Abbot Genetics Rapid Serology Antibody Testing Solutions

27 July 2020

Abbot Genetics Inc. (AG, https://abbotgenetics.com/) is a U.S.-based early-stage In Vitro Diagnostics Company on the front end of the fight to combat the ravaging effects of the coronavirus. AG technology will be essential in putting people back to work, providing post-pandemic influenza/COVID-19 antibody testing solutions to mitigate future outbreaks, and keeping people working. AG's COVID-19 Antibody Test Kits are in use worldwide **with over 100+ million Point of Care (POC) tests**—the most significant usage of any company.

The Harvard Global Health Institute states that the **USA needs a minimum of 30 million tests per week (4,300,000 per day) to suppress new infections and keep them low enough to open public life again safely**. As of 1 July 2020, current testing in the USA is less than 600,000 tests/day, which is half the number the "mitigation goal" to suppress virus growth. [i]

Mass screening and contract tracing are critical tools in opening and restoring local, state, and national economies. New Delhi (India) is currently conducting large-scale testing for its entire population (29 million) as virus cases surge across the country.[ii] During a June 2020 outbreak in Wuhan, the Chinese tested the whole population (11 million) in 10 days.[iii] Considering the recent upturn of infections in the USA, government officials would be wise to adopt similar procedures.

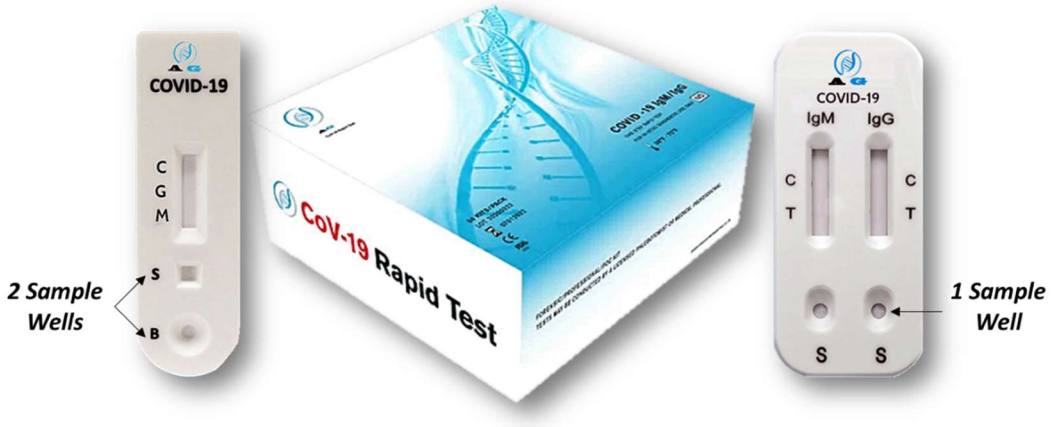
AG's global partners have a manufacturing capacity of 25 million test kits per week and customs agreements to rapidly ship (7 to 10 days) by air freight to any major American city.

AG joined forces with global partners to deliver innovative products for the detection and identification of acute and chronic infection in infected, symptomatic, and asymptomatic populations. Almost half of all infections occur during the asymptomatic stage before a person is showing signs of the virus.[iv]

On 5 March, AG delivered its first test kits to the CDC Director's office in Atlanta. On 1 April 2020, the US FDA approved AG to import and distribute AG's Rapid Serology Antibody Testing Solutions in the USA (see FDA Establishment Registration and Device Listing below). AG kits are also CE (Council of the European Union/ Conformité Européenne) Approved and Certified, as shown below. All of AG's Chinese supplier facilities/labs are on US FDA approved, CLIA certified, and CAP-accredited. AG is in the final stages of the FDA Emergency Use Authorization (FDA Submission Numbers: EUA 201212, 18 May 2020 and 201317, 20 May 2020) and 510(k) number (a notification to demonstrate that the device is as safe and effective[v]).

COVID-19 Rapid Point-Of-Care (POC) Test Kits

Combined IgM/IgG Test or Individual IgM & IgG Tests



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COVID-19 Related Tests

IgM (Immunoglobulin M) antibody that detects COVID-19 infection

IgG (Immunoglobulin G) antibody that remembers a past COVID-19 infection

There are two types of tests being used to extract data about Covid-19 Infections. The first is a Molecular Reverse Transcription Polymerase Chain Reaction (RT-PCR) Test, using a patient's nasal sample, and the other is Antibody Testing using a finger-prick blood sample. AG has two Antibody Test Kits (shown above) that use the finger-prick method that is proven to be significantly more reliable than the nasal swab method. Although Molecular Tests help identify people with an acute viral infection, Antibody Tests can decipher if and when a person has been infected and potentially developed immunity to the virus, including people who have not displayed any symptoms.

