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Application to obtain exemption for Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold) nasal for use as self-test.

VERSION: II

Applicant

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Date of Submission version II : 29 March, 2021

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1. Product name: **Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold) nasal**
Catalogue No. 303036
Referred to as: LYHER COVID-19 antigen test kit (nasal)

Manufacturer: Hangzhou Laihe Biotech Co., Ltd., Hangzhou, Zhejiang, China

2. Specific Conditions and criteria for the exemption procedure

The distributor has satisfied the following conditions and criteria:

■ The rapid antigen test in question already bears a CE-mark for professional use:

Declaration of Conformity (DOC): Attachment 1. The LYHER COVID-19 antigen test kit (Colloidal Gold) for professional use meets the requirements of in vitro diagnostic directive (98/79/EC) and the following harmonized standards EN ISO 14971-2012; EN ISO 18113-2-2011; EN ISO 234640-2015; EN ISO 18113-1-2011; EN 13612:2002+AC:2002; EN 13641-2002.

■ The manufacturer has already started a conformity assessment procedure with a notified body to obtain a CE-mark for the use of the rapid antigen test as a self-test.

The LYHER COVID-19 antigen test kit (nasal) for self-test (home use) contains the exact same extraction buffer tube and test device for which this DOC applies for. The difference is the nasal swab device. The procedure for CE mark for the COVID-19 antigen test kit (nasal) for home use (self-testing) is in progress. Attachment 2.

■ The suitability of the rapid antigen test as a self-test has been demonstrated for a specifically defined target group.

There were two Clinical tests for LYHER COVID-19 Antigen test kit for professional use; August, 2020 (Attachment 3.1.) and February, 2021 (Attachment 3.2.). In Attachment 3.2., the sampling via the nasal swab is compared to the sampling with a nasopharyngeal swab and the sampling with an oropharyngeal swab.

The clinical report on LYHER COVID-19 Antigen test kit (nasal, self-test) dated 08-02-2021 (Attachment 3.3) produced by Hangzhou Laihe Biotech Co., Ltd. showed no statistical significant difference between LYHER COVID-19 antigen test kit results compared to PCR test results measured in nasal swab of patients and the clinical diagnosis results, which were highly consistent. That showed LYHER Kit was suitable for self-testing.

Summary LYHER clinical report on LYHER COVID-19 Antigen test kit (nasal). Attachment 3.3.:

3 Medical institutions in Liaoning, Heilongjiang and Hebei performed the clinical evaluation of Novel Coronavirus (COVID-19) Antigen Test Kit (nasal) developed by Hangzhou Laihe Biotech Co., Ltd.
The clinical trial was compared with PCR test results and clinical diagnosis results to investigate the consistency of the products of Hangzhou Laihe Biotech Co., Ltd. with the clinical diagnosis results. A total of 411 patients' nasal swab were collected in this clinical trial, one by a specialist for PCR detection and one collected by patients themselves or their guardian for LYHER test. Samples for PCR test are blinded before testing, and unblinded after all test are finished. All the cases were diagnosed by Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing) of Sansure BioTech Inc. The analysis of **population of the subjects** are as follows:

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Age distribution of the participants:

Age group	Number	% of total
≤20	38	9.25%
21~40	92	22.38%
41~60	182	44.28%
61~80	89	21.65%
Above 80	10	2.43%

Sex of the participants:

Gender	Number	% of total
Male	221	53.77%
Female	190	46.23%

Educational background of the participants:

Educational group	Number	% of total
Middle School	69	16.79%
High School	191	46.47%
Bachelor	106	25.79%
Others	45	10.95%

Occupational background of the participants:

Profession	Number	% of total
Jobless	55	13.38%
Sales	128	31.14%
Clerk	166	40.39%
Others	62	15.09%

Whether used the COVID-19 testing products before?

	Number	% of total
Yes	0	0
No	411	100

The participants' ages range from 9 to 86, and most of them were from 21 to 80. They also showed different culture backgrounds. None of the participants had used a COVID-19 kit before. 68.13% reported that they were high-school graduates or lower and 53.77% participants were male.

