



Ministerie van Volksgezondheid,
Welzijn en Sport

Contract number:

**PUBLIC SERVICE CONTRACT ("CONTRACT") FOR THE
PROVISION OF LOGISTIC AND COVID-19 TESTING SERVICES**

BETWEEN

**THE STATE OF THE NETHERLANDS
THE MINISTRY OF HEALTH, WELFARE AND SPORTS**

AND

HOW ARE YOU Diagnostics BV

The undersigned:

1. The State of the Netherlands, which has its seat in The Hague, represented by the Minister of Health, Welfare and Sport, Directorate-General for Public Health, legally represented in this matter by [REDACTED] 5.1.2e of Testing Services (Dienst Testen), hereinafter referred to as the "Minister",

and
2. The private limited company HOW ARE YOU Diagnostics BV, which has its registered office at Kamerlingh Onneslaan 6, 8218MA Lelystad, registered with the Chamber of Commerce under number 76049590 legally represented in this matter by [REDACTED] 5.1.2e hereinafter referred to as "Contractor",

Each party also referred to as "Party", and both parties together as "Parties",

WHEREAS:

- a) the Minister has a facilitating role in infectious disease control on the basis of the Public Health Act (Wpg). Pursuant to Article 3(1) of the Wpg, the Minister has the task to promote the quality and efficiency of public health care. In addition, he is responsible for the maintenance and improvement of the so-called support structure. On the basis of article 7(1) of the Wpg, the Minister is also in charge of combating an infectious disease from Group A, such as Covid-19;
- b) The Minister therefore has engaged a number of parties to provide logistic- and diagnostic services in order to urgently provide temporarily additionally needed laboratory capacity to test samples at (community) sampling hubs across the Netherlands for the COVID-19 virus;
- c) Contractor is an innovative diagnostic knowledge center, and offers a wide range of diagnostics and laboratory services amongst in the field of clinical chemistry, immunology and medical microbiology, including COVID-19;

Initials Contractor:

[REDACTED] 5.1.2e

Initials Minister:

[REDACTED] 5.1.2e

- d) Contractor is prepared to do everything reasonable to urgently provide temporary additional laboratory capacity in an efficient and cost-effective way;
- e) As it is strictly necessary for reasons of extreme urgency the Minister, and in accordance with article 2.32, section 1, paragraph c of the Dutch Public Procurement Act 2012 ('Dutch PPA' or 'Aanbestedingswet 2012'), the Minister awards this Contract to Contractor. The Minister has awarded this Contract by a negotiated procedure without publication, as it is strictly necessary where, for reasons of extreme urgency brought about by events related to the COVID 19 pandemic which were unforeseeable by the Minister, the time limits for the open or restricted procedures or competitive procedures with negotiation cannot be complied with (also see EC 2020/C 108 I/01);
- f) the circumstances invoked to justify extreme urgency shall not in any event be attributable to the Minister. The events were unforeseeable by the Minister, because the estimated need for test capacity was reached months earlier than expected;
- g) The extreme urgency makes compliance with general deadlines impossible because the time that is needed for compliance will result in a growing shortage of test capacity. There is a causal link between the unforeseen event and the extreme urgency because the gap between the official estimation of the needed test capacity and the current rise in demand for test capacity is growing every day. This procedure is only used by the Minister in order to cover the gap until more stable solutions can be found;
- h) Parties have discussed the main conditions for the provision of test volumes by Contractor;
- i) Parties wish to lay down their agreements in this Contract. With the signature of this Contract all previously made arrangements are no longer valid and are replaced with the arrangements in this Contract.

AGREE AS FOLLOWS:**Definitions**

The following terms are written with initial capitals in this Contract and defined as follows:

Contract	this contract as defined in article 1.7
CoronIT	CoronIT is the name of registration software
Diagnostic test	detection of SARS-CoV-2 RNA by RT-PCR
First production date:	the date that all processes for providing the Services are in place (week n)
Guaranteed volume	the minimum number of Samples as percentage of the Target capacity, guaranteed by the Contractor
Laboratories	laboratories meeting the quality requirements of this Contract, performing Covid-19 Diagnostics tests
Operational agreements	the agreements as laid down in Schedule 2
RIVM	Rijksinstituut voor Volksgezondheid en Milieu, meaning the National Institute for Public Health and the Environment
Services	the services as defined in Schedule 1, "Services"
Samples	sample material of visitors of the Sample hubs
Sampling hubs	centres where Samples are taken
Sampling kits	kits containing all materials needed for the taking of Samples
Target capacity	the volume the Minister and Contractor agreed upon as reserved volume for use by the Minister
Ultimate capacity	the ultimate volume Contractor can offer to the Minister in the long run
Volumes	amount of Services as defined in Schedule 1, 'Volumes of Services'

