WHAT YOU NEED TO KNOW TO BE INFORMED

VOLUNTARY TESTING FOR ANTIBODIES TO COVID-19 IN SUPPORT OF THE SHELTER IN PLACE ORDER

**** DISCLAIMER: COVID-19 A NEW VIRUS.**
THERE CONTINUE TO BE MANY VARIABLES AND UNKNOWNS. **

The purpose of this form is to obtain your voluntary consent to participate in San Miguel County's collaboration with United Biomedical, Inc. (UBI) to obtain a simple blood sample and analyze it using the UBI® SARS-CoV-2 ELISA (ELISA Blood Test). This blood sample and analysis process is used to determine if you have antibodies directed against SARS-CoV-2, the virus that causes COVID-19. The goal of the San Miguel County **Shelter in Place Order** and community-wide participation in the ELISA Blood Test is to obtain a more accurate assessment of COVID-19 prevalence and to contain community spread.

Specifically, there are **two goals** of testing for COVID-19 antibodies:

- The **first** is to provide County Public Health and your medical doctor with **your specific results** in order to discuss additional medical treatment as necessary.
- The **second** is to obtain a more accurate assessment of COVID-19 in our community. With this information, public health and medical professionals will have better information to inform decisions necessary to contain community spread.

- **Why test for antibodies?** Antibodies are part of your immune system's response to infection. They are proteins your body makes and leaves in our blood once infected with a bacterium or virus. COVID-19 antibodies appear in your blood around 7-10 days after an infection.

- **An initial result of zero antibodies does not mean you do not have COVID-19.**

Important aspects of participating in this collaboration:

- **Your participation is entirely voluntary**. You may choose not to participate without there being any negative effect on you. Your sample will be given an anonymous sample identification number.
- The antibody test is done by drawing approximately 4-8 milliliters of blood from a vein in your arm. When the blood sample is drawn, you may have some discomfort at the site of the needle-stick and a small bruise may develop.
- The **test is free**. Lab results are projected to be available to Public Health Officials within two business days.
- As a participant, you agree to be **voluntarily tested again** (likely in 14 days) in order to allow public health officials to gauge if the County's rate of infection is increasing or decreasing. You will be notified with instructions for subsequent tests.
- You will be contacted by County Public Health to discuss all **positive results**. **Negative results** will be communicated with you using a variety of channels to include but not limited to: phone, mail, electronic/web-based delivery or other reasonable means. Negative results may be posted online using the anonymous sample identification number to expedite the notification process. **NOTE:** Negative results will be reported at the conclusion of **all** testing.

The ELISA Blood Test is different from lab tests currently being used in the United States that detect the active COVID-19 virus by obtaining an oral or nasal swab. If you are active with COVID-19 symptoms, your healthcare provider may want to utilize an oral or nasal swab test as well.

For more information about the ELISA Blood Test, the County's partnership with the United Biomedical, Inc. or the Shelter In Place Order, visit **sanmiguelcountyco.gov/coronavirus**

☐ I HAVE READ THIS

Patient Information

First:	Middle:	Last:
Birthday:	Gender:	Ethnicity:
Physical Address:		PO Box:
City:	State:	Zip:
Neighborhood/Area:		County:
Phone:	Email:	

Signs and Symptoms

Do you now have, or have you recently had?:		Start Date	Stop Date
Fever	N or Y		
Chills	N or Y		
Body Aches	N or Y		
Runny Nose	N or Y		
Congestion	N or Y		
Sore Throat	N or Y		
Cough	N or Y		

Have you recently traveled to a "Hot Spot" or been in contact with a person known to have Coronavirus (COVID-19)?	
N or Y	Date:

SAN MIGUEL COUNTY INFORMED CONSENT FORM

1. **I AM INFORMED**. I received and read San Miguel County's informational sheet regarding the County's use of the UBI® SARS-CoV-2 ELISA test. I understand that my participation is **entirely voluntary,** and if I choose not to participate, there will be no negative effects on me. My sample will be given anonymous sample identification number.

_____
Initials

2. **Personal Information Privacy**. I understand that my sample will be sent directly and anonymously to a third party independent lab for processing and that my results may be anonymously pooled into an epidemiology study for my town and San Miguel County, CO. The results of these studies may be reported and published. However, under no circumstance will any of my personal information be made available or disclosed for the purposes of these studies.

_____
Initials

3. **Personal Information Privacy and Use of Results with Public Health and Medical Professionals.** I understand that my test results may be provided to San Miguel County Public Health and appropriate professionals (including but not limited to the Colorado Department of Public Health & Environment, Telluride Hospital District d/b/a Telluride Regional Medical Center and the Uncompahgre Medical Center) on a need to know basis and as directed by HIPAA. The purpose of this need to know sharing of my results is for the limited purpose of informing medical providers so they may advise me on appropriate medical treatment and for limiting the spread of communicable diseases. My personal information will not be shared with anyone else.

_____
Initials

4. **Assumption of Risk and Release**. I recognize that there are certain inherent risks associated with having my blood sample drawn for analysis. I hereby consent for myself, my heirs, executors, administrators, assigns, or personal representatives, knowingly and voluntarily agree to have my sample drawn and analyzed by the UBI® SARS-CoV-2 ELISA 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 San Miguel County, Telluride Hospital District d/b/a Telluride Regional Medical Center, and Uncompahgre Medical Center, and their affiliates, managers, members, agents, attorneys, staff, volunteers, heirs, representatives, predecessors, successors and assigns, 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.

