# Coronavirus (COVID-19)

## Oxsed RaViD Direct SARS-CoV-2 Test

Instructions for Use (IFU) V1.0

For In-Vitro Diagnostic (IVD) Use

For Professional Use Only

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# Oxsed RaViD Direct SARS-CoV-2 Test

*In-vitro diagnostic test for the detection of COVID-19 in oropharyngeal swab samples.*

This device is for laboratory and point of care testing by professional users, where professional is defined as personnel who are qualified to perform IVD examinations through special education and training.

## Instructions for Use (IFU)

Note: This IFU is an abbreviated version. For further details please request the full version instructions for use by calling the UK Freephone below.

**REF** **RaVID-OQ-01**


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## INTRODUCTION

The Oxsed RaViD Direct SARS-CoV-2 Test is to be used for the in vitro diagnosis of COVID-19 in oropharyngeal samples. The device is based on Reverse Transcription Loop-Mediated Isothermal Amplification (RT-LAMP) Technology.

## INTENDED USE

This kit has been designed for use in laboratories and point of care environments by professional users only for the detection of SARS-CoV-2 virus for the diagnosis of COVID-19.

Users must have good colour perception in order to conduct this test.

## WARNINGS AND PRECAUTIONS ⚠

HEALTH AND SAFETY

- For in vitro diagnostic and professional use only.
- All reagents and patient samples must be treated as potentially infectious and handled accordingly.
- Do not open tubes at any point during or after heating.
- Personal protective equipment (PPE) must be worn when handling patient samples and tests.
- Disposable apparatus must be treated as potentially infectious and placed in appropriate waste.
- Spillages of potentially infectious samples must be absorbed and any materials should be placed in appropriate waste.
- Clean and disinfect the site of any accidental spills with disinfectant such as 0.5% sodium hypochlorite
- followed by wiping down surfaces with a 70% ethanol solution.
- Non-disposable apparatus must be cleaned/ sterilised accordingly and be RNase free.

• Biohazardous waste must be disposed of according to local and national regulations.
• Biohazard bag provided is for the disposal of test tubes and pipettes only. Samples must be retained as per established facility procedure.
• Care must be taken when using hot surfaces.

ANALYTICAL
• Do not use the kit if it is damaged or expired.
• For optimal results test samples as soon as possible after collection.
• Controls have not been validated for use against any other test.
• Test results without controls must be considered invalid.
• Do not alter the order in which the controls conducted – positive controls must be prepared last to prevent nucleic acid contamination.
• Do not reuse – single use device only due to risk of cross contamination.
• Do not use samples prepared with transport medium.
• Use separate lab supplies/equipment in designated areas to minimise risk of contamination.
• To reduce the risk of contamination to tests, cleaning with DNA/RNase and nucleic acid remover must be conducted after each test.
• Handle tubes with care after heating to ensure that the seal is not broken.

## STORAGE AND STABILITY

• Store test tubes at 2 - 8°C up until the expiry date stated on the labelling. (For longer shelf-life, please store test tube at -20 °C)
• Store controls at 2 – 8°C up until the expiry date stated on the labelling.
• Store accessories between 2 – 30°C up until the expiry date stated on the labelling.
• Do not store outside of defined temperature parameters. Do not use after the expiry date.
• Store test tubes upright and sealed until the point of use.

*If the protective kit packaging is damaged upon receipt, please contact the manufacturer for return. Attention should be paid to the expiry date specified on the pack label. After this date, the kit should be discarded following the disposal instructions for COVID-19 waste management guidelines.*

## LIMITATIONS

• For optimal performance specimens should be tested as soon as possible after collection.
• Deviations from the method described within the IFU may lead to invalid results.
• Interpretation of results is subjective and must account for the possibility of false negative and/or false positive readings. In case of invalid results, re-test or use alternative method to confirm.
• False negative results may occur due to unsuitable sample collection, handling and/or storage of samples. False negatives may also occur due to poor sample quality or failure to follow the test methods described herein.
• False positive results may occur due to unsuitable handling of samples containing a high concentration of SARS-CoV-2 viral RNA or positive control templates. False positives may also occur due to unsuitable handling of amplified product.
• The test cannot diagnose diseases caused by other pathogens.

• A negative result does not conclusively rule out the possibility of current COVID-19 infection.
• This method has only been validated for Dacron or polyester flocked swabs.
• It is the responsibility of the end user to validate any software used in conjunction with this test.

