ENGLISH TRANSLATION Basic principles for the deployment of tests by EPSO

(Original text by the Dutch Ministry of Health)

Basic principles for the deployment of tests on COVID-19 (including antigen (rapid) testing) outside the GGD test locations - version 3.0

Introduction

Testing and tracing is an important part of the approach against the Corona virus.

The test strategy in the Netherlands serves two purposes:

1) to combat COVID-19 / SARS-CoV-2 and

2) to continue the economy and society.

That is why the Ministry of Health, Welfare and Sport is working with the GGDs, VNO-NCW and more and more other partners to significantly expand the testing capacity in the Netherlands. We call on everyone in the Netherlands to continue to use the existing (basic) test infrastructure, currently the GGD test locations, but also outside this basic infrastructure of the GGDs, there are other options for testing (such as via employers and commercial test streets). In the supplementary test track 2 for employers (institutions and companies), employers can use rapid tests (especially antigen tests) on their own initiative for their own personnel.

Even now, tests are already being carried out in more and more places (outside the GGD test locations). In this way we continue to expand the possibilities to be tested as quickly and safely as possible. However, the Ministry of Health, Welfare and Sport, RIVM, the GGDs and the Health and Youth Care Inspectorate (IGJ) considers it important that everyone knows which principles these private and public initiatives (hereafter: initiatives)[1] should apply. These starting points are not only important for infectious disease control, but ultimately also important for the continuation of economic and social interaction. This means that the test must be administered safely and carefully and the results must be reliable, even if they do not take place at the GGD test locations.

The National Coordination of Infectious Disease Control (LCI) has drawn up the guide "Testing within companies and companies on COVID-19"[2] for company doctors, occupational health services and test facilities in the private track (hereinafter LCI guide). This LCI guide serves as an aid in assuring the quality of tests that are conducted outside the GGDs. In addition to this, this basic principles memorandum has been written aimed at preconditions and (medical) requirements and a number of practical matters, such as implementation of the notification obligation, are also

[1] These can be (semi-) public institutions (such as healthcare institutions, schools and the police) but also private initiatives, in which employers test their own staff or commercial initiatives that offer their services.

[2] https://lci.rivm.nl/covid-19-testen-binnen-bedrijven

presented. To prevent overlap, reference will be made, where necessary, to the guide that falls under the LCI guide.

Test supervision

IGJ (The Dutch Health Inspectorate) supervises the use of CE marked and validated tests, so that they are used by trained personnel, under hygienic and safe conditions for employees and patients. That is why all providers of COVID-19 tests must meet the requirements set for this in laws, regulations and professional standards. The most important of these are mentioned in this guiding principle. It is important here that the LCI guide is seen by the IGJ as an interpretation of 'good care' as referred to in Article 2 of the Care Quality, Complaints and Disputes Act (Wkkgz).

If the IGJ (Dutch healthcare inspectorate) finds that initiatives do not comply with the laws and regulations, the IGJ can impose measures. Whether or not the IGJ imposes a measure, and if so which one, always depends on the concrete situation. In the most extreme case, the IGJ can decide that closure is necessary.

In future changes to test policy, including the applicability of antigen tests for certain target groups or situations, the initiative, the provider of the tests, will follow these amended guidelines. The initiative itself is responsible for adequately keeping up with all developments and adjusting the working method accordingly. Anyone can report concerns to the IGJ if there are concerns about a (rapid) test location, via the contact form on the website of IGJ.[3]

Starting points

Below we indicate which starting points initiatives should use when they want to test people for COVID-19 / SARS-CoV-2.

1**. Quality & Safety**

- The initiative works with CE marked tests.

- The initiative works with tests that are clinically validated in GGD test lanes.

- Initiative ensures safe collection of samples and performance of tests by specially trained personnel, with adequate personal protective equipment and under the medical responsibility of a (company) doctor with a BIG registration.

2. **Registration & reporting of test results**

- The initiative ensures that data is recorded and guarantees mandatory reporting (on the basis of the Public Health Act) of positive test results of individuals to the regional GGD.

- The initiative has proper handling of data, it must comply with the General Data Protection Regulation (GDPR).

3. **Test policy & communication about the test result**

- The initiative tests according to the national test policy applicable at that time.

- The initiative provides feedback of the results of the test and aftercare to the tested person.

- The initiative ensures that tests are taken on a voluntary basis.