The LYHER Kit tested was 152 positive out of 160 PCR positive, 250 negative out of 251 PCR negative. The **160 positive cases** were all **between 0 and 7 days of onset** and did not involve **asymptomatic patients**. Compared with the results of PCR and clinical diagnosis, the **clinical sensitivity** of LYHER Kit was **95.00%**, the **clinical specificity** of LYHER Kit was **99.60%**, the total coincidence rate was 97.81%, Kappa=0.972. There was no statistically significant difference between the test results of LYHER Kit and the clinical diagnosis results, the results of LYHER Kit were highly consistent with the results of clinical diagnosis and PCR test.

LYHER Results from Patients and PCR

Test Results of LYHER Kit	Clinical diagnosis (PCR results)		
	Positive (+)	Negative (-)	Total
Positive (+)	152	1	153
Negative (-)	8	250	258
Total	160	251	411

Conclusion: Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold) produced by Hangzhou Laihe Biotech Co., Ltd. showed no statistical significant difference between LYHER Kit

test results tested by patients and the clinical diagnosis results, which were highly consistent. That showed LYHER Kit was suitability for non-professional use (self-test).

Additional information on the LYHER COVID-19 antigen test kit (nasal):

- Stability study (Attachment 4.), demonstrates that the test kit is stable for < 21 months under storage conditions between 2-30C. In addition, storage of nasal specimens (2-8C) and transportation has no adverse effect on product quality.
- LoD study (Attachment 5.1.): detection limit is 1.35 x 10^2 $TCID_{50}$/mL.
- Cross reactivity (Attachment 5.2.): the test kit shows no cross reactivity for common viruses, including other corona viruses, and respiratory bacteria.
- Blood, toothpaste and other mouth products do not affect the test results.
- A wide range of anti-viral and anti-inflammatory drugs do not affect the test results.
- The test kit does not show high virus dose hook effect (Attachment 5.3.). Highest dose tested 1 x 10^7 $TCID_{50}$/mL.
- Nasal sample addition to the test kit should be completed within 40 min (Attachment 5.4., p1)
- The volume of specimen added to the test kit should be not less than 2 drops (Attachment 5.4., p2).
- The test provides a correct and valid result interpretation at a read time between 15 and 20 minutes (Attachment 5.4., p3).
- For accurate test results extracting the sample from the swab should be performed within 4 hours (Attachment 5.4., p4).
- Appropriate treatment of nasal swab is to squeeze the swab at least 10 times in the buffer tube and let it stand for 2 minutes (Attachment 5.4., p5).
- Specimens and test kits should be used at room temperature (>16C) and humidity does not affect test results (Attachment 5.4., p6).
- The performance of test kits is not affected when they fall to the ground or their shells are damaged (Attachment 5.4., p7).
- Test results should be read under sufficient lighting conditions (Attachment 5.4., p8).
- The test kit should be put on a flat non-tilted surface (Attachment 5.4., p9).
- Vibration or noise does not affect the test results (Attachment 5.4., p10).

■ The rapid antigen test satisfies the requirements for devices for self-testing as set out in the Decree on *in vitro* diagnostic medical devices (IVDs) and existing standards for self-tests (with the exception of the design-examination certificate for self-tests, issued by a notified body).

Risk Management Report (Attachment 6. and Attachment 19.) according to EN ISO 14971:2016, cl. 4.2 standards all the risk has been identified and the risks which are non-accepted have been controlled by measures taken by the manufacturer.
Essential requirements report for LYHER COVID-19 antigen test kit (nasal) (Attachment 7.).

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3. General conditions and criteria for the exemption procedure

■ The Health Security Committee's 'A common list of COVID-19 rapid antigen tests',[1] published on 17 February 2021.

The LYHER COVID-19 antigen test kit (nasal) is not listed.

■ Another EU member state has already granted an exemption for use of the rapid antigen test as a self-test.