Initials Contractor:

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Initials Minister:

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1. Object of the Contract

- 1.1 Parties agree on the provision by Contractor of temporarily additionally needed diagnostic and logistic services ("Services") in certain volumes ("Volumes") for the duration of this Contract including the supply to Sampling hubs of Sampling Kits and labels, tube racks and containers.
- 1.2 Contractor guarantees to provide to the Minister the Target capacity and the Services under the conditions as set out in this Contract and in specific Schedule 1 (Services, Laboratory, Volumes and Price), attached to this Contract as Annex A.
- 1.3 The Minister is free to order lesser Volumes than the Target capacity and/or only part of the Services as described in Schedule 1.
- 1.4 The Minister guarantees payment to Contractor of 30% of the Target capacity (the Guaranteed Volume), by way of compensation to the Contractor for the reservation of the Target capacity per day as provided for in this article, on the condition that Contractor performs its other obligations in conformity with this Contract.
- 1.5 On request of the Minister Contractor is prepared to explore an increase of the Volumes to the Ultimate capacity as mentioned in Schedule 1 Services, Laboratory, Volumes and Price) attached to this Contract as Annex A. If Parties agree to increase the Target capacity towards the Ultimate capacity, the new Volumes will be the new Target capacity.
- 1.6 Parties will comply with the operational organisation arrangements as mentioned in Schedule 2 Operational Arrangements attached to this Contract as Annex B and the Key Performance indicators as mentioned in Schedule 3 attached to this Contract as Annex C.
- 1.7 The following documents are an integral part of this Contract. In the event of inconsistencies, a higher ranked document takes precedence over a lower ranked document:
1. this document;
 2. Annex A: Schedule 1 – Services, Laboratory, Volumes and Price;
 3. Annex B: Schedule 2 – Operational agreements;
 4. Annex C: Schedule 3 – Key Performance Indicators;
 5. Annex D: General Government Purchasing Conditions 2018 (ARIV 2018);
 6. Annex E: Financial Brochure e-invoicing government ("Financiele Bijsluiter").

2. Formation and duration of the Contract

- 2.1 The Contract will run from the date of signature of this Contract until 11 April 2021 and will then automatically expire without any notice being required, unless it is extended by mutual written agreement 1 (one) month in advance the latest by period(s) of 1 (one) month. The Minister may decide on any such extension in his sole discretion and will not be under any obligation to agree to an extension.
- 2.2 The Guarantee as mentioned in article 1.6 will only be invoked after the mutually agreed First production date.

3. Price and invoicing

- 3.1 The agreed price to be paid to Contractor for all Services to be performed by Contractor ("Price") and the Volumes to be met for the Services are laid down in Schedule 1.
- 3.2 The Price is exclusive of VAT.
- 3.3 The Price includes all Services as mentioned in Schedule 1.
- 3.4 Contractor will invoice every 1 (one) month for the attention of the Minister electronically in the manner prescribed in annex D ("Financiële Bijsluiter").
- 3.5 Contractor will send a copy of the invoice together with a print from CoronIT showing the Volumes tested during the invoiced period, together as attached pdf-files via 1 (one) e-mail message to [REDACTED] 5.1.2e @rivm.nl.
- 3.6 Contractor is allowed to invoice only Volumes actually tested (Real volume) covered by the invoice, with the exception of the situation described in article 3.7.
- 3.7 In case the Real volume per day is less than the Guaranteed volume per day, as defined in this Contract and Annexes, Contractor is allowed to invoice the Price for the Real volume as well as the difference between the Guaranteed volume and the Real volume. In this case Contractor will inform the Minister of this situation via e-mail message to [REDACTED] 5.1.2e @lcdk.nl before sending in the invoice as mentioned in article 3.5
- 3.8 Invoices will be paid with a maximum payment term of 30 (thirty) days from the date of receipt of the invoice.
- 3.9 The Minister will check the invoices on a regular basis. Incorrect invoices will be discussed with Contractor and in mutual consent be corrected immediately.

4. Contacts

4.1 The Minister's contact is:

5.1.2e

5.1.2e of Testing Services ("Dienst Testen")- Ministry for Health, The Netherlands

