LITISCAPE

KNOW YOUR CLIENT, KNOW YOUR RISKS

Presents, in Partnership With

Cellex, Inc

Fully At-Home Rapid COVID-19 Test!

(No Healthcare Professional Administration Necessary)

Who is Cellex, Inc

- Biotechnology Company founded in 2002
- Developer of technologies, instruments and assays for testing of human diseases and conditions, particularly at point-of-care (POC) settings
- Cellex was the first party to receive an Emergency Use Authorization from the US FDA for a COVID-19 antibody test. It has multiple additional tests in its R&D pipeline soon to be approved and released, including but not limited to the first fully at-home (no mailing of sample required) COVID-19 antigen test.

History

2002/08
Formation of company
First patent (microparticle-based-amplification technology)

2003/01
Selected by U.S. Commerce Department's technology mentoring program

2003/03
Developed a prototype HIV- RNA test and a broad-spectrum bacterial test

2005/07
Invented a virus capture technology: HIV-1 RNA, HBV DNA and HCV RNA

2006/01
Invented a novel flu virus capture and detection technologies

2007/05
Invented a Homogeneous Biochemiluminescence Assay (HBA) platform technology: qFLU Combo Test, qFLU Dx Test, qBV Test, qUTI, and qAR tests

2003 – 2017 – Filed and received multiple patents
2003 – 2017 – Received 18 U.S. government grants, including 13 from the National Institutes of Health

In the News!

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Exclusive: Fully at-home rapid COVID test to move forward

Bryan Walsh, author of Future

Gauss/Cellex rapid at-home COVID-19 test. Photo: Courtesy of Gauss

Two companies behind an at-home rapid COVID-19 test are releasing encouraging clinical trial results ahead of applying for an emergency use authorization (EUA), company executives tell Axios.

Why it matters: Antigen tests that could quickly provide results at home would be a major help in identifying and slowing the spread of COVID-19, but they have to get into the hands of consumers at an affordable price.

Driving the news: Cellex, a biotechnology company, and Gauss, a computer vision startup, are announcing today that their rapid at-home coronavirus test achieved sensitivity rates of 94% and specificity rates of 97% compared to the PCR gold standard of lab tests, in a recent clinical trial.

- Sensitivity refers to a test's ability to identify true positive cases, while specificity refers to its ability to find true negatives.
- Those results are encouraging enough for the companies to move forward for an application for an EUA from the FDA, which is needed to fast track the test for home use.

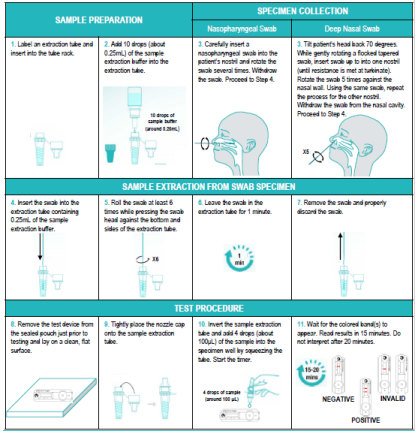
The big picture: Cellex and Gauss are among dozens of companies racing to produce and market rapid at-home tests, but according to the Washington Post this week, no firm has yet applied to the FDA for authorization.

- One concern about at-home tests is that the results may not flow to officials, leaving them in the dark on COVID-19 spread, though Cellex and Gauss have partnered with a data integration platform to transmit test results.

The bottom line: Cheap at-home tests could be a game changer for the pandemic, but only if they're accurate — and only if people take steps to isolate themselves after a positive result.

What is the Cellex q Rapid Test?

- Easy to Use, Affordable
- Self-administered nasal swabs,
- Collect, extract and test with results in 15 minutes
- Under expedited review by the FDA



Rapid Test Clinical Performance

Clinical Performance

Nasopharyngeal Swab Specimens

Clinical performance characteristics of the qSARS-CoV-2 Antigen Rapid Test were evaluated in a multi-site prospective study in the U.S. where 219 direct nasopharyngeal swabs were prospectively collected from enrolled patients. A total of three (3) investigational POC sites throughout the U.S. participated in the study. Testing was performed by operators with no laboratory experience and who represent the intended users at CLIA waived testing sites. Operators used only the test's Quick Reference Guide and received no training. To be enrolled in the study, patients had to be suspected of SARS-CoV-2 infection by exhibiting COVID-19 symptoms or having been exposed to COVID-19 patients.

qSARS-CoV-2 Antigen Rapid Test Performance vs RT-PCR

Method		FDA EUA-authorized RT-PCR		Total
qSARS-CoV-2 Antigen Rapid Test	Results	Positive	Negative	
	Positive	35	1	36
	Negative	2	181	183
Total Results		37	182	219

Positive Percent Agreement: 35/37 = 94.6% (81.81-99.34%)
Negative Percent Agreement: 181/182 = 99.5% (96.98-99.99%)

Numbers may be changed slightly before FDA EUA authorization

Rapid Antigen Kits FAQ's

What is the shelf- life of the test kits?

- Each test kit (25 tests) has an expiration date at the bottom of the package. Typically ~1 year.

How many tests come per box?

- 25 tests/box. The minimum order quantity is 2,000 tests (80 boxes).

How do you properly dispose of the tests?

- The sample swab is inactivated after sample extraction. Used test should be sprayed with disinfectant and disposed of in the regular trash. Test cassettes should be marked as used to avoid accidental repeat use.

When will the tests receive FDA/EUA registration?

- Cellex has be assigned an FDA reviewer and the application is currently under review. Due to backlog of pending applications, the official timeline is unstated.