

To: [redacted] 5.1.5 (Ministerie van VWS) [redacted] 5.1.2e [redacted]@minvws.nl]
Cc: [redacted] 5.1.2e [redacted] 5.1.2e [redacted] 5.1.2e [redacted]@rivm.nl]
From: agtest
Sent: Tue 3/23/2021 3:42:51 PM
Subject: RE: Foto's van Genrui - aanvullend
Received: Tue 3/23/2021 3:42:52 PM

Ha [redacted] 5.1.2e

Met deze foto's zijn de ontbrekende punten geadresseerd en kunnen we dit dossier gaan beoordelen.

Groet,

[redacted] 5.1.2e

[redacted] 5.1.2e [redacted] 5.1.2e
 National Institute for Public Health and the Environment (RIVM)
 Centre for Health Protection (GZB)
 PO Box 1
 NL-3720 BA Bilthoven
 Tel: [redacted] 5.1.2e
 Mob: [redacted] 5.1.2e

Van: [redacted] 5.1.5 (Ministerie van VWS) <[redacted] 5.1.2e [redacted]@minvws.nl>
Verzonden: dinsdag 23 maart 2021 15:34
Aan: agtest <[redacted] 5.1.2e [redacted]@rivm.nl>
CC: [redacted] 5.1.5 (Ministerie van VWS) <[redacted] 5.1.2e [redacted]@minvws.nl>
Onderwerp: Foto's van Genrui - aanvullend

Beste collega's van het RIVM,

Hierbij stuur ik jullie de aanvullende documentatie (in dit geval foto's) voor de aanvraag van [redacted] 5.1.2e Zie de link in de e-mail (het is een heel groot bestand).

Vriendelijke groet,

[redacted] 5.1.2e [redacted] 5.1.2e

[redacted] 5.1.2e [redacted] 5.1.2e [redacted] 5.1.2e
 [redacted] 5.1.2e

Ministerie van Volksgezondheid, Welzijn en Sport
Directie Geneesmiddelen en Medische Technologie
 Parnassusplein 5 | 2511 VX | Den Haag
 Postbus 20350 | 2500 EJ | Den Haag

Email: [redacted] 5.1.2e [redacted]@minvws.nl

Van: [redacted] 5.1.2e <[redacted] 5.1.2e [redacted]@genrui-bio.com>
Verzonden: dinsdag 23 maart 2021 15:01
Aan: [redacted] 5.1.5 (Ministerie van VWS) <[redacted] 5.1.2e [redacted]@minvws.nl>
Onderwerp: RE: Genrui Self Test Antigen application for registration in Netherlands

Dear [redacted] 5.1.2e

Thank you so much for your quick reply.

Please kindly check below link to download the HD pictures of Genrui self test antigen.

https://exmail.qq.com/cgi-bin/ftnExs_download?k=503736360eea5c9868526e1c123352571d5302000c015c5c021a52010d5148510a0e521b0c5606571f5454055406

5000505100500d3349657a7316665c50111040524516535c174575525844405a4516575b501641561611125658425c54000b1c4d5f46350e&t=exs_ftn_download&code=276653ee&s=email

If any question, just feel free to let me know.

Have a nice day.

Best Regards

5.1.2e

Genrui Biotech Inc.

Mobile/WhatsApp/Wechat: 5.1.2e

From: Medical Devices (Ministerie van VWS) [5.1.2e] <5.1.2e@minvws.nl>

Sent: 2021年3月23日 8:39 PM

To: 5.1.2e <5.1.2e@genrui-bio.com>

Cc: 5.1.5 (Ministerie van VWS) <5.1.2e@minvws.nl>

Subject: RE: Genrui Self Test Antigen application for registration in Netherlands

Dear 5.1.2e

Could you send the pictures via WeTransfer or Zipfile? In that case the size of the pictures should (hopefully) not matter.

Kind regards,

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5.1.2e (5.1.2e) 5.1.2e 5.1.2e

5.1.2e

Ministerie van Volksgezondheid, Welzijn en Sport
Directie Geneesmiddelen en Medische Technologie

Parnassusplein 5 | 2511 VX | Den Haag

Postbus 20350 | 2500 EJ | Den Haag

Email: 5.1.2e <5.1.2e@minvws.nl>

Van: 5.1.2e <5.1.2e@genrui-bio.com>

Verzonden: dinsdag 23 maart 2021 12:30

Aan: 5.1.5 (Ministerie van VWS) <5.1.2e@minvws.nl>

Onderwerp: RE: Genrui Self Test Antigen application for registration in Netherlands

Dear 5.1.2e

Good day. Thank you for your feedback.

We have HD pictures for our self test antigen. May I know how much size of picture your mailbox can accept? So that I can adjust the size of pictures accordingly.

I am sending you the sample of HD Picture for kind reference.

Please kindly advise.

Best Regards

5.1.2e

Genrui Biotech Inc.

Mobile/WhatsApp/Wechat: 5.1.2e

From: 5.1.5 (Ministerie van VWS) [5.1.2e] <5.1.2e@minvws.nl>

Sent: 2021年3月23日 7:04 PM
To: [REDACTED] <[REDACTED]@genrui-bio.com>
Cc: [REDACTED] (Ministerie van VWS) <[REDACTED]@minvws.nl>
Subject: RE: [REDACTED] Self Test Antigen application for registration in Netherlands

Dear [REDACTED]

Thank you for the additional information. Could you please also provide me more product information? More specifically: clear photos of all the different components?

Thank you.