Via e-mail: 5.1.2e @lcdk.nl

4.2 Contractor's contact is:

5.1.2e

5.1.2e@howareyoudiagnostics.com

5. Quality

- 5.1 Contractor guarantees to the Minister that before utilization of a Laboratory for Diagnostic tests, this Laboratory meets the Quality Requirements for Laboratories as mentioned in Schedule 1.
- 5.2 During the utilization of the Laboratory the initial quality requirements as referred to in article 5.1 have to be maintained or improved. As soon as Contractor foresees that the Laboratory cannot meet these minimum requirements anymore Contractor shall immediately inform the Minister. In that case the Minister is entitled to terminate the contract with immediate effect without any prior notice being required, by registered letter and without being due any compensation for lost income or other damage by the Contractor.
- 5.3 During utilization of the Laboratories the quality of the Laboratories will be regularly assessed and/or audited on behalf of the Minister.
- 5.4 If during such regular assessment or audit it appears that a Laboratory is no longer meeting the quality requirements as referred to in 5.1, the Minister is entitled to terminate the contract with immediate effect without any prior notice being required, by registered letter and without being due any compensation for lost income or other damage by the Contractor.
- 5.5 Contractor guarantees that the quality of Services is in accordance with prevailing laws and regulations, and practices, which would be considered as good practice of a skilled and experienced organization of a similar scale and professional standing, engaged in the provision of comparable and related services.

Initials Contractor:

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Initials Minister:

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6. Safety stock

- 6.1 Contractor guarantees at the Laboratories a safety stock of reagents and disposables for the assigned Volumes of Diagnostic tests for at least 10 (ten) days based on the average Target volume.
- 6.2 Contractor guarantees at a central place a safety stock of reagents and disposables for the assigned Volumes of Diagnostic tests for at least 30 (thirty) days of the average Target capacity.
- 6.3 Contractor guarantees at the Sample hubs a safety stock of Sampling kits for the assigned Volumes for 7 (seven) days based on the average Target volume.
- 6.4 Contractor guarantees at a central place a safety stock of Sampling kits for the assigned Volumes for 30 (thirty) days of the average Target volume.

7. Throughput time, timely information

- 7.1 Contractor guarantees a maximum throughput time of the Service of 24 (twenty-four) hours, and an average throughput time of the Service of 16 (sixteen) hours.
- 7.2 Contractor shall timely inform Sampling hubs and the Minister about any disturbances leading to delays in publication of test results, but in any case, within 2 (two) hours of arrival of Samples in the Laboratory and shall endeavour to avoid structural complaints from Sampling hubs.
- 7.3 Contractor shall timely inform Sampling hubs about any delays in supplies or Sample collection, but in any case, at least 2 (two) hours in advance.

8. Use of third Parties

- 8.1 In performing the Services of the Contract, Contractor may make use of a third party or a party in which Contractor has a minority interest only if this party has accepted the same quality requirements as laid down in this Contract and Annexes in writing and after Contractor has obtained the prior Minister's consent in writing.
- 8.2 Notwithstanding the Minister's consent, Contractor remains fully responsible for discharging the obligations imposed under this Contract.
- 8.3 In case of sub-contracting the Minister is entitled to make separate agreements in a triangular contract with Contractor and a third Party or a party in which Contractor has a minority of interest. Contractor is obliged to cooperate with such a triangular contract.
- 8.4 In performing the Services of the Contract, Contractor may also make use of transporters (one-man companies). In this case consent of the Minister is not required

and regarding the obligations of the Contract the transporter will be seen as an employee of Contractor.

9. Confidentiality and Media

- 9.1 Unless required by law or necessary in light of the objectives of this Contract, the Parties shall keep the terms and the nature of all discussions between them relating to this Contract and relating to affairs pursuant to the Contract confidential and shall not publish, disclose or provide to third parties any information from this Contract and Annexes. Parties will ensure that their respective employees, agents and sub-contractors fully comply herewith.
- 9.2 Nothing in this Agreement shall prevent the Minister from any disclosure required under the Dutch Act Dutch Act 'Wet Openbaarheid van Bestuur' (*Freedom of information act*) or to comply with the parliamentary rights on information. Such disclosure shall not constitute a default under this Contract.
- 9.3 The fact that this Agreement has been concluded as well as the essence of this Contract may be disclosed by the Minister to the Staten-Generaal (parliament).
- 9.4 The Parties shall consult each other timely in case they are approached by Media or consider to react to publications or news in the Media, or to approach Media, in relation to the subject of this Contract. In their contacts with Media, the Parties will respect each other's reasonable interests.

10. Data protection

- 10.1 In so far as the Contractor, as a processor within the meaning of the General Data Protection Regulation, processes personal data for the Sampling hub(s), the Contractor guarantees the application of appropriate technical and organisational measures, so that processing meets the requirements of the General Data Protection Regulation and the protection of the data subjects is ensured.
- 10.2 Parties agree that personal data will be processed in accordance with the agreements as made between Contractor and the Sampling hub(s) in relation to the connection and use of CoronIT.

11. Limitation of liability

- 11.1 The total aggregate liability of each Party under this Contract (for breach of contract, tort or otherwise) shall not exceed EUR [REDACTED] 2.57.2 AanbW 2012 [REDACTED] in no event shall any party be liable to the other party for any indirect or consequential

damages (*gevolgschade*) out of or in connection with this Contract. Parties do not exclude their liability for gross negligence or wilful misconduct.

