

To: (10)(2e) [(10)(2e)]@rivm.nl
From: (10)(2e)
Sent: Thur 9/17/2020 12:06:49 PM
Subject: RE: COVID-19 NEWS Lumipulse SARS-CoV-2 Ag | sample types: Nasopharyngeal swaps en Saliva!
Received: Thur 9/17/2020 12:06:50 PM

Hoi (10)(2e)

(10)(2e) gaat kijken naar de antigeen testen voor validatie. Ik heb je mail doorgestuurd.

(10)(2e)

(10)(2e)

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Phone: 0031 (10)(2e)

From: (10)(2e) <(10)(2e)@rivm.nl>
Sent: woensdag 16 september 2020 10:39
To: (10)(2e) <(10)(2e)@rivm.nl>
Subject: FW: COVID-19 NEWS Lumipulse SARS-CoV-2 Ag | sample types: Nasopharyngeal swaps en Saliva!

Hoi (10)(2e)

Ik vroeg mij af of we deze ook meenemen met de vergelijking. Ik kreeg deze van (10)(2e) op (10)(2e) dit is de persoon waarmee (10)(2e) de validatie van de Abbott Ag test doet.

(10)(2e)

From: (10)(2e) <(10)(2e)@hotmail.com>
Sent: woensdag 16 september 2020 10:28
To: (10)(2e) <(10)(2e)@rivm.nl>
Subject: Fwd: COVID-19 NEWS Lumipulse SARS-CoV-2 Ag | sample types: Nasopharyngeal swaps en Saliva!

Mss is fujirebio lumipulse een mooi alternatief voor de handmatige antigeen testen....

(10)(2b)

Ik ben benieuwd naar jullie opinie.

(10)(2e)

Of (10)(2e)

From: (10)(2e) <(10)(2e)@fujirebio.com>
Sent: Tuesday, September 15, 2020 16:05
To: (10)(2e); (10)(2e)@hoharuba.com
Cc: (10)(2e)@necarex.nl
Subject: FW: COVID-19 NEWS Lumipulse SARS-CoV-2 Ag | sample types: Nasopharyngeal swaps en Saliva!

Beste (10)(2e)

Hierbij nog wat informatie in de bijlage.

1. Vanaf maart/april dit jaar zijn wij op de markt met de **CE/IVD iAMP COVID-19 detection kit** [Moleculaire assay] deze kit is gebaseerd op de gepatenteerde Omega technologie van Atila.

[een gemodificeerde LAMP technologie] in Europa wordt deze kit op grote schaal gebruikt. Een groot voordeel is dat een extractie niet nodig is want wij werken vanuit

een lysis buffer en daarnaast is de kit gevalideerd op diverse rtPCR systemen naast de eigen Powergene 9600. De iAMP SARS-CoV-2 detection kit heeft een CE/IVD, FDA en is ook

door het gerenommeerde Institut Pasteur goed gekeurd voor het gebruik van COVID screening in (10)(2a) en welke ook op grote schaal wordt toegepast.

Antigeen testen.

2. CE/IVD Lumipulse [CLEIA] SARS-CoV-2 Ag test¹

3. CE/IVD Espline Rapid SARS-CoV-2 Ag test

'op dit moment net als in (10)(2a) revolutionair van start gegaan in (10)(2a) waar meerdere vooraanstaande instituten al in routine zijn gestart of valideren om snel te starten.

ook de overheid in (10)(2a) een studie gestart en heeft positieve feedback gedeeld. We hebben met deze test de nieuws zenders op TV gehaald in (10)(2a) en dan in positieve zin wel te verstaan

<https://www.linkedin.com/feed/update/urn:li:activity:6710554642981412864/>

Hieronder treft u informatie in casu de antigeen testen en in de bijlage IFU's van

Naast de Atila CE/IVD iAMP COVID-19 detection kit [moleculair], komen wij nu met twee nieuwe productlijnen op de markt, te weten de

Espline Rapid SARS-CoV-2 Ag test en de Lumipulse [CLEIA] SARS-CoV-2 Ag test.

Beide testen zijn voorzien van een CE/IVD label, in de bijlage treft u o.a de IFU's en informatie vanuit de (10)(2a) overheid.

