

To: [REDACTED] 5.1.2e [REDACTED] 5.1.2e @rivm.nl]
 From: [REDACTED] 5.1.2e
 Sent: Thur 5/14/2020 10:39:21 AM
 Subject: FW: Xpert Xpress SARS-CoV-2 test
 Received: Thur 5/14/2020 10:39:22 AM
[2020-1D Xpert Xpress SARS-CoV-2 Declaration of Conformity CE signed.pdf](#)
[Xpert Xpress SARS-CoV-2 CE announcement Customer letter.pdf](#)

Geen nieuwe manual dus.

[REDACTED] 5.1.2e

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

From: [REDACTED] 5.1.2e <[REDACTED] 5.1.2e @cepheid.com>
 Sent: donderdag 14 mei 2020 08:43
 To: [REDACTED] 5.1.2e <[REDACTED] 5.1.2e @minvws.nl>; [REDACTED] 5.1.2e <[REDACTED] 5.1.2e @igj.nl>; [REDACTED] 5.1.2e <[REDACTED] 5.1.2e @rivm.nl>
 Cc: [REDACTED] 5.1.2e <[REDACTED] 5.1.2e @igj.nl>; [REDACTED] 5.1.5 @minvws.nl>; [REDACTED] 5.1.2e @cepheid.com>
 Subject: RE: Xpert Xpress SARS-CoV-2 test

Dear all,

I have the pleasure to inform you that the Xpert Xpress SARS-CoV-2 product has received CE-IVD designation in addition to the FDA EUA authorization.

The following documents are attached to this email for information

1. Signed Xpert Xpress SARS-CoV-2 DoC
2. Xpert Xpress SARS-CoV-2 Customer Letter

Best wishes,

[REDACTED] 5.1.2e

[REDACTED] 5.1.2e

MOBILE BE +32 [REDACTED] 5.1.2e
 MOBILE NL +31 [REDACTED] 5.1.2e
www.cepheid.com

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

From: [REDACTED] 5.1.2e
 Sent: Monday, May 4, 2020 14:37
 To: [REDACTED] 5.1.2e <[REDACTED] 5.1.2e @minvws.nl>; [REDACTED] 5.1.2e <[REDACTED] 5.1.2e @igj.nl>; [REDACTED] 5.1.2e <[REDACTED] 5.1.2e @rivm.nl>
 Cc: [REDACTED] 5.1.2e <[REDACTED] 5.1.2e @igj.nl>; [REDACTED] 5.1.5 @minvws.nl>; [REDACTED] 5.1.2e @cepheid.com>
 Subject: RE: Xpert Xpress SARS-CoV-2 test

Dear all,

For your information, please find attached the change notification letter along with the also attached redlined and clean copies of the Xpert Xpress SARS-CoV-2 package insert for GX Dx and Infinity System.

The Xpert Xpress SARS-COV2 test (catalog number XPRSARS-COV2-10) was authorized by the US FDA for Emergency Use Only (EUA) on March 20, 2020. This letter is to notify updates to Xpert Xpress SARS-COV2 Package Insert and the addition of Cepheid AB, Solna, Sweden as a manufacturing location. The revised Product labels and Package Insert are reviewed and approved by the US FDA.

Do not hesitate to reach out in case of questions.

Best wishes,

5.1.2e

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

From: 5.1.2e) <5.1.2e@minvws.nl>

Sent: Wednesday, April 22, 2020 10:29

To: 5.1.2e <5.1.2e@cepheid.com>; 5.1.2e) <5.1.2e@igj.nl>

Cc: 5.1.2e <5.1.2e@igj.nl>; 5.1.2e <5.1.2e@cepheid.com>; 5.1.5
<5.1.5@minvws.nl>

Subject: RE: Xpert Xpress SARS-CoV-2 test

Beste 5.1.2e

Hierbij de brief over de Xpert Xpress SARS-CoV-2 test.

Vriendelijke groet,

5.1.2e

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