The LYHER COVID-19 antigen test kit (nasal) has been granted an exemption for use as self-test by BfArM in Germany.
The LYHER COVID-19 antigen test kit (nasal) is evaluated by Paul-Ehrlich-Institut, Federal Institute for Vaccines and Biomedicines, Langen (Hessen) Germany (Attachment 8.). The LYHER COVID-19 antigen test kit (nasal) for home used was validated compared to PCR positive nasal samples (high viral load CT<25, CT25-30 & low viral load CT>30) and PCR negative samples.
Attached please, find the approval letter for the LYHER COVID-19 antigen test kit (nasal) for home use from the Federal Institute for Drugs and Medical Devices (BfArM) Bonn, Germany. Attachment 9.1. and Attachment 9.2.

■ A post-market surveillance system is in place for recording and assessing experiences with using the rapid antigen test as a self-test, based on which appropriate measures can be taken if necessary

The distributor will outsource the post-market surveillance at BAAT Medical, Hengelo, the Netherlands.

■ Reporting of incidents and safety issues related to self-administering the test in question to the Health and Youth Care Inspectorate (IGJ).

We will report calamities and safety issues related to the self-sampling to the IGJ immediately.

■ The regular statutory vigilance procedures relating to general safety and performance requirements.

We comply with the regular statutory vigilance procedures relating to general safety and performance requirements.

■ CE-mark for use of the rapid antigen test as a self-test

When we will obtain a CE mark (Declaration of Conformity) for the LYHER COVID-19 antigen test (nasal) for self-test, we will inform IGJ and the Pharmaceuticals and Medical Technology Department (GMT) of the Ministry of Health, Welfare and Sport via 5.1.2e minvws.nl.

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4. Check list of required documentation

- 1. Evidence that the rapid antigen test bears a CE-mark for professional use, including the supporting documentation. Attachment 1.

- 2. Evidence that an application has been submitted to a notified body of one of the EU member states to obtain CE-certification for use of the rapid antigen test as a self-test. Alternatively, evidence that a contract has been signed for a conformity assessment procedure via a notified body of one of the EU member states for use of the rapid antigen test as a self-test, including a confirmed plan of action with a timetable for obtaining CE-certification (if available). Attachment 2.

- 3. Product information:

    - Product name/trade name and catalogue number. Attachment 10.

    - General description of the test and how it works. Attachment 11.

    - Intended use of the test, including type of sample/sampling method and description of the testing target group. Attachment 11.

    - Clear (digital) illustrations or photos of the various components of the test and photos of the packaging from all sides and of the labels.
      Attachment 10.

    - Validation studies: reports of analytical and clinical validation studies (describing methods and results) into the test's performance when self-administered without supervision (sensitivity and specificity).
      Nasal specimens were tested by lay persons and obtained results were compared with the clinical diagnosis results and PCR, to evaluate the sensitivity, specificity and other indicators of the product, and to verify the accuracy of the product in clinical determination, so as to determine whether it meets the requirements of safety and effectiveness.
      Attachment 3.3.

    - If the data used for validation is based on a study performed outside the Netherlands, explain how this data can be extrapolated to the Dutch situation.
      The tests have been validated by a German institution. The population of Germany is similar and comparable to the population of the Netherlands.
      Attachment 8., Attachment 9.1. and Attachment 9.2.

    - Validation studies: reports of analytical and clinical validation studies (describing method and results) into the test's performance when administered professionally (sensitivity and specificity).

      There were two Clinical tests for LYHER COVID-19 Antigen test kit for professional use; August, 2020 (Attachment 3.1.) and February, 2021 (Attachment 3.2.).

    - Study into user-friendliness of the rapid antigen test when self-administered, taking due account of the requirements set out in EN-IEC62366-1.
      Attachment 3.3., paragraph 4.2, 4.3, 4.3.1, 4.3.2. and Attachment 19.:

      To evaluate the user-friendliness of the self-test, a questionnaire was drafted for the participants of the clinical evaluation study.

      The number of participants that completed the questionnaire after completing the self-test was 411.