Summary

Espline SARS-CoV-2	Lumipulse SARS-Cov-2 Ag
 • Immuno-chromatography (ICA) • Sample type: nasopharyngeal swab fluid • Sample volume: 20ul • Test result TAT: ~30 minutes • (10)(2a) PMDA cleared on May 13, 2020 • Reimbursement eligible on May 13, 2020 • Recommended in (10)(2a) guideline on May 13, and June 16, 2020	  • Chemiluminescence Enzyme Immunoassay (CLEIA) assay • Sandwich method • Sample type: nasopharyngeal swab fluid and Saliva • Sample volume: 100ul • Measurement range: 0.60~5,000.00pg/ml • LoD: 0.19pg/mL, LoQ: 0.60pg/mL • Test result TAT: 25 minutes • # of tests: 60 tests/hr (on G600II) 120 tests/hr (on G1200) • Japan PMDA cleared on June 16, 2020

Wetende dat er op dit moment veel gekeken wordt naar antigeen testen, wilde ik u toch ook nog eens wijzen op onze opties, o.a de volledig geautomatiseerde cartridge based CE/IVD Lumipulse SARS_CoV_2 Ag [CLEIA] assay welke toepasbaar is op **Nasopharyngeal swaps en Saliva!**

Zoals in de bijlage al aangegeven wordt de test in (10)(2a) al groots ingezet en in Europa zijn vooraanstaande instituten in (10)(2a) [overheid en Universitaire centra], (10)(2a) en zeer binnenkort in (10)(2a) direct een verificatie/validatie studie begonnen.

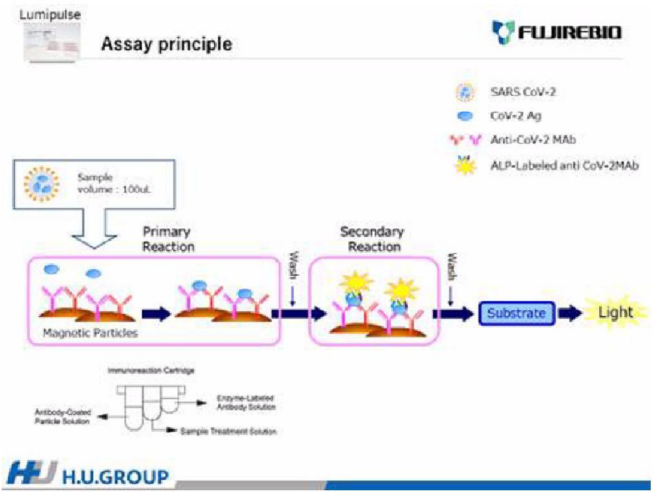
Workflow CE/IVD Lumipulse SARS_CoV_2 Ag [CLEIA] assay

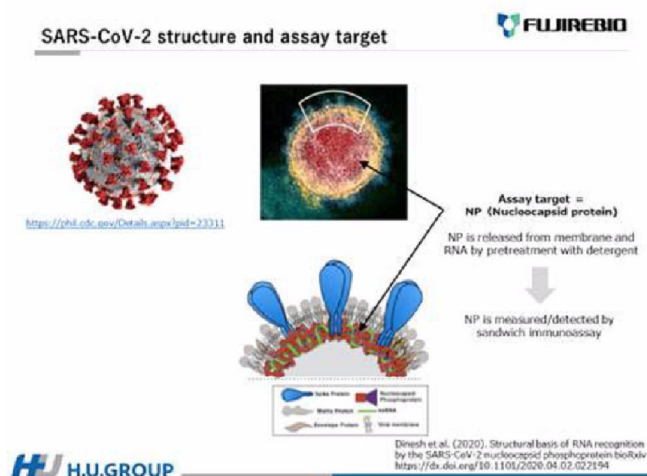
Lumipulse G600: 60 testen per uur en Lumipulse G1200: 120 testen per uur

Bi-directionele LIS connectie, wij hebben in diverse lab's Lumipulse systemen gekoppeld aan het LIS. Minimale hands on time, continuous loading en zeer goede MTBF...



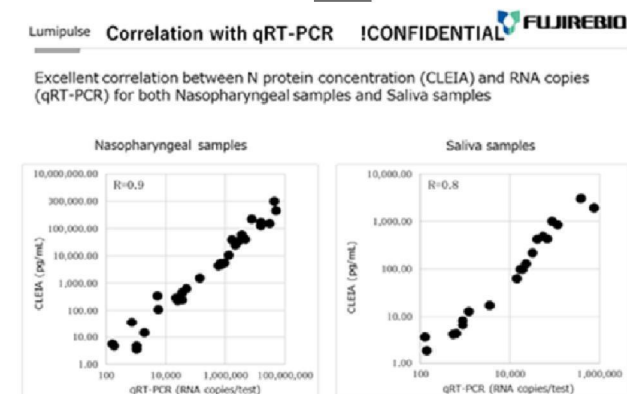
In a nutshell:





We received the kits 3 weeks ago at our warehouse in (10)(2a) and started several studies. In the meantime 4 in (10)(2a) plus the governmental study] one in (10)(2a) this week we will start in (10)(2a) followed by (10)(2a) and (10)(2a). Please let us know if you and your team are interested to start one yourself so we will be able to discuss this with marketing as soon as possible.

So far all data available is coming from (10)(2a). I'm counting on your confidentiality not to share this information for the time being.



