COVID-19 PCR NASAL SWAB CONSENT

I, ___________________________________, authorize and consent to DeLand Wellness Center to perform a PCR Nasal Swab that detects severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) RNA is or is not present and suggests the diagnosis of coronavirus disease 2019 (COVID19).

DISCLAIMER:

This test was developed by Nona Scientific Laboratory, and its performance characteristics were determined by the lab. The laboratory is regulated under CLIA, and is qualified to perform high-complexity testing. This test is used for clinical purposes. It should not be regarded as investigational or for research.

• This test has not been FDA cleared or approved;
• This test has been authorized by FDA under an EUA for use by authorized laboratories;
• This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and
• This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

I further understand, agree, certify, and authorize the following:

I hereby consent and authorize DeLand Wellness Center providers as stated above.

________________________________   ____________________
Print Patient & Guardian Name                      Date