      RESULTS:

      All participants (n=411) understood how to interpret the results.

      Storage of test device

        - 100% of the participants stated that they understood that the test cannot be placed in direct sunlight, nor can be frozen.

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Test procedure

- 100% of the participant understood that the test device was for single use.
- 100% of the participants read the test results at 15 minutes and understood the instruction to interpret the results of the test.
- The time taken from opening the foil bag to add the sample:
  - 24% of the participants: < 5 min
  - 47% of the participants: 5-10 min
  - 28% of the participants: 10-20 min
  - 1% of the participants: 20-30 min

  Note:
  100% of the participants finished the procedure in 30 min. There was no effect of the time taken from opening the foil bag to add the sample into the well (S) of the test device on the test results.

  No risk reduction measure needed.

- Knocking over buffer tube or breaking it: 0% of the participants.

  No risk reduction measure needed.

- 0.5% of the participants broke or had other problems with nose swab before processing the sample.

- Mistakes during processing samples after taking the nose swab:
  - cover the buffer tube with nose swab inside: 1.5 % of the participants.[1]
  - squeeze the buffer tube with nose swab inside less than 10 times: 8% of the participants.2
  - make buffer splash: 0% of the participants.
  - Let stand the buffer tube with nose swab inside less than 30 sec: 3% of the participants.[2]

  Note:
  1. It is not possible to cover the buffer tube with the nose swab inside, therefore this mistake only affects the test time.
  2. Squeezing less than 10 times or letting the buffer tube stand for less than 30 sec., may result in a false negative when the virus concentration in the sample is close to cut-off value.

  Risk reduction measure: ensure clear description of how to process the nose swab in the buffer tube in the Instructions for Use, the Instruction Manual and the instruction Video.

- Mistakes in adding the sample to the well (indicated with 'S' at the test cassette) of the test device:
  - adding the buffer directly to the well (S) of the test device: 0.2 % of the participants.[1]
  - adding sample to the well (S) of the test device without using dripper on buffer tube: 0.7% of the participants.[2]
  - adding more than 3 drops to the well (S) of the test device: 4% of the participants.[3]
  - adding less than 3 drops to the well (S) of the test device: 1.9 % of the participants.[4]
  - not adding sample to the well (S) of the test device: 0% of the participants.

  Note:
  1. adding the buffer directly to the well (S) of the test device will lead to a negative result.
  2. adding sample to the well (S) of the test device without using dripper on buffer tube will result in overflow of the well and lead to an invalid result.
  3. adding more than 3 drops of sample to the well (S) of the test device will not affect the test result.
  4. adding less then 3 drops of sample to the well (S) of the test device may lead to an invalid or false negative test result.

  Risk reduction measure: ensure clear description of how to add sample to the well (S) of the test device in the Instructions for Use, Instruction Manual and the instruction Video.

Reading results

- Mistakes regarding reading results:
  - reading the results before 15 min : 0% of the participants.

- reading the results after 20 min : 0.2% of the participants.
- reading the results in the sun light : 0% of the participants.
- reading the results in the dark light : 0.7% of the participants.

CONCLUSION

A total of 411 * 16 'mistake categories' = 6.576 actions were done. Regarding the mistakes in the test procedure and reading results, out of the 6.576 actions, 86 mistakes were made of which 63 mistakes may develop wrong or invalid test results. The total effective ratio is 84.7% (calculation: 63/411*100)

- Instructions for use in Dutch. This is mandatory for all self-tests. If available: instruction videos in Dutch, and a link to or information about where these videos can be found.
  Please see the Dutch Instruction for Use and the Instruction Manual, Attachment 10. and Attachment 11.
  On the instruction for Use there is reference made to the website www.aenerg.com and a QR code linking to a Dutch Instruction Video.

- Description of the test kit components (device, reagents, accessories) needed for administering the self-test, as well as a description of differences compared to the original test for professional use; the names of suppliers of the individual components must also be provided.
  All test kit components: test device, prepacked extraction buffer device, Instructions for Use, Instruction Manual are provided by the manufacturer. The difference compared to the original test for professional use is the nasal swab device.
  Attachment 10., Attachment 11., Attachment 14., Attachment 15., Attachment 16., Attachment 17. and Attachment 18.