By using bio-markers from the body's immune response to COVID-19 instead of looking for the virus itself, COVID-19 IgM/IgG tests can determine if a person has been infected with the coronavirus even after the infection is no longer present. This information helps experts understand how the virus spreads through populations and how to control the continued spread of the pandemic. AG's two Rapid Test Kits (shown above) can identify the virus in an infected patient within 4-10 minutes.

Microfluidic Lab-On-A-Chip (LOC) Test Kit

IgM, IgG, CRP & SAA Tests

INFLUENZA Related Tests

CRP (C-reactive protein) an acute phase reactant in response to inflammation

SAA (Serum amyloid A) a critical inflammation marker for deciphering the lack of a virus infection

Lab-On-A-Chip is a miniaturized device that integrates onto a single chip for several analyses, bringing comprehensive laboratory solutions in two test cards, which deliver In-depth biochemical detection of COVID-19 antibodies and inflammation insights caused by colds, influenza, and other infections. The LOC uses a tiny volume of samples to perform immediate reactions within the chip. The responses vary from nucleic acid amplification and detection to cell count and immunoassays. As a result, Microfluidic Diagnostics Test Cards perform a specific range of laboratory tests at a lower cost and can benefit low-income settings and remote areas.

As opposed to being an exclusive distributor for foreign manufactured POC kits, AG is a joint venture partner in the Microfluidic Lab-On-A-Chip (LOC) Test Kit offering with plans to **manufacture this system in the United States**.

According to the CDC Director, Dr. Redfield, "Next fall and winter, we're going to have two viruses circulating, and we're going to have to distinguish between which is flu and which is the coronavirus."[vi] Consequently, the FDA &

CDC are fast-tracking, our new Microfluidic Lab-on-a-Chip test kits, that can differentiate between the coronavirus (IgM and IgG) and influenza (CRP and SAA markers).

AG's powerful Serology Antibody Test kits can be used as early indicators for determining effective screening, regardless of the time and phase of the infection. For population stratification, IgM and IgG antibodies are early indicators for determining valid selection, observing the recovery process, and collecting data on groups infected in the recent past. **These solutions are critical in monitoring the patient's disease progression and epidemiological screening of previous infections.**

On 21 April 2020, the CDC Director stated that the second coronavirus wave could be worse than the current outbreak and likely occur during the onset of the regular flu season.[vii] By adding CRP and SSA testing to our cloud-based Microfluidic Lab-On-A-Chip Test Kit, healthcare and medical professionals can determine whether a person has influenza or coronavirus. This testing will be tomorrow's new safety protocol for all first responders, medical workers, and essential employees. Unlike sputum (nose and throat culture) tests, AG's finger-prick blood tests are 99% accurate (see Clinical Evaluation Results at https://abbotgenetics.com/coronavirus-tests) within 10-minutes for the patient as well as online medical and diagnostic professionals.

By using bio-markers from the body's immune response to COVID-19 instead of looking for the virus itself, the COVID-19 IgM/IgG test can help determine if a person has been infected with the coronavirus even after the infection is no longer present. This information helps experts understand how the virus spreads through populations. It also improves our strategic approach to control the spread of the pandemic.

Abbot Genetics offers solutions that meet or exceed the highly critical objectives necessary to reduce the clinical impact of this current pandemic, thereby, presenting and prioritizing a controlled 'return-to-work' strategy that serves our national interests.

