DermaCare
BIOSCIENCES
Division of DermaCare Packaging & Private Label

EasyRapidNow™ Nasal Swab Antigen Tests is pending FDA EUA Authorization for Diagnostic Procedures as a Class I Medical Device.

Currently, these kits can provide for Surveillance Testing Only, Not for Diagnostic Procedures.

Example of Surveillance Test Plan

December 1, 2020

Surveillance Plan – DermaCare – Easy Rapid Now™

Buyer will utilize the Easy Rapid Now™ Nasal Antigen Test in a controlled surveillance environment. Buyer will pool a volunteer sample of the general United States population to help mitigate the spread of COVID-19 by quickly identifying "Hot Spots" of infection and inform health officials to help manage outbreaks.

The Easy Rapid Now™ Nasal Antigen test collects a nasopharyngeal specimen on a swab, processes them in a buffer provided with the test, and applies the extracted buffer to the cassette provided with the kit. The cassette contains tagged antibodies that detect the COVID-19 virus. Results are known within 15 mins. These test kits have the following performance characteristics:

Sensitivity: 98.72%
Specificity: 97.32%
Accuracy: 97.89%

Based on these statistics, you will be able to get a reliable baseline of spikes or trends in the pooling environment.

On the advice of health care providers, Buyer will randomly select populations to sample and administer the nasal swab tests. Using Primary Care Physician's (PCP's), specialty physicians, clinics, healthcare professionals, and trained service providers.
Buyer shall pool the specimens and surveil any spikes in infection and further classify the data by age groups, ethnicity, and sex.

Buyer will then report its findings of trends to local health officials to make additional guidelines or mandates based on the findings.

With utilizing a small portion of tests, Buyer will be able to get a baseline to see if surveillance testing is a logical sampling set of a larger population.

Acknowledgment of Liability and Assumption of the Risk ("Acknowledgment"):

Buyer does hereby indemnify and holds harmless Seller and its Affiliates and their respective owners, agents, officers, and employees from and against any and all claims (including, without limitation, product liability), liability, loss, cost, expense (including reasonable attorneys' fees), judgments, and damages which may arise from using the EasyRapidNow™ Nasal Swab Antigen Tests ("Tests") for any other purpose other than for surveillance purposes. Buyer assumes any and all risk associated with the improper use of the Tests, if any.

This Acknowledgement shall be in addition to any and all Agreements previously entered into by the parties. This Acknowledgement is for an indefinite term and applies only to the specific Test referenced herein. If this Acknowledgment contradicts any terms or conditions in any previous Agreements entered into by the parties, then this Acknowledgment shall supersede and control.

This Acknowledgement can only be revoked in writing, agreed upon by both parties.

BUYER:

_____
Name:
Title:
Date:
Buyer's Authorized Representative