12. Insurance

- 12.1 The Contractor has taken out and will retain insurance cover for the total aggregate liability as mentioned in article 11.1.
- 12.2 At the Ministers request, the Contractor will immediately present either the original or certified copies of the policies and proof of the payment of premium for the insurances referred to in paragraph 1 or a statement from the insurer to the effect that these policies exist and the premium has been paid. The insurance premiums owed by the Contractor are deemed to be included in the agreed prices and fees.

13. Cancellation and termination

- 13.1 Without prejudice to the other provisions of this Contract, either Party may cancel the Contract in full or in part with immediate effect by registered letter, without recourse to the courts, if the other Party is in default or compliance is permanently or temporarily impossible.
- 13.2 In case Contractor is not able to meet the target capacity and/or the minimum agreed total score as defined in Annex C / Schedule 3 during a period of 3 (three) consecutive weeks or 3 (three) times in a total time period of 13 (thirteen) weeks, the Minister is entitled to cancel the Contract in full with immediate effect by registered letter, without recourse to the courts and without any compensation of Contractors loss of profit incurred.
- 13.3 The Minister may cancel the Contract forthwith out of court by registered mail, without being required to send any demand or notice of default, if the Contractor does not meet the target capacity and/or minimum total score as referred to in 13.2, if the Contractor applies for or is granted a provisional or definitive suspension of payment, files for bankruptcy, is declared bankrupt, if its business is wound up, if it ceases trading, if a substantial proportion of its assets are seized, if it undergoes a merger or a division or is dissolved which reasonably effects the compliance to the Contract, or if it should reasonably be deemed on any other grounds to be no longer capable of discharging its obligations under the Contract.

14. Force Majeure

- 14.1 In the event either Party is unable to perform its obligations under the terms of this Contract, because of causes reasonably beyond its control (including but not limited to government restrictions or lack of access to equipment, unforeseen at the moment of signing this Contract) or damage reasonably beyond its control, such Party shall not be liable against the other Party for any damages resulting from such failure to perform or otherwise from such causes.
- 14.2 The term 'Force Majeure' is in any event understood not to include: allocation of testing capacity by Contractor for the benefit of other clients, staff shortages, strikes, staff illness, shortages of materials (with exception of an acknowledged worldwide shortage), transport problems, late delivery or the unsuitability of items required for the performance of the Services, liquidity or solvency problems on the part of the Contractor or failures on the part of parties engaged by the Contractor.
- 14.3 If a Force Majeure event prevents the Contractor meeting its Target capacity as defined in Schedule 2, the Contractor will give notice thereof within 48 (forty-eight) hours of the occurrence such event, failing which it will not be entitled to rely on paragraph 1 of this Article 14. In this case Contractor will not be relieved from providing its Services in respect of the volumes it can reasonably supply despite such Force Majeure.
- 14.4 A notice of Force Majeure shall be well motivated and, in the event of foreign Government restrictions, be accompanied by an authorized statement from the relevant government evidencing such fact.

15. Other Terms and Conditions

- 15.1 This Contract is subject solely to the General Government Purchasing Conditions 2018 (ARIV 2018), in so far as the Contract does not depart from them. Any general and special terms and conditions drawn up by the Contractor do not apply. These General Terms are attached to this Contract in Annex D.
- 15.2 Parties will discuss in good faith and will mutually decide to any amendments and/or additional conditions to this Contract and/or Annexes in case unforeseen circumstances affect the performance of the agreed contractual obligations. Amendments to this Contract and/or Annexes shall not be binding unless they are agreed upon and made in writing and signed by both parties.

15.3 Contractor will provide all relevant information and after timely pre-announcement grant access to utilized locations on the Minister's reasonable request for verification purposes of (the quality of) the utilized Locations and the agreed Services.

16. Governing law and jurisdiction

16.1 This Contract is governed by the laws of the Netherlands.

16.2 Any dispute that arises between the parties in relation to the explanation or application of this Contract, or any agreement resulting from this Contract, shall be settled by the competent court of the Hague, the Netherlands. Before starting court litigation, Parties agree to jointly attempt to come to a solution through mediation unless one of the Parties is of the opinion that this is not effective under the circumstances. In the case of mediation, Parties will jointly appoint an MfN-registered mediator.

17. Final provisions

17.1 This Contract sets out the entire agreement between the Parties. Any derogations from, amendments of or additions to this Contract and/or Annexes, including changes in the scope of the Services are binding only if expressly agreed in writing by the Parties.

17.2 Any written or oral agreements previously made by the Parties about the Services that are the object of this Contract are nullified by the signature of this Contract.

