Convergys® POC RT- PCR COVID-19 Detection Kit

for use with Convergys® POC RT-PCR Nucleic Acid Detection System

Instructions for Use

Version: V2.0
Product Name: Convergys® POC RT-PCR COVID-19 Detection Kit
REF: 1100-5220

Contents

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1 Introduction

1.1 Intended Use

This kit is used for the qualitative *in-vitro* detection of nucleic acid sequences of SARS-CoV-2 in nasopharyngeal swabs, oropharyngeal swabs, sputum or bronchoalveolar lavage fluid. It can provide molecular biological reference for clinical screening of suspected cases of pneumonia and other upper respiratory tract infections.

SARS-CoV-2 is an enveloped RNA virus and belongs to the Betacoronaviridae. It can cause an acute respiratory infectious disease, known as COVID-19.

Common signs of infection can include respiratory symptoms, fever, cough, shortness of breath and breathing difficulties; but many infections are showing only mild symptoms or none at all.

The kit can be used as evidence of infection. The kit is only for clinical reference and should not be used as the only standard for diagnosis. Please refer to the patient's clinical symptoms and/or other methods' results to define the patient status.

1.2 Working Principle

This kit needs to be used with the Convergys® POC RT-PCR nucleic acid detection system, produced by Convergent Technologies. The system uses real-time PCR detection technology combined with integrated automatic sample nucleic acid extraction & purification, nucleic acid amplification, fluorescence detection and result analysis.

The system works with single-use, disposable cartridges which contain the required reagents for extraction, purification, amplification and fluorescence detection. Magnetic Beads are added to the cartridge to conduct the transport of the extracted nucleic acids within the cartridge.

The kit uses rTth DNA polymerase, which has both reverse transcription and PCR amplification function, to amplify the conserved target sequences. In combination with specific TaqMan probes, each amplified target sequence is detected by the release of the assigned fluorophore.

This kit targets conserved sequences of the SARS-CoV-2 S gene (FAM) and N gene (ROX). In addition, a human genomic sequence is targeted as non-competitive, internal control (Cy5) to confirm the quality of the amplification / testing process.

For a full description of the nucleic acid detection system, please refer to the user manual of the Convergys® POC RT-PCR System.

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1.3 Kit Components

Component Name	Specification	Kit Contents	Main Components
Test Cartridge	1 Test/Cartridge	24 Tests	Lysate, Wash Buffer I, Wash Buffer II, Realtime RT-PCR Master Mix, Primers, Probes, Mg^{2+} ions, etc.
Magnetic Beads	280 µl/Tube	1 Tube	Magnetic microspheres in aqueous suspension

Note: The components of different batch kits are not interchangeable.

1.3.1 Equipment to be supplied by user

Pipettes and sterile tips for 10 µl and 200 µl volumes are required. We recommend to use tips with filters to reduce the risk of contamination.

A vortex mixer is recommended to achieve proper mixing of sample material.

2 Workflow

2.1 Preparations Before Testing

1. Instrument: Power on the Convergys® POC RT-PCR instrument and log in. Operate the machine according to the instrument's manual.
2. Test Program: If you use this kit for the first time, you might need to install the dedicated test program "nCoVB" if it is not already installed in your instrument. Access the Library menu and press the "New" button to add a new program and select "Scan QR Code". Scan the nCoVB installation QR code. After installation, the nCoVB program will appear in the instrument's Library list of available programs. In case the program was already present on the instrument, a message will state that the program already exists and the installation will abort.
3. Test Cartridge: Take the required number of test cartridges and the magnetic beads and let them adjust to room temperature. The magnetic beads should be mixed well and fully resuspended before use.

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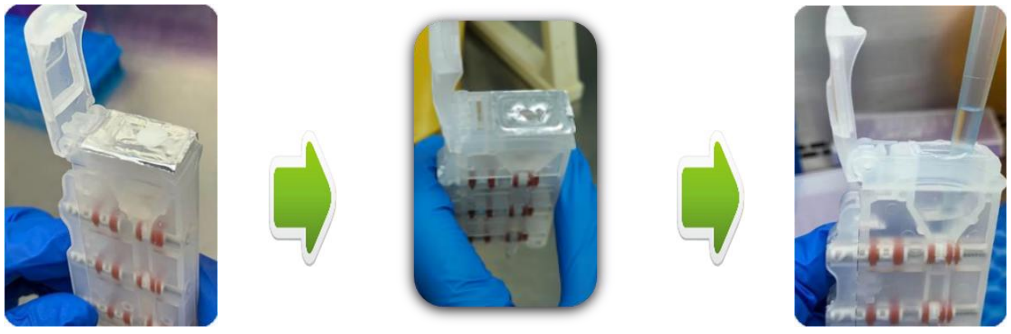
2.2 Sample Testing

2.2.1 Loading the Test Cartridge

1. Open the lid of the test cartridge and break the sealing film.
2. Mix the patient sample well and add 200 µl to the top cartridge chamber. Mix by pipetting up and down a few times.
3. Mix/resuspend the magnetic beads properly and then add 10 µl to the cartridge's top chamber.
4. Mix the liquids in the top chamber thoroughly by pipetting up and down several times. While doing so, change the pipetting angles to prevent adherence or sedimentation of the magnetic beads to any of the walls or corners of the chamber. Use an appropriate pipette volume (≥200 µl) for this.
5. Close the cartridge lid firmly (it should snap in).

