capital Institute of Pediatrics
Shanghai Children's Medical Center	Shanghai Xinhua Hospital
Shanghai Children's Hospital	Affiliated Children's Hospital of Fudan University
Henan Provincial Center for Disease Control	Shanghai Children's Hospital
Guangdong Provincial Center for Disease Control	Suzhou Children's Hospital
Sichuan Provincial Center for Disease Control	Xuzhou Children's Hospital
Beijing Centers for Disease Control	Tianjin Children's Hospital
Disease Control Center of Shanxi Province	Shenyang Children's Hospital
Wuhan Tongji Hospital	Children's Hospital of Hebei Province

Distribution Table of 2019-nCoV Ab Test

No.	Receiving agency	Quantity (PCS)
1	Union Hospital, Tongji Medical College, Huazhong University of Science and Technology	7,000
2	Tongji Hospital, Tongji Medical College, Huazhong University of Science and Technology	7,000
3	People's Hospital of Wuhan University	7,000
4	Zhongnan Hospital of Wuhan University	7,000
5	Wuhan First Hospital	2,000
6	Wuhan Central Hospital	1,000
7	Wuhan Third Hospital	2,000
8	Wuhan Fourth Hospital	2,000
9	Wuhan Children's Hospital	1,000
10	Wuhan Hospital of Traditional Chinese Medicine	1,000
11	Wuhan Hankou Hospital	2,000
12	Wuhan Wuchang Hospital	2,000
13	Wuhan Pulmonary Hospital	2,000
14	Wuhan Jinyintan Hospital	2,000
15	Wuhan Red Cross Hospital	1,000
16	Wuhan Ninth Hospital	1,000
17	Dongxihu District People's Hospital	1,000
18	Wuhan Mental Health Center	1,000
19	Wuhan Wudong Hospital	500
20	Wuhan Donghu Hospital	500
	Total	50,000

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US Regulatory Approvals

FDA U.S. FOOD & DRUG ADMINISTRATION

Acknowledgment Letter

3/22/2020

The Commonwealth of Massachusetts

DEPARTMENT OF PUBLIC HEALTH

DIVISION OF HEALTH CARE FACILITY LICENSURE AND CERTIFICATION

CLINICAL LABORATORY LICENSE

In accordance with the provisions of the General Laws, Chapter 111D and regulations established thereunder, a license is hereby granted to

KBMO DIAGNOSTICS LLC

56 DEPOT STREET, DUXBURY, MA 02331

for the maintenance of

KBMO DIAGNOSTICS 5393

4 BUSINESS WAY, HOPEDALE, MA 01747

Classification: FULL

Immunology Non-Syphilis; Clinical Chemistry Routine Chemistry

LICENSE № 5393 is valid from June 16, 2019 to June 15, 2021 subject to revocation for cause.

JUNE 16, 2019

POST CONSPICUOUSLY

CENTERS FOR MEDICARE & MEDICAID SERVICES

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

CERTIFICATE OF COMPLIANCE

LABORATORY NAME AND ADDRESS
KBMO DIAGNOSTICS
4 BUSINESS WAY
HOPEDALE, MA 01747

CLIA ID NUMBER
22D2095272

EFFECTIVE DATE
10/16/2019

LABORATORY DIRECTOR
JIA HE PHD, NRCC, MB

EXPIRATION DATE
10/15/2021

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.

This certificate shall be valid until the expiration date above, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.

CMS CENTERS FOR MEDICARE & MEDICAID SERVICES

Karen W. Dyer, Director
Division of Laboratory Services
Survey and Certification Group
Center for Clinical Standards and Quality

17 certs2_092419

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How to get a C-19 kit

- The serum test is available now via the website: https://kbmodiagnostics.com/
- The test we launch with will be a blood draw and then we will be validating the fingerstick in the next week
- The price is $100 plus $50 which includes overnight shipping to the client and back
- Payment is required before we ship the test kit out
- The Turnaround time is 24-48 hours from arriving at the Lab
- If you are not a Provider you need to set up and account by contacting KBMO Diagnostics or going to our website
- Patient results will be uploaded to the Provider's Box.com folder a HIPPA compliant CLOUD

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At Home Phlebotomy Services

We have over 6000 carefully selected phlebotomists in or database. We cover almost every city in the United States.

The prices for mobile phlebotomy services

- Single draw: $100.00
- Multiple draws; $100.00 for first and $50.00 for each additional at same location
- Hourly draws (3 hour minimum) $100.00 per hr

PLEASE CONTACT the link below to schedule

https://shop.evexiadiagnostics.com/ provide:

Patient Name and address and availability and phone number for the patient

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For more resources on COVID19 visit

https://www.drkarafitzgerald.com/covid-19/

For more professional development opportunities visit drkfeducation.com

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