



**It's “*kinda*” like a pregnancy test, but for COVID.**

**PRODUCT:** We are developing the **QXD-3 COVID NOW** at-home COVID **antigen** lateral flow test. This test will measure antigens produced by the virus during a 2-12 days incubation period **BEFORE** any symptoms. Results in 15 min. Please note, this is **NOT** an "antibody" test but an antigen. While, the COVID NOW can be read by the naked-eye “*kinda*” like a pregnancy test. We will also have a **smart phone reading** app for easier reading, quick and reliable results and data collection. This app, will allow connectivity directly to tele-medicine service. Additionally, the app will provide semiquantitative data collection on the backend, which can also support contact tracing. The app can then be connected to a telemedicine service (see potential collaboration letter) for more efficient physician to patient medical guidance.

**Distribution** of this product can be **mailed directly** to the consumer **or can be picked up from drug store kiosks** with a popular tele-medicine service (see letter of intent) which is located in 40 states, with drug store kiosks already established in those states.

**Fundraising ask for the QXD-3 COVID NOW: Total 250K**

- 50K-Prototype optimization and sensitivity data-3-4 weeks
- 200K-Manufacturing, CRO, Clinical Data, EUA, in 3 months or less.

**REGULATORY:**

It is important to remember that this will be a Class II medical Device requiring a 510K with several predicates. Hence, we will be asking for EUA approval (2 weeks) and a CLIA Waiver.

**TEAM:**

**Dr. Maria Nagy, Ph.D.**-(CEO) microbiologist with 14 years-experience

**Dr. Angel A. Rivera, M.D./Ph.D.**-(CTO) with 25 years' experience with 85+ peer reviews

**TECHNICAL:**

**Sampling method: nasal, oral and sputum:**

- The cross-reactivity studies were completed using sputum and bronchoalveolar samples
- Present LOD is 125ng/ml and Specificity: 100%
- Expected Sensitivity 95%
- Expected unit cost: \$3. Expected wholesale \$25, Retail cost \$50 per test kit. COVID IgG/IgM antibody tests presently on the market are between \$60-200 per kit.

**CHART I: GANTT CHART-ACCELERATED PLAN QXD-3 COVID NOW DEVELOPMENT**

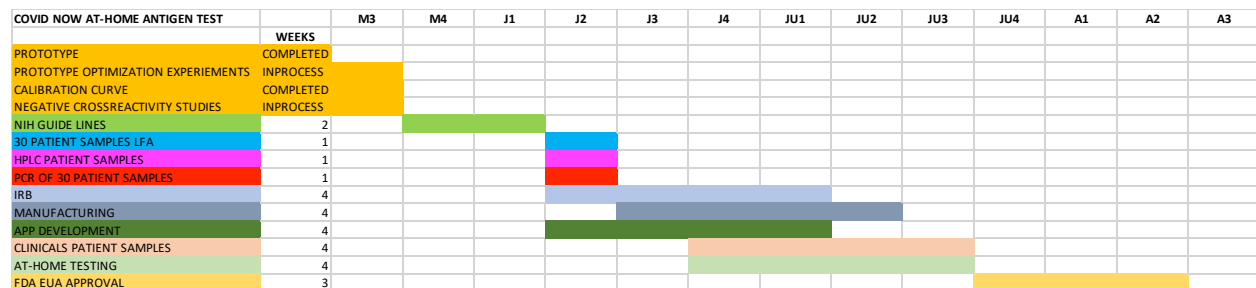




TABLE I: TRACTION

	QXD-3 COVID NOW	QXD-1 FAST TEST for Pseudomonal Pneumonia
<b>Prototype</b>	Completed	Completed
<b>Testing against patient samples</b>	Waiting for patient samples	38 patient samples Completed
<b>Preliminary Sensitivity and Specificity Data</b>	LOD:125ng/ml Specificity: 100%	Presently 87% sensitivity, 100% specificity, will improve dramatically with manufacturing optimization.
<b>Expected Sensitivity and Specificity</b>	95% Sensitivity 100% Specificity	95% Sensitivity 100% Specificity
<b>Manufacturing Optimization</b>	Will utilize QXD-1 relationship	Manufacturer identified
<b>Patent</b>	Will utilize QXD-1 relationship	International PCT Patent Filed
<b>FDA Pre-submission</b>	Not needed-EUA template already provided	Submitted application waiting on feedback
<b>Clinical trial partners</b>	Will utilize QXD-1 relationships	3 hospital partnerships ready, see letters of intent
<b>FDA application</b>	EUA	Class 2 device - 510K
<b>FDA timeline</b>	1-2 weeks	3 months
<b>Distribution Channels</b>	Will utilize QXD-1 relationship	Relationship with Tele-doc service located in 40 states with drugstore test kiosks, see letter of intent

\*QXD-1 Pseudomonal test development was halted in April 2020, to focus on the QXD COVID NOW test.

**CONCLUSION:**

For the COVID NOW test, we used a commercially available antigen to mimic an infected patient sample. Our preliminary data show a Limit of Detection of 125ng/ml with the SARS-CoV-2 antigen. Remarkably, we saw no cross reactivity when tested against 3 *Pseudomonas aeruginosa*, 1 *Staphylococcus aureus* or Human Corona Virus 229E, hence, giving a specificity of 100%.

While this proposal is written explicitly for the development of QXD-3 COVID NOW, there is potential for development of the QXD-1 Fast test for Pseudomonal Pneumonia in the future. Finally, it is interesting to note that the pathology of a SARS-CoV-2 patient mimics a Cystic Fibrosis (CF) syndrome. Hence, the utility of both tests combined will allow us to determine the infection of the patient with SARS-COVID-2 together with a positive or negative diagnostic of *P.aeruginosa*, a very prominent secondary bacterial infection seen in CF and ventilator patients.