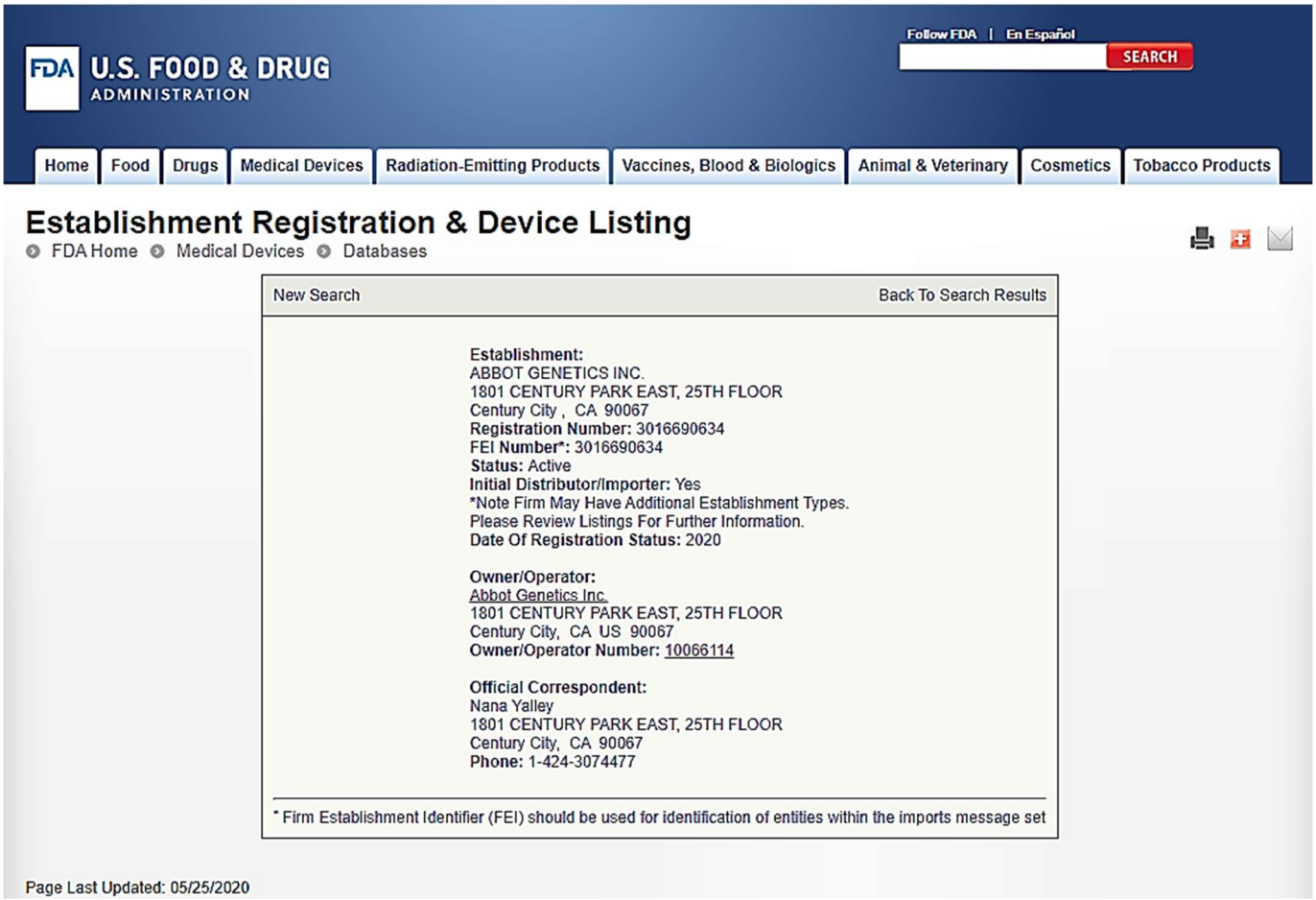
Points of Contact:

Charles D. (Chuck) Vollmer, EVP Strategic Services, Washington DC Office
703-407-4747 cell, chuck.vollmer@Jobenomics.com (primary),
chuck@AbbotGenetics.com

Nana Yalley, Chairman & CEO, Los Angeles Office
424-307-4477 office, nana@AbbotGenetics.com

FDA Establishment Registration and Device Listing

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm?rid=247819



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Establishment:
ABBOT GENETICS INC.
1801 CENTURY PARK EAST, 25TH FLOOR
Century City , CA 90067
Registration Number: 3016690634
FEI Number*: 3016690634
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
Date Of Registration Status: 2020

Owner/Operator:
Abbot Genetics Inc.
1801 CENTURY PARK EAST, 25TH FLOOR
Century City, CA US 90067
Owner/Operator Number: 10066114

Official Correspondent:
Nana Yalley
1801 CENTURY PARK EAST, 25TH FLOOR
Century City, CA 90067
Phone: 1-424-3074477

