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

COVID NOW AT-HOME ANTIGEN TEST		M3	M4	J1	J2	J3	J4	JU1	JU2	JU3	JU4	A1	A2	A3
	WEEKS													
PROTOTYPE	COMPLETED													
PROTOTYPE OPTIMIZATION EXPERIEMENTS	INPROCESS													
CALIBRATION CURVE	COMPLETED													
NEGATIVE CROSSREACTIVITY STUDIES	INPROCESS													
NIH GUIDE LINES	2													
30 PATIENT SAMPLES LFA	1													
HPLC PATIENT SAMPLES	1													
PCR OF 30 PATIENT SAMPLES	1													
IRB	4													
MANUFACTURING	4													
APP DEVELOPMENT	4													
CLINICALS PATIENT SAMPLES	4													
AT-HOME TESTING	4													
FDA EUA APPROVAL	3													

TABLE I: TRACTION

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