- The CE declaration of conformity for professional use of the rapid antigen test.
  Attachment 1.

- The CE declaration of conformity for any components not included in the professional test, if applicable. Not applicable.

- Checklist of essential requirements.
  Attachment 7.

- Risk management documentation, including an overview of risk estimation, risk control measures and residual risks, in accordance with EN ISO 14971. Clearly indicate any risks connected specifically to using the test as a self-test, for example by highlighting the relevant passages.
  According to the analysis of the risks, all the risks has been identified and the risks which are none accepted have been controlled by measure taken by the manufacturer.
  Attachment 6., Attachment 13. and Attachment 19.

  POTENTIAL PUBLIC HEALTH RISKS

  The LYHER Novel Coronavirus (COVID-19) Antigen Test Kit for non-professional use is not suitable for use by persons that have been in contact with a SARS-CoV2 infected person to take responsibility to avoid self-isolation (quarantine) or reduce the time of self-isolation.

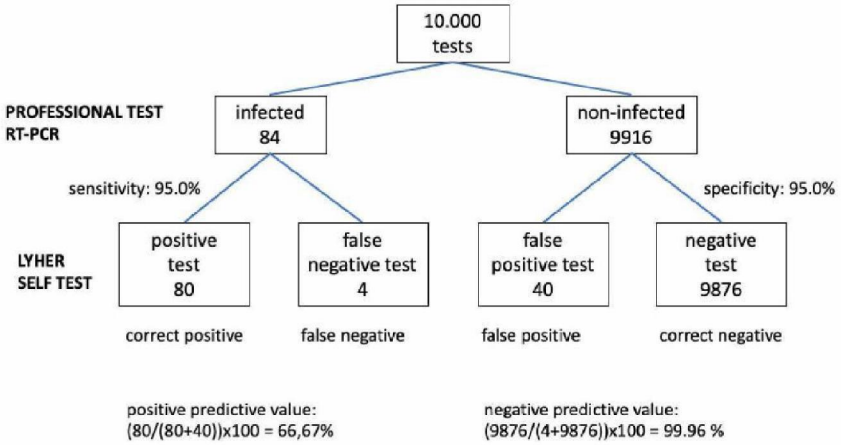
  Risk reduction measure: ensure clear description with regard to contact tracing by GGD in the Instructions for Use and Instruction Manual.

  The question of how likely a person with a positive (or negative) test result actually is (not) infected, can be calculated from the sensitivity and specificity values of the test only taking in consideration the proportion of those actually infected among those tested (pre-test probability).

  For the Netherlands dated March 2021 the pre-test probability is calculated according to Dr. Janna Seifried et al. 20211 and the Robert Koch Institut (https://rki-wiko.shinyapps.io/test_qual/)

[1] Seifried J. et al. 2021. Was ist bei Antigentests zur Eigenanwendung (Selbsttests) zum Nachweis von SARS-CoV-2 zu beachten? Epidemiologisches Bulletin 8, 25 Februar 2021 (online vorab) Attachment 20.

In the period between March 19-25, 2021 8.4% of the GGD RT-PCR tests was positive in the Netherlands. The clinical sensitivity of LYHER Novel Coronavirus (COVID-19) Antigen Test Kit for non-professional use is 95.0% and the clinical specificity is 99.6%.



The figure above demonstrated that the LYHER Novel Coronavirus (COVID-19) Antigen Test Kit for non-professional use has:

- a positive predictive value of 66.67%; a quantification of the probability that a person is infected when tested positive.
- a negative predictive value of 99.96%; a quantification of the chance that a person is not infected when tested negative.

In conclusion, the public health risk due false negative results is very small (<1%). No risk reducing measures are required.