[3] http://www.igj.nl/onderwerpen/klacht-of-vraag-over-zorg-of jeugdhulpverlening/contact/contactvorm

The development, validation and application of tests and rapid tests is in full swing and will regularly lead to adjustment of the basic principles of the memorandum and adjustment of the overview below, for example following the publication of the LCI guide, the full validation of new test methods or the become available from registration via CoronIT.

Version	Date	Adjustment	Comment
1.0	3-11-2020	no	no
2.0	9-11-2020	Addition of new validated antigen (rapid) tests and some textual adjustments	No
3.0	17-12-2020	Reference to LCI guide and further refinement of the description of relevant regulation and supervision.	No

Below you will find a further explanation of the above principles with a reference to the relevant part in the guide "Testing within companies and companies for COVID-19" belonging to the LCI Guideline.

1. Quality & Safety

- The initiative works with CE marked tests.

 For information about this, reference is made to the LCI guide under "Where can tests be performed?"

- The initiative works with tests that are clinically validated in GGD test lanes.

 For information on this, reference is made to the LCI guide under:

o "When can antigen tests be used / not used"

o "Where can tests be performed?"

o "Antigen rapid testing and validation".

 For information on which antigen (rapid) tests are currently validated for testing persons with complaints in the setting of the GGD test streets in the Netherlands, please refer to the document "Status validation SARS-CoV-2 antigen rapid tests" [4]. For information about the advice of the OMT on the validation of LAMP and other antigen (rapid) tests, see document "Advice OMT validation

[4] https://www.rivm.nl/documenten/status-validatie-sars-cov-2-antigeen-sneltesten, paragraph 2.3 point 3, this document is regularly updated.

LAMP and other rapid antigen tests". [5] For detailed information about which tests there are, see the information on the RIVM website about this. [6]

 The application of the type of test must be carried out within the existing legislation and regulations.

- The initiative ensures safe collection of samples and execution of tests by specially trained personnel, with adequate personal protective equipment and under the medical responsibility of a (company) doctor with a BIG registration

 When tests are taken under the responsibility of someone other than the GGD, such as by a company or organization, a hospital or an occupational health and safety service, the Healthcare Quality, Complaints and Disputes Act (Wkkgz) applies. According to the Wkkgz, these test customers are in that case "healthcare providers".

 On the grounds of the Wkkgz, the requirement for care providers is that they must provide good care. This means that the care must be of a good quality and level.

 According to the Wkkgz, the obligation to provide good care includes that the rights of the clients must be respected and that care must be safe, effective and client-oriented. The obligation to provide good care also means that care providers must act in accordance with their responsibility, arising from the professional standard, including the quality standard.

 In addition to the Wkkgz, other laws and regulations apply. For a complete overview, reference is made to the LCI guide, but to provide an overview of these principles, a summary of what is stated in the LCI guide follows below . "The collection of the sample and the execution of the test at the test location takes place in accordance with the instructions of the manufacturer and under the ultimate medical responsibility of a (company) doctor with a BIG registration affiliated with the test provider. This (test / care) provider is responsible for the entire process of registration, test administration, reporting, application of laws and regulations regarding privacy, reporting and aftercare. In addition, the location where the tests are carried out must comply with the relevant and current laws and regulations, guidelines and professional standards. Moreover, in addition to the CE marking, tests must meet all requirements set by the Medical Devices Act (Wmh) and the In-Vitro Diagnostics Decree (Bivd) for medical devices and in vitro diagnostics. Finally, one must comply with the Public Health Act (Wpg). "

2. Registration & reporting of test results

- The initiative ensures that data is recorded and guarantees mandatory reporting (pursuant to the Public Health Act) of positive test results of individuals to the regional GGD.

 For information on this, reference is made to the LCI guide under "Reporting to GGD in the context of the Public Health Act".

 Every laboratory or doctor under whose auspices a COVID-19 (antigen rapid) test is obliged (under the Public Health Act (Wpg)) to report a positive finding to the regional GGD without delay.

[5] https://www.rivm.nl/documenten/advies-omt-validatie-lamp-en-andere-antigeensneltesten.
[6] https://www.rivm.nl/coronavirus-covid-19/testen

 The GGD will accept reports of positive tests within the private test track according to the conditions recommended by the OMT (for the time being these are validated PCR and antigen rapid tests in people with complaints) . [7]

 Test results and other data are recorded, preferably in a (laboratory)) information system, so that it is always possible to find out who, when and with what type of test tested positive or negative.