Done on the date stated below and signed by Parties.

The Hague, the Netherlands,
For the State, Minister of Health

Lelystad, the Netherlands,
For HOW ARE YOU Diagnostics BV

20/12/2020

7/1/2021

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5.1.2e of Testing Services

5.1.2e

Initials Contractor:

5.1.2e

Initials Minister:

5.1.2e

Annex A**Schedule 1 Services, Laboratories, Volumes and Price****1. Services**

Contractor will provide the following services ("Services"):

- Set-up and distribution of an appropriate introduction of relevant persons to be contacted and an instruction letter to the Sampling hubs;
- Self-sufficient procurement of all materials needed for the execution of the Services;
- Supply of Sampling kits and containers and/or tube racks to Sampling hubs;
- Collection and transportation of Samples from Sampling hubs to Laboratories;
- Diagnostic test of Samples;
- Registration of the results of the Diagnostic test in CoronIT;
- Appropriate and traceable storage of positive tested Samples;
- Destruction of tested Samples;
- Dedicated, appropriate and where relevant pro-active Support to the Services.

For operational details of the Services see Schedule 2 'Operational details of Services'.

For key performance indicators of the Services see Schedule 3 'Key Performance Indicators'.

2. Sampling hubs

Contractor will provide Sampling kits and containers to and will pick up Samples from the Sampling hubs in the Netherlands as assigned on behalf of the Minister (via "Dienst Testen").

3. Quality requirements laboratories

Before utilization by the Contractor Laboratories first have to meet the following initial quality requirements:

- The Laboratory is capable in processing potential SAR-CoV-2 positive specimens at BSL-2 (ML-2) level;
- The Laboratory has at least one dedicated Medical Microbiologist medically responsible for the quality of the Diagnostic services and available for Sampling hubs for answering questions about the test results;
- The laboratory has a valid certificate for ISO15189, ISO17025 with RT-PCR in scope provided by a conform European standard accredited certification institute.

After a Laboratory has met all initial quality requirements the Laboratory has to be validated by the RIVM in the following way:

- Successful execution of a diagnostic sensitivity test of samples provided by the RIVM;
- Successful execution of a diagnostic specificity test of samples provided by the RIVM;
- Both tests are only successful if at least the core/reference Samples are diagnosed.

After the validation the Implementation phase starts in the following way:

- A between the Parties agreed implementation plan;
- A site visit;
- An audit;
- A between the Parties agreed plan how to build up the Target volume.

After the successful fulfilment of all quality requirements Contractor accepts for the purpose of monitoring the quality of the Laboratory during utilization regular proficiency tests.

4. Approved Laboratories

At the moment of concluding this Contract the following Laboratories are used and approved:

Location	% of shares	Initial requirements RIVM Approval	Max test capacity per laboratory	Remarks
Poseidonweg 11, 8239DK, Lelystad		Yes		

If Contractor after the signature of this Contract wishes to use another Laboratory Contractor will see to it that before utilization the Laboratory in accordance with article 5 of this Contract meets the Quality requirements and that the Minister has given approval before utilization.

5. Allowed third parties

Party	% of shares	Activities	Remarks
n/a			

If Contractor after the signature of this Contract wishes to use another third party, Contractor will inform the Minister before utilization in accordance with this Contract.

6. Volumes of Services (tests per day)

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Initials Contractor:

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Initials Minister:

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Regarding the Volumes of Services four kinds of volumes are identified:

1. Target capacity the Volume the Minister and Contractor agreed upon as reserved Volume for use by the Minister
2. Real volume the total actual tested Samples for a particular day
3. Guaranteed volume the minimum guaranteed number of tested Samples as a percentage of the Target capacity.
4. Ultimate capacity the ultimate Volume Contractor can offer to the Minister in the long run.

The Parties have agreed to build up to the Target capacity as described in table below and the Minister agrees to a Guaranteed volume in the following way:

Target capacity build up and Garanteed volume		
Milestones	Target Capacity per day	Garanteed volume per day*
Start contract Week 2		
Week 3		
Week 4		
Week 5		
Week 6		
Week 7		
Week 8	5.1.1c	5.1.1c
Week 9		
Week 10		
Week 11		
Week 12		
Week 13		
Week 14		
Ultimate Capacity : 5.1.1c tests per day Maximum contracted volume (Target) = 5.1.1c tests per day		

)* Measured as average per calendar week

Initials Contractor: [Redacted] 5.1.2e

Initials Minister: [Redacted] 5.1.2e

7. Pricing Table

Pricing table (excl. VAT) based on bandwidths of Volumes		
Till 10.000 tests per day: [redacted] Euro, after 10K each extra 5.000 tests price decreases till [redacted] Euro		
NUMBER OF REPORTED TESTS PER DAY*		PRICE PER REPORTED TEST
Minimum	Maximum	
0	9.999	€ [redacted]
10.000	14.999	€ [redacted]
15.000	19.999	€ [redacted]
20.000	24.999	€ [redacted]
>25.000	>25000	€ [redacted]

)* Measured as average per calendar week

For the first 10.000 reported tests Contractor will be paid [redacted] euro, for the next 5.000 reported tests [redacted] euro, for the next 5.000 reported tests [redacted] euro, for the next 5.000 reported tests [redacted] euro and the number of reported tests thereafter [redacted] euro per reported test.