Note: Avoid contamination of the magnetic beads or tips during operation. If it happens, please discard.



Open the lid | Break the seal | Add sample and mix

Add magnetic beads | Pipette up and down several times to mix | Close the lid

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2.2.2 Start Test Program:

The test program can be started two ways:

1a. Access the Library menu. Select the nCoVB program and press the Run button. In the next window, you enter the sample ID via the onscreen keyboard by pressing the Sample Info. text field or by pressing the scan button and scanning the sample's QR or barcode (if applicable). Continue with step 2.

1b. If the cartridge has a QR code label, you can also start the program by entering the Rapid Run menu. Press the scan button next to the Detect Name field and scan the cartridge's QR code. Then enter the Sample Info. and continue with step 2.

2. In the next window, pick a free cartridge channel that you want to use and insert the cartridge firmly into the selected channel position. The instrument will detect the cartridge and show a summary of the entered test information. Check if the displayed information is correct before pressing the start button (arrow in lower right corner) to initiate the test run.

3. The channel's status indicator light will turn green to indicate a test is running. The progress of the test run can be monitored in the Real-time Graphics menu.

2.3 Results

2.3.1 Data Analysis:

1. After the test is finished, the Real-time Graphics display shows the test's amplification curves.

2. The result analysis can be accessed by pressing the Data tab in the Real-time Graphics display and then pressing the Analysis button, or by entering the Analysis menu from the homescreen and selecting the test record from the list.

3. If the "Accept automatic analysis of results?" message appears, confirm by pressing "Yes" to get the automatic qualitative analysis of the test result.

4. The Analysis screen shows a graph of the detected fluorescence amplification curves on the left. On the right, you can see the Ct values that were calculated by the device, and the Result judgement for each detection parameter.

5. Legend:

   - SARS-CoV-2 S gene: FAM, displayed in blue
   - SARS-CoV-2 N gene: ROX, displayed in yellow
   - Internal control: Cy5, displayed in red

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Note: Do not solely rely on the automatic analysis for judgement of the results. Pay attention to the fluorescence graphs and use your professional judgement. In case of unusual or suspicious results, contact technical support.

2.3.2 Result Judgement

Target Amplification			On-screen Analysis Result	Result Judgement	Result Acceptable
S gene FAM	N gene ROX	Int. contr. Cy5			
Neg	Neg	Neg	**Retest, Retest**	Invalid test; retest recommended	No
Neg	Neg	Pos	**Neg, Neg**	Negative Test	Yes
Pos	Pos	Pos	**Pos, Pos**	Positive Test	Yes
Pos	Pos	Neg	**Pos, Pos**	Positive Test	Yes
Pos	Neg	Pos	**Pos, Neg**	Suspected positive; retest recommended	Ambiguous
Neg	Pos	Pos	**Neg, Pos**	Suspected positive; retest recommended	Ambiguous
Pos	Neg	Neg	**Pos, Retest**	Suspected positive; retest recommended	Ambiguous
Neg	Pos	Neg	**Retest, Pos**	Suspected positive; retest recommended	Ambiguous

- Detection parameters with Ct values ≤35 are considered positive. Ct values >35 or shown as ∞ are considered negative.

  Each hospital or laboratory can establish a corresponding positive judgment value according to the requirements of the respective laboratory.

- Positive target amplification should show a typical sigmoidal curve (s-shaped curve that has not reached the plateau stage) in the graphic display.
- The internal control targets a human gene in the sample. It is meant to verify functionality of the cartridge's reagents and to avoid false negative results. If no other detection parameter was amplified, the Ct value of the internal control should be <35, otherwise the test is considered invalid and the patient should be re-sampled and tested.
- If only one of S and N gene is positive, the sample is considered as suspicious. It is recommended to retest or resample 3-5 days later. If the results are still the same, it is suggested to use other methods for review.
- A Retest result indicates that the amplification of the internal control failed. This could be caused by inadequate sample material, e.g. due to incorrect sample collection or handling, leading to insufficient amounts of nucleic acid template. Another reason could be a failure

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of the biochemical reactions in the cartridge, e.g. due to inhibition. In such cases, retesting is recommended (preferably with newly collected sample material).