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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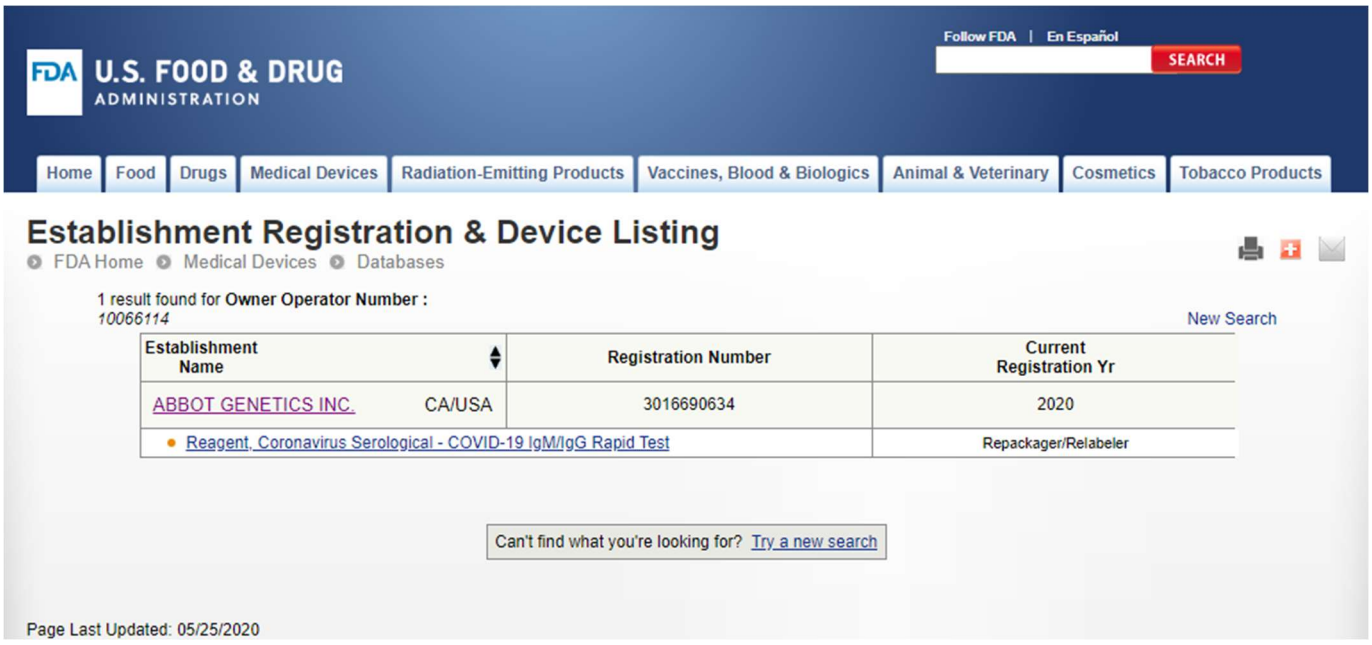

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10066114

New Search

Establishment Name		Registration Number	Current Registration Yr
ABBOT GENETICS INC.	CA/USA	3016690634	2020
• Reagent, Coronavirus Serological - COVID-19 IgM/IgG Rapid Test			Repackager/Relabeler

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Declaration of Conformity

Manufacturer:	Jiangsu Dabo Pharmaceutical Co., Ltd. No. 86-5, Gaochun District, Nanjing, Jiangsu, China
whose single Authorized **EU**-*Representative*::	Luxus Lebenswelt GmbH Kochstr.1, 47877, Willich, Germany DIMID: DE/0000047791 Lin Sun Tel: 0049- 1715605732 E-mail: info.m@luxuslw.de
Product Name:	Diagnostic Kit for Detection of IgG/IgM Antibody to SARS-CoV-2(Colloidal Gold)

Classification: **Others of ANNEX II of IVDD**

Conformity Assessment Route: **Annex III**

We here with declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

General applicable directives:
In Vitro Diagnostic Medical Devices DIRECTIVE

Harmonized standards:

EN ISO 13485:2016	ENISO13975:2003	EN13612:2002
EN13641:2002	ENISO15223-1:2016	EN18113-1:2011
ENISO17511:2003	EN13975:2003	EN ISO 14971:2012
EN18113-2:2011	ENISO23640:2015	EN62366:2008

Signature:	Vili Sun 2020.3.10
Name:	Vili Sun
Title:	General Manager
Position:	Nanjing

CE

[i] NPR & Harvard Global Health Institute, THE CORONAVIRUS CRISIS
As Coronavirus Surges, How Much Testing Does Your State Need To Subdue The Virus?
June 30, 2020, https://www.npr.org/sections/health-shots/2020/06/30/883703403/as-coronavirus-surges-how-much-testing-does-your-state-need-to-subdue-the-virus

[ii] Medical Press, New Delhi plans mass screening effort as virus cases surge, 25 June 2020, https://medicalxpress.com/news/2020-06-delhi-mass-screening-effort-virus.html?campaign_id=154&emc=edit_cb_20200626&instance_id=19810&nl=coronavirus-briefing&regi_id=121720090&segment_id=31998&te=1&user_id=ec01a61d5b601b400fb3cb50c62899ed

[iii] BBC News, Coronavirus: China's plan to test everyone in Wuhan, 8 June 2020, https://www.bbc.com/news/world-asia-china-52651651

[iv] Nature Medicine, Temporal dynamics in viral shedding and transmissibility of COVID-19, 15 April 2020, https://www.nature.com/articles/s41591-020-0869-5

[v] US Food & Drug Administration, 510(k) Premarket Notification, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm

[vi] CNBC, US officials prepare for 'two viruses' next fall: coronavirus and the flu, 22 April 2020, https://www.cnbc.com/2020/04/22/trump-says-cdc-directors-coronavirus-warning-was-totally-misquoted.html

[vii] Washington Post, Health, CDC director warns second wave of coronavirus is likely to be even more devastating, By Lena H. Sun, 21 April 2020, https://www.washingtonpost.com/health/2020/04/21/coronavirus-secondwave-cdcdirector/