8. Safety stock

At Laboratories

- Contractor guarantees at the Laboratories a safety stock of reagents and disposables for the assigned Volumes of Diagnostic tests for at least 10 days based on the average Target volume.
- Contractor guarantees at a central place a safety stock of reagents and disposables for the assigned Volumes of Diagnostic tests for at least 30 days of the average Target capacity.

At Sample hubs

- Contractor guarantees at the Sample hubs a safety stock of Sampling kits for the assigned Volumes for 7 days based on the average Target volume.
- Contractor guarantees at a central place a safety stock of Sampling kits and containers for the assigned Volumes for 30 days of the average Target volume.

9. Example

This paragraph contains an **example** of how a situation in practice may work out on a specific day. For instance, Parties agree to 5.1.1c test per day as Ultimate capacity and a maximum Target capacity of 5.1.1c tests per day.

EXAMPLE

Milestones	Target Capacity per day	Garanteed volume per day	Real Volume per day
Start contract Week n			
Week n+1			
Week n+2			
Week n+3			
Week n+4			
Week n+5			
Week n+6	5.1.1c	5.1.1c	5.1.1c
Week n+7			
Week n+8			
Week n+9			
Week n+10			
Week n+11			
Week n+12			
Ultimate Capacity =	5.1.1c per day; Maximum contracted volume (Target) =		5.1.1c



5.1.1c

EXAMPLE

Initials Contractor: 5.1.2e

Initials Master: 5.1.2e

Annex B

Schedule 2 Operational agreements

1. Organization

- The Minister is overall responsible for the execution and the management of the Contract and the payment of the Contractor.
- RIVM is responsible for the validation and approval of the quality prior to the utilization of the Laboratories of Contractor.
- The Minister (via Dienst Testen) is responsible for the assignment of Sampling hubs and Volumes to Contractor and the monitoring of the quality of Contractors Laboratories throughout utilization.
- Sampling hubs are responsible for stock keeping of the by Contractor provided Sampling Kits, sample taking and registration of the samples and citizens in CoronIT.
- Contractor is responsible for:
 - the assignment of dedicated and knowledgeable teams of medical microbiologists, logistical experts and project management for troubleshooting, (pro-active) analysis and continuous improvement of the quality of the Services and answering questions about these Services;
 - the supply of Sampling Kits, labels, tube racks and containers;
 - collection and transportation of the samples;
 - the testing of the samples and the registration of the testing results in CoronIT;
 - the traceable storage and/or the destruction of Samples;
 - monthly reports about complaints, responses and solutions to the Minister (via "Dienst Testen").

2. Supply of Sampling kits, containers and/or tube racks

- Contractor provides Sampling kits with the following materials:
 - A pre-labelled collection tube with cap filled with buffer (Lyses, UTM or GLy) or an unlabelled collection tube with cap filled with buffer (Lyses, UTM or GLy) and separate labels, to be chosen by the Sampling hub;
 - The label is resistant to methyl alcohol (70%), storage at -80°C, cannot be erased by thermal heat and is provided with a unique barcode, containing information of the Contractor or Laboratory and a tube number, which can be scanned with a maximum failure rate of 0,01% or 100 ppm;

- The buffer is compatible with the Diagnostic test and not dangerous during use by the Sampling Hub staff;
- A CE-marked and patient-friendly nasopharyngeal- and throat swab;
- A seal bag with absorption filter for a safe transportation of the Sample.
- Contractor supplies beside the Sampling kits also appropriate disinfected containers and/or tube racks in an amount so that the sample taking process never must wait and, in a quality, so that collection and transportation of the Samples can be securely executed.
- Contractor supplies the Sampling kits, containers and/or tube racks in consultation with the Sampling hubs minimum once a week, during opening times and free of charge.
- Contractor is responsible for an appropriate registration of the supplies.
- Contractor provides for its risk and costs a safety stock of Sampling kits at Sampling hubs for a minimum of 7 days of the assigned Volumes.
Contractor provides for its risk and costs a safety stock of Sampling kits at Contractor or a central location in the Netherlands for a minimum of 30 days of the assigned number of tests.