General public health risks:

1. If the result of the antigen self-test for lay person use is positive, there is a risk that a positive tested person will not initiate a follow-up test by a physician or appropriate testing centre (GGD). In this case, there is no diagnosis with a subsequent report to the health authorities. As a result, health authorities may not be able to initiate necessary treatments or measures (notification, isolation, contact tracing, quarantine).

Risk reduction measure: ensure clear description with regard to the follow-up after testing positive in the Instructions for Use and Instruction Manual.

2. A positive antigen self-test result without professional explanation or a low-threshold offer for advice (online, by telephone) and re-testing can also lead to an incorrect assessment of the person concerned and thus to more uncertainty. A positive result of an antigen self-test should always be confirmed by an appropriate testing centre (GGD) using RT-PCR test.

Risk reduction measure: ensure clear description with regard to the follow-up after testing positive in the Instructions for Use and Instruction Manual.

3. High demands are placed on the understanding and personal responsibility of the lay person user. For example, it may be difficult for a lay person to read weak test responses with certainty.

Risk reduction measure: ensure photographic documentation of the test reaction ("lines") in the Instructions for Use and Instruction Manual.

4. If the nose swab is used incorrectly, the informational value of the test may be limited. Because lay person users independently carry out the sampling and the testing, the correct

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execution of the sampling (nose swab) and the correct time at which the investigation is as reliable as possible cannot be guaranteed.

Risk reduction measure: ensure clear description in the Instructions for Use, Instruction Manual and Instruction Video.

5. The quality of the sampling with nose swab is crucial for testing. A false negative test result, caused by improper removal or testing of the nose swabs, for example, carries the risk that an undetected acutely infected person will spread SARS CoV2 further, with potentially serious consequences. Broad communication and information transfer taking into account the special circumstances of personal use can make an important contribution to minimizing these risks.

Risk reduction measure: ensure clear description in the Instructions for Use, Instruction Manual and Instruction Video.

■ Evidence that another EU member state has already granted an exemption for use of the rapid antigen test as a self-test.

Attachment 9:
granted exemption for the LYHER COVID-19 antigen test kit (nasal) for self-test by Federal Institute for Drugs and Medical Devices (BfArM) Bonn, Germany.

■ The instructions for use must contain the instructions laid down by the government, and explain the steps to be taken in response to a negative or positive test result, respectively.

Attachment 10 and Attachment 11.

The 'Instructions for Use in Dutch' contain the following:

HOE TE HANDELEN NA TESTRESULTAAT

Vragen? Kijk voor meer informatie op: www.rijksoverheid.nl/uitslag-coronatest of bel met 0800-1351.
Met deze zelftest kunt u testen of u op dit moment corona heeft. Hieronder leest u wat de uitslag betekent en wat u met de uitslag moet doen.

POSITIEF:
U heeft waarschijnlijk corona. Maak direct een afspraak voor een hertest bij de GGD via 0800-1202 of via www.coronatest.nl. Tot de uitslag van de hertest bekend is, gaat u in isolatie, blijft u thuis in isolatie, vermijd u contact met huisgenoten en ontvangt u geen bezoek. Als de hertest ook positief is start de GGD samen met u het bron- en contactonderzoek.
Waarom een hertest?
Een zelftest is minder betrouwbaar dan de test op de GGD-testlocatie. Hierdoor is er kans dat uw positieve uitslag vals alarm is. Als de hertest bij de GGD negatief is dan mag u uit isolatie.

NEGATIEF:
Een negatief resultaat wijst op de afwezigheid van SARS-CoV-2-antigenen. Een negatieve uitslag van een zelftest is niet 100% betrouwbaar. Bij een negatieve uitslag is een recente besmetting met SARS CoV-2 niet uitgesloten. Als u denkt dat u in contact bent gekomen met het virus (met een besmette persoon) in de laatste dagen voor de uitvoering van de test, raden we u aan om een Laboratoriumtest te doen bij de GGD via 0800-1202 of via www.coronatest.nl. Blijf de corona regels volgen; houd afstand, draag een mondkapje, was vaak uw handen en blijf letten op klachten. Als u klachten krijgt of contact heeft gehad met een besmet persoon, laat u dan zo snel mogelijk testen bij de GGD. Vragen? Kijk voor meer informatie op www.rijksoverheid.nl/uitslag-coronatest of bel met 0800-1351.

