BioReference Laboratories Stone Agency Corp T/A
Bella MediSpa and Salon
277 Newton Sparta Road, Newton NJ 07860

WAIVER FORM ANTIBODY BLOOD COLLECTION TEST

PATIENT INFORMATION

FIRST: _____ LAST: _____
BIRTHDAY: _____ GENDER: M ☐ F ☐
ETHNICITY: _____ PHYSICAL ADDRESS:
_____
CITY: _____ STATE: _____ ZIP: _____
COUNTY: _____ PHONE: _____
EMAIL: _____

SIGNS AND SYMPTOMS

DO YOU HAVE, OR HAVE YOU RECENTLY HAD THE FOLLOWING:

FEVER: NO ☐ OR YES ☐
CHILLS: NO ☐ OR YES ☐
BODY ACHES: NO ☐ OR YES ☐
RUNNY NOSE: NO ☐ OR YES ☐
CONGESTION: NO ☐ OR YES ☐
SORE THROAT: NO ☐ OR YES ☐
COUGH: NO ☐ OR YES ☐

HAVE YOU RECENTLY TRAVELED TO A “HOT SPOT” OR BEEN IN CONTACT WITH A PERSON KNOWN TO HAVE CORONAVIRUS (COVID-19)?

NO ☐OR YES☐

DATE: _____

SIGNATURE: _____

INFORMED CONSENT
ANTIBODY COVID-19

The purpose of this form is to obtain your consent to collect a blood sample and analyze it using the TH99 - COVID-19 Antibody IgG to determine if you have antibodies directed against SARS-CoV-2, the virus that causes COVID-19. Please carefully read the items on this form and indicate your acknowledgement and consent to the following by initialing and signing in the spaces provided. 1. I AM INFORMED. I received and read the FAQs sheet regarding the TH99 - COVID-19 Antibody IgG. I understand that this test is not a clinical trial and my participation is entirely voluntary. If I choose not to participate there will be no negative effects on me. 2. Personal Information Privacy and Use of Results. The UBI Group (defined below) will not receive your individual named sample or results from this test and will not retain any right to test your sample for any purpose other than determining if you have antibodies directed against SARS-CoV-2. The UBI Group will only use the results obtained from this test for further research and validation of the TH99 - COVID-19 Antibody IgG and as required by law, rule, regulation, guidance, etc. Your results may be anonymously pooled with the results of others in order to determine community prevalence or other statistics related to COVID- 19, and these results may be reported or published. However, under no circumstance will any personal information be made available or disclosed, with the exception of this Consent Form. 3. Assumption of Risk and Release. I recognize that there are certain inherent risks associated with having my blood sample analyzed. I hereby consent for myself, my heirs, executors, administrators, assigns, or personal representatives, knowingly and voluntarily agree to have my sample analyzed by the TH99 - COVID-19 Antibody IgG and hereby waive any and all rights, claims, or causes of action of any kind whatsoever arising out of my participation in this activity, and do hereby release and forever discharge I, its affiliates, managers, members, agents, attorneys, staff, volunteers, heirs, representatives, predecessors, successors, and assigns Revitalizing Remedies LLC, Fiorella Paradisi LLC. Bella MediSpa, Evolve Total Wellness Group LLP, for any physical or psychological injury, including but not limited to illness, paralysis, death, economical or emotional loss, that I may suffer as a direct result of my participation in this activity, including traveling to and from any location related to this activity. In the event that I should require medical care or treatment, I agree to be financially responsible for any costs incurred as a result of such treatment. I am aware and understand that I should carry my own health insurance. 4. Indemnification. I agree to indemnify and hold harmless Revitalizing Remedies LLC, Fiorella Paradisi LLC. Bella MediSpa, Evolve Total Wellness Group LLP, against any and all claims, suits, or actions of any kind whatsoever for liability, damages, compensation, or otherwise brought by me or anyone on my behalf, including attorney's fees and any related costs, if litigation arises pursuant to any claims made by me or by anyone else acting on my behalf. If the aforementioned entities incurs any of these types of expenses, I agree to reimburse them for these expenses. 5. FDA Guidance. I understand that the FDA has allowed the use of the TH99 - COVID-19 Antibody IgGeven though it has not yet been formally approved. According to FDA Guidance, we are required to inform you of the following:

● 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 NO 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 INFECTIONS WITH THE NON-SARS-COV-2 CORONAVIRUS STRAINS, SUCH AS CORONAVIRUS HKU1, NL63, OC43, OR 229E.
● THIS TEST IS NOT FOR THE SCREENING OF DONATING BLOOD. What is a COVID-19 antibody test and what do the results tell me? After SARS-CoV-2, the virus that causes the coronavirus disease, 2019 (COVID-19), infects a person, that person's immune system will produce antibodies against the virus to fight the infection. A COVID-19 antibody test is able to detect the antibodies made by the body against the SARS-CoV-2 virus from a small sample of blood to diagnose whether a person has (or previously had) COVID-19. FEATURES OF THIS ANTIBODY TEST:
● ACCURATE → 95% SPECIFICITY AND SENSITIVITY
● PRECISE - CAN DIFFERENTIATE BETWEEN SARS-COV-2 VS. OTHER CORONAVIRUSES CIRCULATING IN US.
● FAST RESULTS IN 12 HOURS.
● SCALABLE CAN BE DEPLOYED T0 SCREEN HUNDREDS OR THOUSANDS OF SUBJECTS EASILY. The results of the test tell you whether you have been exposed to the virus. Antibodies may be detected starting 10 days after infection, or generally shortly after onset of symptoms. The antibodies stay in your blood for a long time and, thus, the detection of antibodies using our test can also inform whether you have been previously exposed to the virus and have now recovered and developed immunity. How accurate is the test? Bioreference Laboratories are currently running two platforms. Both were validated in-house before being put into use: Roche: Received EUA from the FDA on 5/2 Sensitivity (≥ 14 days, PPA): 100% Specificity: 99.8% Qualitative test result DiaSorin: Received EUA from the FDA on 4/24. Sensitivity (≥ 15 days, PPA): 97.6% Specificity: 99.3% Currently has a semi-quantitative result (numerical value with categories of negative, equivocal, and positive), however we will be changing this to a pure qualitative result to be consistent with Roche.
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 assay 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 or to determine infection status.
BioReference offers a semi-quantitative immunoassay which measures SARS-CoV-2 specific IgG antibody levels, correlating with the patient's immune response after COVID-19 infection. Based on early evidence, IgG is expected to be elevated in the majority of patients by 14 days after the onset of symptoms. The timeline for IgG elevation in asymptomatic patients is still being studied. Antibody tests play a critical role in the fight against COVID-19 by assessing the levels of immune response in populations and individuals. A significant number of asymptomatic or mildly symptomatic COVID-19 patients will not be diagnosed with molecular testing. Antibody

blood testing from BioReference can assist healthcare professionals and public authorities make decisions about people returning to work, and easing social distancing and shelter-in-place measures. Antibody tests offered by BioReference are performed on high-volume instruments and have been verified for sensitivity and specificity. They have been reviewed by appropriate state Departments of Health and registered with the FDA. TESTING ANTIBODIES IN COMBINATION WITH MOLECULAR TESTING Patients who are asymptomatic or have recovered from COVID-19 may have immunity from re-infection if IgG is positive, based on past behavior with other types of infections. Ongoing studies will further detail COVID-19 specific immunity to reinfection. • During infection PCR results are more likely to be positive during the acute phase, with IgG rising later as part of the body's immune response. • Patients with symptoms who test negative with molecular tests may still be suspected of having COVID-19. If IgG is elevated in these patients, they are likely to have been infected and had a false negative PCR result. IMPORTANT NOTES • IgG may remain elevated for a significant time after recovery, though the duration of any immunity to reinfection from COVID-19 is not yet known. • Symptomatic COVID-19 patients with elevated antibody levels can still be infectious. • Antibody testing should not be used to diagnose acute COVID-19 infections, and antibodies are unlikely to be detected in the first few days of infection. • The rates of false positives and negatives will depend on the population being tested, which is not yet fully defined. When will I get the results? The test takes 12-48 hours to get results. However, it may take two or more days to get your results as there are currently lab processing capacity constraints. Many of our labs are in cities with shelter-in-place so the manpower to process has decreased significantly. We appreciate your patience and understanding while we work our hardest to get these done. Is this test FDA approved? We have submitted an application to the FDA for Emergency Use Authorization (EUA). Based on new guidance issued by the FDA recognizing the urgent need for access to these types of tests, the BIOREFERENCE antibody test is now available for use by and marketed to U.S. laboratories prior to EUA. The FDA has not approved any antibody tests under EUA. Per the guidance, until the EUA has been reviewed, we are required to inform you in the test results:

• 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. What about the nasal swab RT-PCR tests being used? How is this different? The need for large-scale testing has become apparent in the past weeks. The RT-PCR nasal swab tests are
currently being used and are helpful to test active infections because they detect the genetic material of the virus itself, so will tell you if you have an ongoing infection. However, there are important limitations and restrictions. These include the fact that they are technically demanding to conduct, there is variability in accuracy with high false negatives (up to 50%), difficulty to scale up to test large populations of people, and the ability to only detect active infection but

inability to determine if someone has been previously infected but recovered. As a result, the RT-PCR tests have been restricted in application, challenging to roll out, and unable to inform public health officials the true scope of outbreak. In the past few weeks, the CDC finally called for use of antibody tests and the WHO urged all outbreak areas to immediately begin testing with such tests to better track and contain community spread of the virus. How can communities use large scale screening using these tests? We have had many governments and corporations inquire about large-scale testing. Antibody tests can be used as a quick screen to identify who has been infected within a community. This can provide leaders, public health officials, and the public with more accurate information about the prevalence of infection in a given population, which can help everyone take steps to contain community spread. Antibody tests, such as the TH99 - COVID-19 Antibody IgG, can be used to complement RT-PCR tests for a more accurate diagnosis of current infection in symptomatic patients. It can also identify those who have been infected, but have already recovered and developed a level of immunity to the virus. People who have not yet been exposed are still susceptible to the virus and should exercise caution and social distancing to avoid infection. In addition, people may get infected but not know that they are infected because they either have mild symptoms or no symptoms at all. These people, with mild or no symptoms, are still able to spread the virus to other people who may be more at risk of developing severe infections. Therefore, large-scale testing is important to understand this information, which can help communities stay safe while staying open.
We are now up and running with the Roche assay in addition to Diasorin. We have chosen to discontinue use of the Diazyme assay for now.

Both the Roche and Diasorin platforms have EUA from the FDA. Both are IgG only with a qualitative result of "Detected" or "Not Detected"

Specifics of each platform can be found below:

Roche Elecsys Anti-Sars CoV-2
Sensitivity: 100% (≥ 14 days after diagnosis)
Specificity: 99.8%

DiaSorin Liaison Sars CoV-2 S1/S2
Sensitivity: 97.6% (≥ 15 days after diagnosis)
Specificity: 99.3%

TAT is 1-3 days, although most are being conducted in 24 hours and running 7 days a week.

□ I HAVE READ THIS

SIGNATURE: _____ DATE: _____

NAME PRINTED: _____

Fiorella Paradisi LLC
Evolve Total Wellness Group LLP
Revitalizing Remedies LLC
17 Davis Road, Sparta NJ 07871
(201)727-3241

Patient Information

First Name: _____ Last Name: _____

Address: _____ City: _____

State: _____Zip Code: _____

Cell Phone: _____Home Phone: _____

Gender: ☐Male ☐ Female

Date of Birth: _____

Insurance Information

Primary Insurance Company: _____

Subscriber Name: _____

ID Number: _____

Insurance Address: _____

City: _____ State: _____Zip Code: _____

Group Number: _____

Relationship to Insured: _____

You are responsible for providing the correct and complete insurance information

Please make a copy of the front and back of all insurance cards and attach to this document

Credit Card Authorization Form

Please complete all fields. You may cancel this authorization at any time by contacting us. This authorization will remain in effect until cancelled.

Credit Card Information
Card Type: ☐Mastercard ☐ VISA ☐Discover ☐ AMEX ☐ Other_____
Cardholder Name (as shown on card):_____
Card Number:_____
Expiration Date (mm/yy): _____ CVV:_____
Cardholder ZIP Code(from credit card billing address): _____

I,_____,authorize_____ to charge my credit card above for agreed upon purchases. I understand that my information will be saved to file for future transactions on my account.

_____ _____

Customer Signature Date