Communication	Service window	Telephone Number	Response time
Logistic issues	8:00 – 22:00; 7 days/week	06 5.1.2e	15 minutes

3. Storage of Sampling kits

- Sampling hub will store the Sampling kits on its own costs at a temperature between 15 and 25°C.

4. Sampling

- The Sampling Hub registers the used collection tube and the information of the sampled citizen in CoronIT
- The Sampling Hub collect samples in accordance with the instructions of Contractor and RIVM (www.lci.rivm.nl/richtlijnen/COVID-19).
- The Sampling Hub is responsible for the careful packaging of the samples in the sealing bags or tube racks and the containers.

5. Collection and transportation of the Samples to the Laboratories

- Contractor collects in consultation with the Sampling hubs during opening times the Samples minimum twice a day, the last moment of collection just before closure time of the Sample hub.
- Contractor keeps a registration of the collected Samples.
- Contractor consolidates and/or transports the Samples to the Laboratory in accordance to UN3373.
- Contractor chooses a collection frequency and way of consolidation and/or transportation so that the total agreed maximum throughput time will be as short as reasonably possible, but at any time within the agreed maximum throughput time.
- Contractor keeps a registration so that collected and transported Samples can be traced.

Communication	Service window	Telephone Number	Response time
Logistic issues	8:00 – 22:00; 7 days/week	06 5.1.2e	15 minutes

6. Diagnostic test of Samples

- Contractor assures that the connection with CoronIT is up and running before starting the testing of the Samples.
- Contractor keeps a registration of the received Samples. Contractor will check the received tubes and will scan the tubes for registration in CoronIT.
- Missing tubes and/or missing or unreadable labels will be immediately (within 2 hours) reported to the Sampling hubs where the batch Samples came from.
- If Contractor foresees that the agreed throughput time cannot be met, Contractor will immediately inform the Sampling hub and timely (< 2 hours after reception of the Samples) inform the Sampling hub and the Minister ("Dienst Testen") about the causes, the corrective actions and when the test results than can be expected;
- Contractor tests all received Samples.
- Contractor reports the results of these tests in CoronIT in an accurate way.
- Contractor will do its utmost to keep the number of 'undetermined' test results as low as reasonable possible, but at any time < 1%.
- Contractor will do its utmost to realize the shortest possible throughput time between the moment of Sampling at the Sampling hubs and the publication of the test results of the Samples in CoronIT, but anyway within the agreed maximum throughput time.

Initials Contractor:

5.1.2e

Initials Contractor:

5.1.2e

Communication	Service window	Telephone Number	Response time
Logistic issues	8:00 – 22:00; 7 days/week	06	15 minutes
Microbiological issues	8:00 – 22:00; 7 days/week	06	15 minutes

Missing tubes and/or missing or unreadable labels reporting	a.s.a.p.
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Any foreseen delay of publication of the test results reporting	a.s.a.p.
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Contractor reports the test results of Samples in CoronIT	a.s.a.p.
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The between Parties agreed average throughput time per week is:	
For Laboratories situated in the Netherlands;	< 16 hours
For Laboratories situated outside the Netherlands.	< 22 hours

The between Parties agreed maximum throughput time per week is:	
For Laboratories situated in the Netherlands;	24 hours
For Laboratories situated outside the Netherlands.	24 hours

7. Storage and destruction of Samples

- Negatively and undetermined tested Samples will be appropriately destroyed by Contractor 3 (three) days after publication of the test result of the Samples in CoronIT.
- Positively tested Samples will be appropriate and traceable stored by Contractor for 2 (two) months after publication of the test result of the Samples in CoronIT.

Total days of storage of negative or undetermined Samples	3 days
Total days of storage positive Samples	2 months