Mentioned in the IFU :

A. Clinical data

1) Nasopharyngeal swab specimen using virus preservation solution

Using 325 (10)(2a) clinical specimens (Nasopharyngeal swab specimen), we examined the correlation with the RT-PCR method. For COVID-19 patients, a high correlation was observed between the RNA copy number calculated from the RT-PCR Ct (Cycle Threshold) value and the antigen concentration measured from this assay.

The cut-off value of this product calculated by Youden's index by ROC analysis was 1.34 pg/mL. When the correlation was confirmed using this value, the sensitivity (positive concordance rate) was 91.7% (22/24 cases), specificity (negative concordance rate) was 97.3% (293/301 cases), overall concordance rate was 96.9% (315/325 cases)

Lumipulse



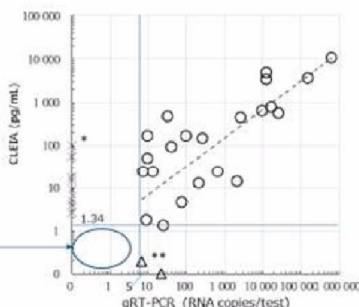
Comparison with qRT-PCR



CLEIA shows the same level of detection performance as RT-PCR

The cut-off value of this product calculated by Youden's index by ROC analysis was 1.34 pg/mL. When the correlation was confirmed using this value, the sensitivity (positive concordance rate) was 91.7% (22/24 cases), specificity (negative concordance rate) was 97.3% (293/301 cases), overall concordance rate was 96.9% (315/325 cases) (Table 1).

CLEIA	qRT-PCR		
	+	-	total
	+	-	total
+	22	8*	30
-	2**	293	295
total	24	301	325



*All 8 samples (X) have history of RT-PCR positive. Out of 8, 4 samples showed slight amplification at high Ct although those were determined as RT-PCR negative.

**Another nucleic acid test indicated that one of two samples (Δ) was negative (the other sample was not tested because of sample volume constrain).



2) Saliva specimen

Correlation to RT-PCR method was studied by using 1,924 specimens (from Airport quarantine group and Close contact group) in (10)/(2a)

A ROC analysis was implemented, and cutoff value calculated from results with Youden's index was determined at 0.67 pg/mL.

Results from correlation study with the cutoff values showed as follows: sensitivity (positive concordance rate) 100.0% (4/4 cases), specificity (negative concordance rate) 99.3% (1,746/1,759 cases), overall concordance rate 99.3% (1,750/1,763 cases) on Airport quarantine group, and sensitivity (positive concordance rate) 70.5% (31/44 cases), specificity (negative concordance rate) 100.0% (117/117 cases), overall concordance rate 91.9% (148/161 cases) on Close contact group (see Table 3). For 13 discordant samples on Close contact group for RT-PCR

method, the Ct value for RT-PCR was 33-35 for 4 cases and 35 or over for 9 cases.

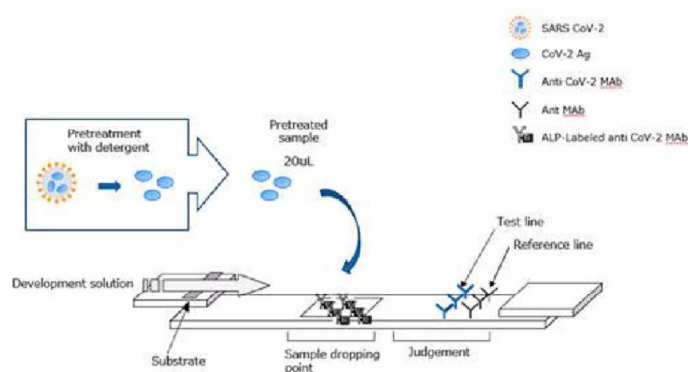
We hope to receive more data soon, we will share them with you as soon as possible.

CE/IVD Espline SARS CoV 2 Ag assay

Simple test procedure



Easy result interpretation



(10)(2a) guidelines

<https://www.mhlw.go.jp/content/000640554.pdf>

<Unofficial translation by Fujirebio>

Guideline for the use of SARS-CoV-2 Antigen detection kit

Initial version: May 13, 2020

Updated: June 16

Ministry of Health, Novel Coronavirus Response Headquarters

This guideline describes the approach and important notes to promote the appropriate use of the rapid antigen detection kit (Product name: Espline SARS-CoV-2, manufacturer: Fujirebio, Inc.) for the diagnosis of Novel Coronavirus infection (COVID-19). At this point the purpose of the use of this kit is to detect positive patients quickly.

When tested positive by this kit, it can be considered as a definitive diagnosis. For a patient with suspected infection and **in between the 2nd to 9th day after symptom onset, negative result of this test kit does not require additional PCR testing.** On the other hand, this kit requires a higher amount of virus in sample than PCR, at this point **it is not suited to use this kit to a patient who has not presented symptom, because of the detectability limitation of this kit.**

Ik hoop dat je hier iets mee kan en ben benieuwd naar jullie feedback.

Met vriendelijke groet

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