

To: [redacted] 5.1.2e [redacted] 5.1.2e [redacted] 5.1.2e [redacted] @rivm.nl]; [redacted] 5.1.2e [redacted] 5.1.2e [redacted] 5.1.2e [redacted] @rivm.nl]; [redacted] 5.1.2e [redacted] 5.1.2e
5.1.2e [redacted] 5.1.2e [redacted] @rivm.nl]
From: [redacted] 5.1.2e [redacted] 5.1.2e
Sent: Tue 3/30/2021 10:17:44 AM
Subject: FW: Vaccine COVID Astra Zeneca - Italian batches
Received: Tue 3/30/2021 10:17:45 AM

FYI, dit is wat we gerapporteerd hebben aan de Italiaanse autoriteiten, daaronder staat het verzoek van AIFA.

grM

[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)
Department for Biologicals, Screening & Innovation (BSI)
P.O. Box 1
3720 BA BILTHOVEN, The Netherlands
T: [redacted] 5.1.2e [redacted] or [redacted] 5.1.2e [redacted] (mobile)

-----Original Message-----

From: [redacted] 5.1.2e [redacted] @aifa.gov.it <[redacted] 5.1.2e [redacted] @aifa.gov.it>
Sent: dinsdag 30 maart 2021 09:05
To: [redacted] 5.1.2e [redacted] 5.1.2e <[redacted] 5.1.2e [redacted] @rivm.nl>
Cc: [redacted] 5.1.2e [redacted] <[redacted] 5.1.2e [redacted] @aifa.gov.it>; [redacted] 5.1.2e [redacted] <[redacted] 5.1.2e [redacted] @aifa.gov.it>; [redacted] 5.1.2e [redacted] <[redacted] 5.1.2e [redacted] @aifa.gov.it>
Subject: Re: Vaccine COVID Astra Zeneca - Italian batches

Dear [redacted] 5.1.2e

thank you very much for your quick reply. Of course, you can share these results with Astra Zeneca.

Kind regards

[redacted] 5.1.2e

Inspections and Certification Department Product Quality and Pharmaceutical Crime Counteracting Office Italian Medicines Agency Via del Tritone, 181 - 00187 Rome

----- Messaggio originale -----

Da: "[redacted] 5.1.2e [redacted] 5.1.2e" <[redacted] 5.1.2e [redacted] @rivm.nl>
A: "rapidalertit" <[redacted] 5.1.2e [redacted] @aifa.gov.it>
Cc: [redacted] 5.1.2e [redacted] <[redacted] 5.1.2e [redacted] @aifa.gov.it>, [redacted] 5.1.2e [redacted] <[redacted] 5.1.2e [redacted] @aifa.gov.it> [redacted] 5.1.2e [redacted] <[redacted] 5.1.2e [redacted] @aifa.gov.it>
Inviato: Martedì, 30 marzo 2021 8:51:06
Oggetto: RE: Vaccine COVID Astra Zeneca - Italian batches

Dear colleagues,

As requested we have performed additional tests on 4 batches of COVID-19 Vaccine AstraZeneca. For all 4 batches we have received 2 retention samples from AstraZeneca and have tested each vial for potency, identity and appearance. Visual inspection for all batches passed and no irregularities were observed. Also the ID test passed for all lots, confirming the presence of DNA sequences for Covid-spike and flanking region. For the potency, all lots conformed to the specifications (release specification: $\geq 7.0 \times 10^8$ ifu/ml) and were in line with results obtained previously (see table below). Please note that the results come from an infectivity assay and are therefore more variable than the number of significant digits indicate; differences seen between original tests and retest or between two vials in additional test are not expected to be meaningful.

Would it be OK for you if we also share these results with AstraZeneca?

Original results (in 108 ifu/ml)

Additional tests RIVM (in 108 ifu/ml)

Potency AZ

Potency RIVM

Vial 1

Vial 2

ABV6096

17.0

15.1

11.2

11.5

ABV5811 (ABV5094)

13.0

10.7

10.2

11.0

ABV2856 (ABV0519)

9.8

14.9

12.9

11.6

ABV3374 (ABV1953)

10.0

11.3

10.6

8.4

Please, let us know if you have additional questions.

Best regards,

5.1.2e

5.1.2e (5.1.2e) 5.1.2e

National Institute for Public Health and the Environment (RIVM) Centre for Health Protection (GZB) Department for Biologicals, Screening & Innovation (BSI) P.O. Box 1
3720 BA BILTHOVEN, The Netherlands

T: 5.1.2e or 5.1.2e

From: 5.1.2e @aifa.gov.it <5.1.2e @aifa.gov.it>

Sent: woensdag 24 maart 2021 12:42

To: 5.1.2e | 5.1.2e <5.1.2e @rivm.nl>

Cc: 5.1.2e <5.1.2e @aifa.gov.it>; 5.1.2e <5.1.2e @aifa.gov.it>; 5.1.2e <5.1.2e @aifa.gov.it>

Subject: Vaccine COVID Astra Zeneca - Italian batches

Dear 5.1.2e

We have been informed by Astra Zeneca that the company has sent to RIVM the retain samples of some batches (ABV6096, ABV5811, ABV2856, ABV3374) of COVID-19 Vaccine Astrazeneca in order to perform the release tests. We would inform you that Italy agree with this decision, and we would ask you to inform us about the results as soon as they would be available.

We would thank you for your helpful collaboration.

Best regards,

Dit bericht kan informatie bevatten die niet voor u is bestemd. Indien u niet de geadresseerde bent of dit bericht abusievelijk aan u is verzonden, wordt u verzocht dat aan de afzender te melden en het bericht te verwijderen. Het RIVM aanvaardt geen aansprakelijkheid voor schade, van welke aard ook, die verband houdt met risico's verbonden aan het elektronisch verzenden van berichten.
www.rivm.nl<<http://www.rivm.nl>> De zorg voor morgen begint vandaag

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