Initials Contractor: 5.1.2e

Initials Contractor: 5.1.2e

ANNEX C

Schedule 3. Key Performance Indicators

Key Performance Indicators	Score	Score																																																																						
<p>Reliability of average throughput time per week *</p> <table border="1"> <tr> <td>For Laboratories situated in the Netherlands;</td> <td>< 16 hours</td> </tr> <tr> <td>For Laboratories situated outside the Netherlands.</td> <td>< 22 hours</td> </tr> </table> <p>- 50 points for agreed throughput time - minus x points (progressive) per hour > agreed throughput time - bonus x points (progressive) per hour < agreed throughput time</p> <table border="1"> <thead> <tr> <th colspan="3">AVERAGE THROUGHPUT TIME IN THE NETHERLANDS</th> </tr> </thead> <tbody> <tr> <td>Average TPT ≤ 12,5 uur</td> <td>+20</td> <td>70 points</td> </tr> <tr> <td>12,5u < Average TPT ≤ 13,5u</td> <td>+10</td> <td>60 points</td> </tr> <tr> <td>13,5u < Average TPT ≤ 14,5u</td> <td>+5</td> <td>55 points</td> </tr> <tr> <td>14,5u < Average TPT ≤ 15,5u</td> <td>+2</td> <td>52 points</td> </tr> <tr> <td>15,5u < Average TPT ≤ 16,5u</td> <td>0</td> <td>50 points</td> </tr> <tr> <td>16,5u < Average TPT ≤ 17,5u</td> <td>-2</td> <td>48 points</td> </tr> <tr> <td>17,5u < Average TPT ≤ 18,5u</td> <td>-5</td> <td>45 points</td> </tr> <tr> <td>18,5u < Average TPT ≤ 19,5u</td> <td>-10</td> <td>40 points</td> </tr> <tr> <td>20,5u < Average TPT ≤ 21,5u</td> <td>-15</td> <td>35 points</td> </tr> <tr> <td>21,5u < Average TPT ≤ 22,5u</td> <td>-20</td> <td>30 points</td> </tr> <tr> <td>22,5u < Average TPT ≤ 23,5u</td> <td>-30</td> <td>20 points</td> </tr> <tr> <td>Average TPT > 23,5u</td> <td>-40</td> <td>10 points</td> </tr> </tbody> </table> <table border="1"> <thead> <tr> <th colspan="3">AVERAGE THROUGHPUT TIME OUTSIDE THE NETHERLANDS</th> </tr> </thead> <tbody> <tr> <td>Average TPT ≤ 18,5 uur</td> <td>+20</td> <td>70 points</td> </tr> <tr> <td>18,5u < Average TPT ≤ 19,5u</td> <td>+10</td> <td>60 points</td> </tr> <tr> <td>19,5u < Average TPT ≤ 20,5u</td> <td>+5</td> <td>55 points</td> </tr> <tr> <td>20,5u < Average TPT ≤ 21,5u</td> <td>+2</td> <td>52 points</td> </tr> <tr> <td>21,5u < Average TPT ≤ 22,5u</td> <td>0</td> <td>50 points</td> </tr> <tr> <td>22,5u < Average TPT ≤ 23,5u</td> <td>-10</td> <td>40 points</td> </tr> <tr> <td>23,5u < Average TPT ≤ 24,5u</td> <td>-25</td> <td>25 points</td> </tr> <tr> <td>Average TPT > 24,5u</td> <td>-40</td> <td>10 points</td> </tr> </tbody> </table>	For Laboratories situated in the Netherlands;	< 16 hours	For Laboratories situated outside the Netherlands.	< 22 hours	AVERAGE THROUGHPUT TIME IN THE NETHERLANDS			Average TPT ≤ 12,5 uur	+20	70 points	12,5u < Average TPT ≤ 13,5u	+10	60 points	13,5u < Average TPT ≤ 14,5u	+5	55 points	14,5u < Average TPT ≤ 15,5u	+2	52 points	15,5u < Average TPT ≤ 16,5u	0	50 points	16,5u < Average TPT ≤ 17,5u	-2	48 points	17,5u < Average TPT ≤ 18,5u	-5	45 points	18,5u < Average TPT ≤ 19,5u	-10	40 points	20,5u < Average TPT ≤ 21,5u	-15	35 points	21,5u < Average TPT ≤ 22,5u	-20	30 points	22,5u < Average TPT ≤ 23,5u	-30	20 points	Average TPT > 23,5u	-40	10 points	AVERAGE THROUGHPUT TIME OUTSIDE THE NETHERLANDS			Average TPT ≤ 18,5 uur	+20	70 points	18,5u < Average TPT ≤ 19,5u	+10	60 points	19,5u < Average TPT ≤ 20,5u	+5	55 points	20,5u < Average TPT ≤ 21,5u	+2	52 points	21,5u < Average TPT ≤ 22,5u	0	50 points	22,5u < Average TPT ≤ 23,5u	-10	40 points	23,5u < Average TPT ≤ 24,5u	-25	25 points	Average TPT > 24,5u	-40	10 points	10 - 70	
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Timely information (> 2 hours in advance) of Sampling hubs about delays in supplies or Sample collection - bonus 5 points if no structural complaints** from Sampling hubs	0 or 5	
No non-performance caused by shortage in agreed safety stocks - bonus 5 points if no disturbance of sample taking/testing process	0 or 5	
Total points	100	

The minimum total score per week is	70
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* based on information derived from CoronIT)

** Structural complaints mean more non-conformances from two or more Sampling hubs reported by e-mail to Contractor [redacted] 5.1.2e @contractor.com with a copy to [redacted] 5.1.2e [redacted] t@lcdk.nl and accepted by Contractor.

Dienst Testen will weekly set up and share with Contractor the score on KPI's. The score on KPI's, Strategic and operational issues will be discussed in meetings every week.