- If only one of the two SARS-CoV-2 target genes is positive, it usually mean that one of the target gene s could not be amplified. It is possible that the amplification of the affected target gene is prevented by mutagenesis of the virus in that specific sample. Another reason could be that the sample had been contaminated.
- The sample can be considered a suspected case for a COVID-19 infection. We recommend to retest the sample. If the result remains the same, it should be treated like a positive result as a precaution, and additional testing with other methods is recommended.

2.3.3 Limitations of Detection Methods

- The products must be used with the Convergys® POC RT-PCR System produced by Convergent Technologies. If it is used on any other equipment, the performance of the product cannot be guaranteed.
- The test results of this kit are only for clinical reference. It should not be used as the sole basis for clinical diagnosis or management. The clinical diagnosis and treatment of patients should be combined with their symptoms / signs, medical history, other laboratory tests and treatment reactions.
- Unreasonable sample collection, transferring, storage and handling processes can lead to false results.
- Variations of the target sequences or sequence changes caused by other reasons may lead to false negative results.
- The optimal sample type for detection and the optimal sampling time after infection might vary. Therefore, taking multiple samples from different locations at different times in the same patient could reduce the false negative result probability.
- Other kinds of interference or PCR inhibitors may cause false negative results.
- The accuracy of detection depends on the sample used for the test, and reliable results depend on proper sample collection, processing, and storage. In order to avoid incorrect results, the operating procedure in the user manuals must be followed carefully.

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3 Specifications

3.1 Storage Conditions and Expiration Date

This product must be stored at 2°C to 8°C in a dark place and is valid for 6 months from the date of production. The expiration date can be found on the product label.

The temperature in the box should be maintained at 2°C ~ 8°C during transportation. Ice bags can be used. The kits must not be placed below 0°C.

3.2 Applicable Instrument

Convergys® POC RT-PCR Nucleic Acid Detection System produced by Convergent Technologies GmbH & Co. KG.

3.3 Sample requirements

3.3.1 Appropriate sample types:

Human nasopharyngeal or oropharyngeal swab, sputum or bronchoalveolar lavage fluid.

3.3.2 Sample collection:

- **Swab Sample:**

  Use synthetic fiber swabs with plastic shafts.
  Do not use calcium alginate swabs or swabs with wooden shafts, as they may contain substances that impair the test.

  - Nasopharyngeal Swab:

    Insert swab with a flexible shaft through the nostril parallel to the palate (not upwards) until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient, indicating contact with the nasopharynx. Gently rub and roll the swab. Leave swab in place for several seconds to absorb secretions. Slowly remove swab while rotating it. Specimens can be collected from both sides using the same swab, but it is not necessary to collect specimens from both sides if the swab is saturated with fluid from the first collection. If a deviated septum or blockage leads to difficulties in obtaining the specimen from one nostril, use the same swab to obtain the specimen from the other nostril. Then put the swab into an aseptic, leak proof and screw cap container (can contain guanidine salt nucleic acid inactivation preservation solution).

  - Oropharyngeal Swab:

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Insert swab into the area of posterior pharynx and tonsillar. Rub swab over both tonsillar pillars and posterior oropharynx; avoid touching the tongue, teeth, and gums.

- **Sputum:**

  Be aware of the difference between sputum and oral secretions (saliva). Ask the patient to rinse the mouth with water and then to expectorate sputum directly into a sterile, leak-proof, screw-cap collection cup or sterile dry container.

- **Bronchoalveolar Lavage:**

  Collect 2-3 ml into a sterile, leak-proof, screw-cap container.

3.3.3 Packaging:

After collection, no matter how far or near the transportation distance is, packaging and marking should be carried out according to the local requirements, such as specimen number, date of onset and date of specimen collection.

3.3.4 Transportation and preservation:

Samples can be stored for more than 5 days between -20°C and -70°C. Avoid repeated freezing and thawing during transportation and storage. If the condition of ≤ -20°C cannot be ensured, clinical specimens can be stored at 1°C~8°C for up to 3 days.

3.3.5 Sample Treatment:

Swab sample:
Add 1-2 ml of normal saline or inactivating guanidine salt preservation solution to the container in which the swab is placed (not necessary if solution was already in container). Vortex for 1-2 min to mix and elute completely before using the liquid for testing.

Sputum:
The following methods are for reference only.
One of the following methods can be used for liquefying a sputum sample:

a) Mix with normal saline or PBS and pipette up and down several times. Use supernatant.
b) Digest the sample with 1% trypsin for 15 minutes.
c) Digest the sample with 1% pancreatin for 15 minutes.
d) Digest the sample with 4% NaOH for 10 minutes.
e) Liquefy with a commercial sputum dissolving reagent.

