Regards,

[redacted]
From: [redacted] <[redacted]anlovells.com>
Sent: Thursday, March 26, 2020 2:46 PM
To: CDRH-EUA-Templa[redacted]X@fda.hhs.gov>; F[redacted]a
<[redacted]m@fda.hhs.gov>
Cc: [redacted]ff <[redacted]me.com>; D[redacted]N. <[redacted]ganlovells.com>
Subject: Notification of Serology Testing for the Detection of Antibodies to SARS-C0V-2 Virus - WatMIND

CDRH COVID19DX Mailb[redacted]m,
Consistent with FDA's 16 March 2020 Guidance, " https://www.fda.gov/media/135659/download,"
Hogan Lovells US LLP is providing on behalf of USAT and WatMIND notification to FDA of the companies' intent to distribute for U.S. clinical laboratory and hospital point of care use four serological tests for the detection of antibodies to SARS-CoV-2 virus. These four serological assays are not intended for over the-counter or home use settings, nor are they intended for use as the sole basis to diagnose or inform infection status. The four serological tests include:

- Two instrument read, cartridge based serological assays, referred to as the M2 and M5 tests, together with the instrumentation needed to perform the tests in clinical laboratory and point-of-care settings (see attached M2&M5 product brochure); and
- Two SARS-CoV-2 Ab Diagnostic Test Kit (Colloidal Gold, lateral flow) tests, one to detect IgM and a second version to detect IgG antibodies.

Both the instrument versions and the lateral flow versions are intended exclusively for use during the current emergency and for use only in clinical laboratories and point of care locations, or as part of hospital-based, IRB reviewed investigational clinical studies where the tests are not used as to diagnose or inform infection status.
Consistent with FDA policy, we understand that “FDA does not intend to object to the development and distribution by commercial manufacturers or development and use by laboratories of serology tests to identify antibodies to SARS-CoV-2, where the test has been validated, notification is provided to FDA…”
This e-mail provides the requested notification. USAT and WatMIND also confirm that the following information will be included in the test reports generated using the listed serological tests:

- 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.

We would be happy to address any questions FDA may have about this notification.

Sincerely,

R[redacted]a

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Partner

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From: CDRH-EUA-Templates [mai[redacted]X@fda.hhs.gov]
Sent: Thursday, March 26, 2020 3:08 PM
To: P[redacted]J.; CDRH-EUA-Templates; Fe[redacted]ra
Cc: E[redacted]ff; [redacted]N.
Subject: RE: Notification of Serology Testing for the Detection of Antibodies to SARS-C0V-2 Virus - WatMIND

if you do not intend to pursue EUA, then the device labeling (i.e., instructions for use) should reflect specific validation studies i.e., Cross-reactivity/Analytical Specificity, Class Specificity and Clinical Agreement Study, in addition to other information necessary for the proper use of your test. Your antibody test report should also include the following as specified in FDA guidance:

- 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.
- Not for the screening of donated blood

If your device does not produce an actual test report, the Instruction for Use for your device use should specify that the laboratory must include this information in their test report.

Notification to FDA can be sent to C[redacted]s@fda.hhs.gov. Please include in the subject line, **NOTIFICATION FOR COVID-19 ANTIBODY TESTS.** Your notification should include your assigned tracking number (e.g., PEUA2000XX, if applicable), the name of your device, contact information, and a copy of the assay instructions for use with a statement that the information cited in Section D of the guidance for inclusion in your test reports has been addressed by your device.

We strongly recommend you review this policy and reassess whether an EUA is appropriate or necessary for distribution of your serological test. For any additional questions, please contact:
C[redacted]s@fda.hhs.gov

Please note the following exception to the above mentioned policy as you intend to distribute the device to patients' homes for in home testing:
The policy described applies to developers of serology tests that identify antibodies (e.g., IgM, IgG) to SARS-CoV-2 from clinical specimens. This policy is limited to such testing in laboratories or by healthcare workers at the point-of-care. This policy does not apply to at home testing.

Please provide the device labeling to proceed with a notification.