ONGELDIG:
De test is niet geldig, doe een nieuwe test. Herlees de procedure en herhaal de test met een nieuwe cassette. Onvoldoende monstervolume of een te stroperig neusslijmmonster, onjuiste procedure-technieken (onjuiste neusslijm afname, temperatuur- en vochtigheids-condities voor het uitvoeren van de test) of tests die langer dan een uur openstaan of zelfs verlopen zijn, zijn de meest waarschijnlijke redenen voor het niet verschijnen van de controlelijn.

INFORMATIE VOOR GEBRUIKERS VAN ZELFTESTEN

Let op, doe in de volgende gevallen geen zelftest maar maak een afspraak bij een GGD-

testlocatie:
• u heeft coronaklachten
• u heeft contact gehad met een besmet persoon
• u bent de afgelopen 10 dagen teruggekomen uit een oranje gebied

Meer informatie:

- Meer weten over het testen op corona?
  Kijk op: www.rijksoverheid.nl/coronatest.
- De regels voor isolatie vindt u op: www.rijksoverheid.nl/quarantaine.
- Hulp of ondersteuning nodig tijdens de isolatie- of quarantaineperiode?
  Ga naar: www.rijksoverheid.nl/quarantainegids.
- Melden van klachten en/of incidenten kan via: 5.1.2e @aenerg.com.
- De zelftesten waar de Rijksoverheid een ontheffing voor heeft verleend, vindt u op: www.rijksoverheid.nl/ontheffingen-antigeentesten.

Voor het gebruik van dit product als zelftest heeft het Ministerie van VWS een ontheffing verstrekt. Informatie over de ontheffing is te vinden op de volgende website: www.rijksoverheid.nl/ontheffingen-antigeentesten.

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5. Table of attachments

Attachment n°	Name
1	Declaration of Conformity LYHER COVID-19 antigen test kit
2	TUV Application of COVID-19 Antigen test Kit for self-testing
3.1	Lyher Clinical Evaluation Report of Antigen Test August 2020
3.2	3.2 LYHER Clinical Evaluation Report of Antigen test Februari 2021 professional use (20210205)
3.3	3.3 LYHER Clinical evaluation Report of Antigen (Nasal self -test) Februari 2021 (20210328)
4	Stability study for nasal LYHER COVID-19 antigen test kit
5.1	LoD study for nasal LYHER COVID-19 antigen test kit
5.2	Cross reactivity for LYHER COVID-19 antigen test kit
5.3	High-dose hook effect LYHER COVID-19 antigen test kit
5.4	Flex studies for nasal LYHER COVID-19 antigen test kit
6.	Risk Management Report 20210328
7	Essential Requirements Report 20210129 COVID-19 antigen test kit (nasal)
8	Germany PEI evaluierung-sensitivitate-sars-cov-2-antigentests 14-12-2020
9.1	BfArM approval letter for home test
9.2	BfArM Self-test listing
10	Product information
11	IFU Gebruiksaanwijzing - LYHER Antigeen zelftest
12	Certificate of Analysis
13	Design and Development Control Procedure
14	Stability Study for Nasal OK
15	In Vitro Cytotoxicity Test of Collection Swabs SDWH-M202004512-1-En
16	Skin Sensitization Test of Collection Swabs SDWH-M202002486-2-En
17	Skin Sensitization Test of Collection Swabs SDWH-M202002486-3-En
18	Intracutaneous Reactivity Test of Collection Swabs SDWH-M202002486-4-En
19	LYHER Novel Coronavirus (COVID-19) Antigen Test Kit for non- professional use User friendliness study for lay persons Potential Public Health Risks
20	Seifried J. et al. 2021, Epidemiologisches Bulletin 8: 25 Februar, 2021.