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3.4 Product performance index

- Level of Detection (LOD): 250 copies/ml.
- This kit has no non-specific amplification for endemic human coronavirus (HKU1, OC43, NL63 and 229E), SARS coronavirus, MERS coronavirus, H1N1, H3N2, H7N9, influenza B, Respiratory syncytial virus, Parainfluenza virus type 1, 2, 3, Adenovirus, Rubella virus, Vesicular stomatitis virus, Haemophilus influenzae, Staphylococcus aureus, Streptococcus pneumoniae, Mycobacterium tuberculosis, Candida albicans, Candida glabrata and human genome.
- Interference: The assay of this kit will not be affected by Mucin, Phenylephrine hydrochloride, Oxymetazoline, Sodium chloride, Beclomethasone, Dexamethasone, Triamcinolone acetonide, mometasone, fluticasone, Histamine dihydrochloride, α-Interferon, Ribavirin, Oseltamivir, Arbidol, levofloxacin, Azithromycin, Ceftriaxone and Tobramycin.
- Intra- and inter-assay imprecision: CV values are less than 10%.

3.5 Quality Controls

This kit tests for an internal control target (human RNase P) to avoid false negative results.

The kit does not provide external positive or negative quality controls. External quality control testing can be established according to actual needs. Positive and negative controls can be processed like clinical samples for testing.

3.6 Warnings and Precautions

- Please read this manual carefully before usage. The kit is only meant for *in vitro* testing (IVD).
- Relevant laboratory management standards should be implemented in strict accordance with the relevant guidelines for clinical gene amplification laboratories of medical institutions, other molecular biology laboratories and clinical gene amplification laboratories. The laboratory personnel must be professionally trained and use dedicated instruments and equipment in each stage of testing operation.
- Provide biosafety cabinet for specimen preparation and reagent handling. Use disposable gloves without fluorescent substances, disposable centrifuge tubes, disposable filter tips and detachable filter pipettes. When handling specimens and reagents, please wear lab coat and protective glasses, and establish good personal protection. Wash hands thoroughly after handling specimens and test reagents.
- When processing several samples simultaneously, only one cartridge should be opened at

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the same time. Add sample and close the cartridge, then carry out operation on the next cartridge.

- The used samples should be thawed completely before use (repeated freezing and thawing should be avoided).
- After the test, the cartridge should be taken out immediately, put in an assigned container and placed in the designated place for eventual disposal.
- Product performance is verified only for the sample types and the sample collection and processing methods (including sample collection media, etc.) described in this document. Other sample types or collection and processing methods cannot guarantee the product performance.
- The pipette tips used in the experiment should be directly disposed into an assigned container for medical waste and be sterilized and discarded as per the applicable guidelines.
- The workspace and equipment should be disinfected regularly with 1% sodium hypochlorite, 75% alcohol or UV light.
- Do not mix products of different batches and use them within the validity period.
- When adding the sample to the cartridge, the sample should be added into the reaction solution completely. Prevent sample residues on the cartridge walls.
- Ensure that test cartridges are inserted completely into the detection channels. Otherwise, any gap between the cartridge and the channel will seriously affect the detection efficiency.

⚠ Do not mix reagents of different batch numbers, and use them within the validity period.

⚠ Keep the cartridge lid closed except when adding the sample and magnetic beads.

⚠ Do not drop or shake the cartridge violently after adding the sample, to avoid liquid leakage.

⚠ Do not use a cartridge if it appears wet or if the lid seal appears to have been broken.

⚠ Do not use a damaged or broken cartridge.

⚠ Do not reuse cartridges. Each cartridge is meant to be used only once.

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 Treat all biological specimens, including used cartridges (even if they do not contain any human or animal-derived substances) as if capable of transmitting infectious agents. All disposable consumables, such as used tips, should be put directly into a waste tank containing 1% sodium hypochlorite, and be discarded after sterilization together with other waste products. It is often impossible to know what might be infectious, so all biological specimens should be treated with appropriate precautions.
Check your regional/country hazardous and medical waste disposal guidelines. If regulations do not provide clear direction on proper disposal, biological specimens, including used cartridges, should be treated as capable of transmitting infectious agents. Dispose used cartridges as hazardous medical waste in durable waste containers per WHO “World Health Organization” medical waste handling and disposal guidelines.

4 Symbols

Symbol	Introductions	Symbol	Introductions
	Warnings and Precautions		Biohazard Warning
	In Vitro Diagnostic Device		Batch Code
	Manufacturer		Manufacture Date
	CE Symbol		Expiry Date
	Refer to Manual		Acceptable Temperature Range

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5 Manufacturer

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