_____
Initials

5. **Indemnification**. I agree to indemnify and hold harmless San Miguel County, Telluride Hospital District d/b/a Telluride Regional Medical Center and the Uncompahgre Medical Center, and their affiliates, managers, members, agents, attorneys, staff, volunteers, heirs, representatives, predecessors, successors and assigns 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.

_____
Initials

6. **Governmental Immunity.** San Miguel County and the Telluride Hospital District are governmental entities who do not intend to waive, by any provision of this consent, any rights, immunities, and protections provided by the Colorado Governmental Immunity Act, C.R.S. §24-10-101, *et seq*, as currently in effect and as it may be subsequently amended. _____ Initials

7. **FDA Guidance**. I understand that the FDA has allowed the use of the UBI® SARS-CoV-2 ELISA even though it has not yet been formally approved. I further understand that:
   - 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 (oral or nasal swab) 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. _____ Initials
   - 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.

8. Notification of Test Results. I understand that I will be contacted by County Public Health to discuss all positive results. Negative results will be communicated with you using a variety of channels to include but not limited to: phone, mail, electronic/web-based delivery or other reasonable means. Negative results may be posted online using the anonymous sample identification number to expedite the notification process. NOTE: Negative results will be reported at the conclusion of all testing. _____ Initials

☐ I agree to voluntarily participate in the COVID-19 antibody testing, which will require subsequent blood tests and to observe the San Miguel County **Shelter in Place Order**. I have been informed about this testing and have had a chance to ask questions which were answered to my satisfaction. I understand the benefits and risks of this test and consent to the testing.

NAME _____ DATE _____

SIGNATURE _____

UBI - FREQUENTLY ASKED QUESTIONS

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. United Biomedical, Inc. (UBI) has developed a COVID-19 antibody test that is called the UBI® SARS-CoV-2 ELISA.

Features of our antibody test:

- Accurate — >95% specificity and sensitivity
- Precise — can differentiate between SARS-CoV-2 vs. other coronaviruses circulating in US
- Fast — results in 2-3 hours
- Scalable — can be deployed to 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?
Validation tests conducted in China, Taiwan and California have demonstrated that the UBI® SARS-CoV-2 ELISA is highly sensitive, specific, and accurate.

100% of the blood samples collected post seroconversion of infection from patients who tested positive to COVID-19 by other methods were found to be positive using the UBI® SARS-CoV-2 ELISA ((after infection with the virus it takes about 10 days for the person's immune system to produce enough antibodies for them to be detectable in the blood, this period is called "seroconversion"). We have also tested over 900 blood samples that were collected before the present COVID-19 outbreak and none of these samples tested positive using our test, which means that our test has not produced a false positive result. These samples included blood samples from patients who have previously tested positive for other human coronaviruses (e.g., NL63 or HKU-1) as well as other infectious diseases (e.g., HIV, HCV, and HBV).

When will I get the results?
The test takes 2-3 hours to get results. However, it may take two or more days to get your results as there is 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 UBI 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.

Last week, 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 UBI® SARS-CoV-2 ELISA, 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 others people who may be more at risk in developing severe infections. Therefore, large-scale testing is important to understand this information, which can help communities stay safe while staying open.

Who are we?
C19 is a subsidiary of UBI Group. UBI Group was founded in 1985 and currently has over 5 operating entities and 950 employees globally. We have facilities in China, Taiwan, Ireland and the US. For the past three decades, we have developed, manufactured and sold HIV, HCV, HTLV and FMDV blood diagnostic kits worldwide through various distribution partners including Organon Teknika and BioMerieux. We have also developed, manufactured and sold over 4.5 billion vaccines and ~500 million doses annually through partners. Dr. Chang Yi Wang, our Chief Scientific Officer, is inventor and author of over 100 patents and peer-reviewed publications. She developed 4 blood diagnostic kits and 2 licensed vaccines globally distributed. She has been awarded Inventor of the Year Award (NYPLA), Pioneer in Medicine Award (BMSF), and recipient of funding from Gates Foundation, MOEA and 4 NIH grants over $20M, including for SARS diagnostic work. She is currently collaborating with Dr. Anthony Fauci/NIAID and also advised by Dr. Robert Redfield on HIV functional cure program, both leaders in the coronavirus response today.

☐ **I HAVE READ THIS**

INFORMED CONSENT FORM

The purpose of this form is to obtain your consent to obtain a blood sample and analyze it using the UBI® SARS-CoV-2 ELISA 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 UBI® SARS-CoV-2 ELISA. 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 to me.

   _____ Initials

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 UBI® SARS-CoV-2 ELISA, 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 to, or disclosed by, The UBI Group, with the exception of this Consent Form.

   _____ Initials

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 UBI® SARS-CoV-2 ELISA 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 UBI, its affiliates, managers, members, agents, attorneys, staff, volunteers, heirs, representatives, predecessors, successors, and assigns (collectively, "The UBI Group"), 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.

   _____ Initials

4. **Indemnification**. I agree to indemnify and hold harmless The UBI Group 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 UBI Group incurs any of these types of expenses, I agree to reimburse The UBI Group for these expenses.

   _____ Initials

5. **FDA Guidance**. I understand that the FDA has allowed the use of the UBI® SARS-CoV-2 ELISA even 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 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 test is not for the screening of donated blood

   _____ Initials

_____

Signature Date

_____

Name Printed