 By the end of December it is possible to register all positive and negative test results via a reporting portal in CoronIT, registration via this reporting portal will become the preferred option for reporting test results

 The reporting of positive results will run until reporting via the CoronIT reporting portal is possible , via secure mail (healthcare mail, zivver or similar - please contact the regional GGD) until the interface for CoronIT is available to all providers. Sending personal data (such as a test result) by unsecured email, SMS, WhatsApp (or similar apps) is insufficiently secure and therefore not permitted.

 In case of a positive test result, the following information must be reported to the GGD

o Name

o Address (place of residence or place of residence)

o Gender

o Date of birth

o BSN

o Telephone number *

o Email address *

o Requesting doctor

o Name used (antigen) test (if applicable)

o Laboratory concerned (if applicable) o Company / institution concerned

o *) Please note: ask permission from the tested person to pass on his / her telephone number and e-mail address to the GGD. In this way, the GGD can make the process of the source and contact investigation run as smoothly as possible.

 Separate agreements are still being made about the method of reporting negative results via the CoronIT reporting portal.

- <u>The initiative has proper handling of data, it must comply with the General Data Protection Regulation (GDPR).</u>

 For information on this, reference is made to the LCI guide, under “Confidentiality of the data”.
 Tests and test locations comply with prevailing requirements for the processing of personal data as described in the GDPR. Privacy of the patient must be guaranteed. Even if the test is taken in the

[7] https://www.rivm.nl/documenten/status-validatie-sars-cov-2-antigeen-sneltesten, paragraph 2.3 point 3, this document is regularly updated.

context of an employer-employee relationship, the provisions in the GDPR must be followed. The Dutch Data Protection Authority supervises this. By involving occupational health and safety services within initiatives, such aspects can be safeguarded, the employer is not allowed to collect / record medical data.

3**. Test policy & communication about the test result**

- The initiative tests according to the national test policy applicable at that time.

 For information on this, reference is made to the LCI guide under "Testing according to national test policy" and "When can rapid antigen tests be used / not used".

 Note: initiatives outside of healthcare are not intended to test patients and / or people with serious complaints. These persons must contact their GP (by telephone) and are not tested via the initiative.

 Currently, two groups of people can be tested in the Netherlands: "people with complaints that may indicate infection with SARS-Cov-2" and "people without complaints who have been in contact with someone with COVID-19". These people can be tested 5 days after the last risky contact. If the test result is negative, they no longer need to remain in quarantine.

 In all other cases, home quarantine rules continue to apply. [8]

 Note: Rapid antigen tests have not (yet) been clinically validated for use in people without symptoms, so not even for the group of people who are tested without symptoms, when they have been in contact with someone with COVID-19.

 Note: For persons with serious complaints in an institution and for persons working in healthcare, a retest with a PCR is always necessary to confirm a negative antigen rapid test result.

- The initiative provides feedback of the results of the test and aftercare to the tested person.

 For information on this, reference is made to the LCI guide under "Feedback of results".

 With good oral and written communication, the tested person is informed about the interpretation of the test result, including clear (behavioral) instructions. In case of a positive test result, the GGD is always informed and the rules of life apply, of which isolation is the most important. See "Precepts and information letters for source and contact research" in the LCI guideline COVID-19 [9]. In case of a negative test result, the result must be seen in the light of the time of administration. The tested person should receive information about this, including advice on retesting, quarantine and any additional measures.

- The initiative guarantees that tests are taken on a voluntary basis.

 For information about this, reference is made to the LCI guide under "Testing according to national test policy".

 For the deployment of tests among personnel, these tests are offered to the personnel on a voluntary basis. For employees without complaints, there is no legal basis to insist on a test. There should be no coercion or sanctions in any way. Also indirectly, this cannot be the case by making a

[8]https://www.rijksoverheid.nl/onderwerpen/coronavirus-covid-19/openbaar-en-dagelijk-leven/in-thuisquarantaine-doorcorona

[9] 9 https: // lci .rivm.nl / rules

test compulsory as a condition for participation in (compulsory) business activities, where there is strictly no need to test.

 When testing employees, the costs of the test that is administered at the request of the employer and any travel costs may not be passed on to workers.

 On the basis of Article 3 of the Working Conditions Act and on the basis of his duty of care ex. Article 7: 658 BW, to guarantee a safe working environment.

 Workers can still report complaints to the Basic Test Infrastructure (including the GGD test streets).