

To: [5.1.2e] [5.1.2e]@minvws.nl]
From: [5.1.2e]
Sent: Thur 12/17/2020 8:26:28 AM
Subject: RE: FDA Authorizes Antigen Test as First Over-the-Counter Fully At-Home Diagnostic Test for COVID-19
Received: Thur 12/17/2020 8:26:29 AM

Dank!

Van: [5.1.2e] <[5.1.2e]@minvws.nl>
Verzonden: donderdag 17 december 2020 09:26
Aan: [5.1.2e] <[5.1.2e]@minvws.nl>
Onderwerp: RE: FDA Authorizes Antigen Test as First Over-the-Counter Fully At-Home Diagnostic Test for COVID-19

Abott heeft ook gisteren aankondiging gedaan van FDA approval van BinaxNOW zelftest voor gebruik thuis op recept met een virtuele begeleiding:

<https://www.abbott.com/BinaxNOW-Test-NAVICA-App.html#/>

<https://abbott.mediaroom.com/2020-12-16-Abbotts-BinaxNOW-COVID-19-Rapid-Test-Receives-FDA-Emergency-Use-Authorization-for-First-Virtually-Guided-At-Home-Rapid-Test-Using-eMeds-Digital-Health-Platform>

Van: [5.1.2e] <[5.1.2e]@minvws.nl>
Verzonden: donderdag 17 december 2020 09:08
Aan: [5.1.2e] <[5.1.2e]@minvws.nl>
Onderwerp: RE: FDA Authorizes Antigen Test as First Over-the-Counter Fully At-Home Diagnostic Test for COVID-19

Oeps

Van: [5.1.2e] <[5.1.2e]@minvws.nl>
Verzonden: donderdag 17 december 2020 09:08
Aan: [5.1.2e] <[5.1.2e]@minvws.nl>
Onderwerp: RE: FDA Authorizes Antigen Test as First Over-the-Counter Fully At-Home Diagnostic Test for COVID-19

Ja bekend. Via [5.1.2e] / LCDK proberen we testen te bestellen. [5.1.2e] neemt contact op met collega's in Australië. Test is eenmalig gebruik, maar bevat wel electronica voor BT connectie met smart phone.... Niet heel duurzaam

Van: [5.1.2e] <[5.1.2e]@minvws.nl>
Verzonden: donderdag 17 december 2020 09:04
Aan: [5.1.2e] <[5.1.2e]@minvws.nl>
Onderwerp: FW: FDA Authorizes Antigen Test as First Over-the-Counter Fully At-Home Diagnostic Test for COVID-19

Ter info

Van: [5.1.2e] <[5.1.2e]@minbuz.nl>
Datum: woensdag 16 dec. 2020 11:45 PM
Aan: [5.1.2e] <[5.1.2e]@minvws.nl>
Onderwerp: FW: FDA Authorizes Antigen Test as First Over-the-Counter Fully At-Home Diagnostic Test for COVID-19

FYI. Gezien link met digitaal doorgeven van testresultaten aan autoriteiten.

Groet [5.1.2e]

Sent with BlackBerry Work
(www.blackberry.com)

From: [5.1.2e] <[5.1.2e]@minbuz.nl>

Date: Wednesday, Dec 16, 2020, 11:09 PM

To: [REDACTED] <[REDACTED]@minvws.nl>, [REDACTED] <[REDACTED]@minvws.nl>

Cc: [REDACTED] <[REDACTED]@minvws.nl>

Subject: FW: FDA Authorizes Antigen Test as First Over-the-Counter Fully At-Home Diagnostic Test for COVID-19

Ha [REDACTED]

Een kort bericht over een nieuwe antigeensneltest die recent is goedgekeurd (emergency use) door de FDA.

Het is de eerste sneltest die thuis uitgevoerd kan worden zonder recept/verwijzing van een arts. Hij viel mij echter vooral op omdat de terugkoppeling van de tests via de telefoon automatisch maar de publieke autoriteiten gaat. Ik weet dat jullie daar eerder mee bezig waren mbt thuistesten.

' Results are delivered in as little as 20 minutes to individuals via their smartphone. The mobile application requires individuals to input their zip code and date of birth, with optional fields including name and e-mail address, and reports the results as appropriate to public health authorities to monitor disease prevalence. Ellume expects to produce more than three million tests in January 2021.'

Wat betreft de productie worden geen wonderen verwacht en de kosten voor de test zijn ook vrij hoog (\$30 naar ik begrijp). De foutmarge zou echter wel vrij goed zijn.

Sterkte weer met alle drukte!

Groet!

[REDACTED]

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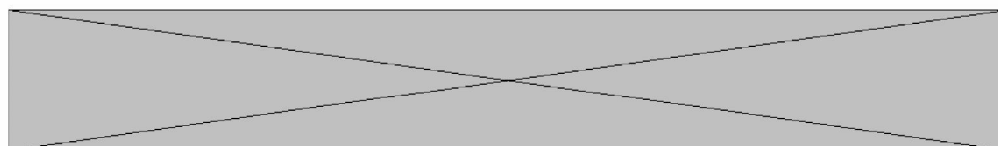
From: [REDACTED] <[REDACTED]@public.govdelivery.com>

Date: Tuesday, Dec 15, 2020, 5:45 PM

To: [REDACTED] <[REDACTED]@minbuza.nl>

Subject: FDA Authorizes Antigen Test as First Over-the-Counter Fully At-Home Diagnostic Test for COVID-19

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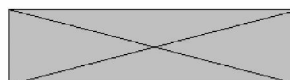
Coronavirus (COVID-19) Update: FDA Authorizes Antigen Test as First Over-the-Counter Fully At-Home Diagnostic Test for COVID-19

Test is authorized for individuals two years of age or older, including those not showing symptoms

Today, the U.S. Food and Drug Administration issued an emergency use authorization (EUA) for the first over-the-counter (OTC) fully at-home diagnostic test for COVID-19. The Ellume COVID-19 Home Test is a rapid, lateral flow antigen test, a type of test that runs a liquid sample along a surface with reactive molecules. The test detects fragments of proteins of the SARS-CoV-2 virus from a nasal swab sample from any individual 2 years of age or older.

“Today’s authorization is a major milestone in diagnostic testing for COVID-19. By authorizing a test for over-the-counter use, the FDA allows it to be sold in places like drug stores, where a patient can buy it, swab their nose, run the test and find out their results in as little as 20 minutes,” said FDA Commissioner Stephen M. Hahn, M.D. “As we continue to authorize additional tests for home use, we are helping expand Americans’ access to testing, reducing the burden on laboratories and test supplies, and giving Americans more testing options from the comfort and safety of their own homes.”

The announcement today of the first fully at-home OTC COVID-19 diagnostic test follows last month’s [authorization](#) of the first prescription COVID-19 test for home use and last week’s announcement of the first non-prescription test system, in which a lab processes the self-collected sample. The FDA has authorized more than 225 diagnostic tests for COVID-19 since the...



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