Kind regards,

[REDACTED] [REDACTED]

[REDACTED] [REDACTED] [REDACTED] [REDACTED]
[REDACTED] [REDACTED]

Ministerie van Volksgezondheid, Welzijn en Sport
Directie Geneesmiddelen en Medische Technologie
Parnassusplein 5 | 2511 VX | Den Haag
Postbus 20350 | 2500 EJ | Den Haag

Email: [REDACTED]@minvws.nl

Van: [REDACTED] <[REDACTED]@genrui-bio.com>
Verzonden: dinsdag 23 maart 2021 03:04
Aan: [REDACTED] (Ministerie van VWS) <[REDACTED]@minvws.nl>
Onderwerp: RE: [REDACTED] Self Test Antigen application for registration in Netherlands

Dear [REDACTED],

Good to be in touch again with you. Hope my mail finds you well.

We are sorry that we forgot to send the validation study on nasal swab for professional use.

Please kindly check attached professional use clinical evaluation report for Nasopharyngeal swab, Oropharyngeal swab, Nasal Swab and Saliva. And also I am sending you the self test clinical evaluation report for saliva.

Besides, I am sending you the package box for saliva for kind reference, which is also for self test antigen.

If any question, just feel free to let me know.

Thanks and have a nice day.

Best Regards

[REDACTED]

Genrui Biotech Inc.

Mobile/WhatsApp/Wechat: [REDACTED]

From: [REDACTED] (Ministerie van VWS) [REDACTED]@minvws.nl
Sent: 2021年3月19日 11:15 PM
To: [REDACTED] <[REDACTED]@genrui-bio.com>
Cc: [REDACTED] (Ministerie van VWS) <[REDACTED]@minvws.nl>
Subject: RE: [REDACTED] Self Test Antigen application for registration in Netherlands

Dear [REDACTED]

Thank you for your this explanation. We will further proceed with the assessment of your documentation. If there are any additional questions we will inform you.

Best regards,

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5.1.2e

Ministerie van Volksgezondheid, Welzijn en Sport
Directie Geneesmiddelen en Medische Technologie

Parnassusplein 5 | 2511 VX | Den Haag
Postbus 20350 | 2500 EJ | Den Haag

Email: 5.1.2e @minvws.nl

Van: 5.1.2e <5.1.2e@genrui-bio.com>

Verzonden: vrijdag 19 maart 2021 16:03

Aan: 5.1.5 (Ministerie van VWS) <5.1.2e@minvws.nl>

Onderwerp: RE: 5.1.2e Self Test Antigen application for registration in Netherlands

Dear 5.1.2e,

Thank you so much for your quick response to our application.

Actually our SARS-CoV-2 Antigen Test Kit has met the current minimum standards of the Paul Ehrlich Institute (PEI) in Germany. After validation in Germany, we are in the list of the Paul Ehrlich Institute (PEI).

Attached is the documents for your kind reference. We do hope this document from the Paul Ehrlich Institute (PEI) can be used to support the validation based on a study performed outside the Netherlands.

If any question, just feel free to let us know. Thanks again and have a nice day.

Best Regards

5.1.2e

Genrui Biotech Inc.

Mobile/WhatsApp/Wechat: 5.1.2e

From: 5.1.5 (Ministerie van VWS) [5.1.2e@minvws.nl]

Sent: 2021年3月19日 10:36 PM

To: 5.1.2e <5.1.2e@genrui-bio.com>; 5.1.5 (Ministerie van VWS) <5.1.2e@minvws.nl>

Subject: RE: 5.1.2e Self Test Antigen application for registration in Netherlands

Dear 5.1.2e

Thank you for your interest in our derogation procedure. I performed a quick assessment on whether your dossier is complete and there seems to be 1 document missing.

In our conditions as attached we require that if the data used for validation is based on a study performed outside the Netherlands, you need to explain how this data can be extrapolated to the Dutch situation. I could'n find this in your file. Please provide us this information as soon as possible and we will further proceed with your applications.

Best regards,

5.1.2e 5.1.2e 5.1.2e 5.1.2e

5.1.2e

Ministry of Health, Welfare and Sport
Department of Pharmaceutical Affairs and Medical Technology
Parnassusplein 5 | 2511 VX | The Hague
P.O. Box 20350 | 2500 EJ | The Hague

5.1.2e @minvws.nl
www.minvws.nl

Van: 5.1.2e <5.1.2e@genrui-bio.com>
Verzonden: vrijdag 19 maart 2021 11:46
Aan: 5.1.5 (Ministerie van VWS) <5.1.2e@minvws.nl>
Onderwerp: 5.1.2e Self Test Antigen application for registration in Netherlands

Dear Sir/Madam,

Greetings from Genrui Biotech Inc. My name is 5.1.2e in Genrui Biotech Inc. It is my pleasure to contact with you.

We would like to introduce that **Genrui Biotech Inc.** is professional in In-vitro diagnostics products for nearly 20 years, as one of the best IVD product manufacturers in China, after the COVID-19 outbreak, we have developed the COVID-19 relevant diagnostic reagents and instrument from March 2020 and have helped more than 80 countries on fighting against COVID-19, and received much satisfactions from our clients all over the world.

Currently we would like to apply for the registration of Genrui Self Test Antigen in Netherlands. Please kindly find attached documents for registration.

If you need more documents or have any question, please feel free to contact us.

Thanks in advance and have a nice day.

Best Regards

5.1.2e

Genrui Biotech Inc.

Address: 4-10F, Building 3, Geya Technology Park, Guangming District, 518106, Shenzhen, China

Tel: 5.1.2e Fax: 5.1.2e

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