# MATERIALS

## FOR POINT OF CARE USE

| MATERIALS PROVIDED | | | |
|---|---|---|---|
| Kit Type | Component | Pack Format | |
| | | 16T | 32T |
| | | Quantity | |
| Test Kit Part A: RaVID-OQ-01 | Test Tubes | 16 | 32 |
| | IFU | 1 | 1 |
| Control Kit Part B: RaVID-Ctrl-01 | Positive Control Solution | 1 x 0.1mL | 2 x 0.1mL |
| | RNase Free Wate | 1 x 0.1mL | 2 x 0.1mL |
| Accessory Kit Part C: RaVID-Acce-01 | Pipettes | 16 | 32 |
| | Biohazard Bag | 1 | 1 |

| MATERIALS REQUIRED BUT NOT PROVIDED |
|---|
| Heat Block(s) (Recommend: Scottech Medical Ltd MVS-100) |
| Scanner (Recommend: QuickScan™ QD2430 Bar Code Reader from DATALOGIC) |
| Disposable gloves and other PPE for protection against COVID-19 according to Good Laboratory Practice (GLP) |
| RNase remover (Recommend: PCR Clean™, Minerva Biolabs) |

| MATERIALS MAY BE REQUIRED |
|---|
| Swab Vials |
| RNase-Free Saline |
| RNase-Free Water |



# MATERIALS

## FOR LABORATORY USE

| MATERIALS PROVIDED | | | |
|---|---|---|---|
| Kit Type | Component | Pack Format | |
| | | 16T | 32T |
| | | Quantity | |
| Test Kit Part A: RaVID-OQ-01 | Test Tubes | 16 | 32 |
| | IFU | 1 | 1 |
| Control Kit Part B: RaVID-Ctrl-01 | Positive Control Solution | 1 x 0.1mL | 2 x 0.1mL |
| | RNase Free Wate | 1 x 0.1mL | 2 x 0.1mL |

| MATERIALS REQUIRED BUT NOT PROVIDED |
|---|
| Heat Block(s) (Recommend: Scottech Medical Ltd MVS-100) |
| Calibrated micro-pipettes with capability of dispensing 25µL volumes |
| Filtered pipette tips for use with micro-pipette |
| Scanner (Recommend: QuickScan™ QD2430 Bar Code Reader from DATALOGIC) |
| Biohazard Bin/Disposal method |
| Disposable gloves and other PPE for protection against COVID-19 according to Good Laboratory Practice (GLP) |
| RNase remover(Recommend: PCR Clean™, Minerva Biolabs) |

| MATERIALS MAY BE REQUIRED |
|---|
| Swab Vials |
| RNase-Free Saline |
| RNase-Free Water |

# METHOD

SAMPLE PREPARATION

If samples have been pre-prepared, no agitation of these samples required before taking sample solution.

If samples have not been eluted from swabs, insert the swab into a swab vial with 1mL of saline solution.

## HANDLE ONE SAMPLE AT A TIME

Break the swab handle at the perforation, close the cap. Label the vial appropriately.

## ALL SAMPLES MUST BE THERMALLY INACTIVED BEFORE VIALS ARE OPENED AND THE TEST IS CONDUCTED

## SAMPLES MUST BE PREPARED IN ISOLATION PRIOR TO THE TEST BEING CONDUCTED DUE TO THE RISK OF RNASE CONTAMINATION.

SAMPLE INACTIVATION

In order to inactivate the samples*, use the following steps:

• Pre-warm the heat block to 95°C

• Place all swab samples in the heat block for 10 minutes1

• Remove the samples and leave to cool for a **minimum** of 2 minutes at 23°C ±2°C

**Will achieve viral inactivation to the detection limit of the assay*

CONTROL METHOD

• Ensure work area has been cleaned thoroughly with RNase and nucleic acid remover

• Prepare negative control by adding 25µL of RNase-free water to the negative control tube. Label with the pink label.

• Take 25µL of positive control solution and add it to a test tube. Label with the yellow label.

## TAKE CARE WHEN HANDLING THE POSITIVE CONTROL TO AVOID CROSS CONTAMINATION TO SAMPLES AND NEGATIVE CONTROL

TEST METHOD

• Before and after each run, decontaminate work surfaces and equipment with nucleic acid remover.

• Add 9mL of water into a heat inactivated patient's sample. Using a pipette to take from the diluted sample and add one drop (25µL) to a properly labelled test tube.

• Only open one tube at a time and close immediately after adding sample

• Repeat for all individual samples

All solutions at this stage should appear pink.

• Ensure heating block is pre-warmed to 65°C ±3°C

• Place test tubes in heating block for 30 – 45 minutes. **DO NOT EXCEED 45 MINUTES.**

• Remove the test tubes and leave to cool for a **minimum** of 2 minutes at 23°C ±2°C

# INTERPRETATION OF RESULTS

• Read the results under white light with white background. Assay end point stability is at least 60 minutes at room temperature 23°C

• See the table below for evaluation of control tubes. Any invalid results must be discarded and the test repeated.

| Positive Control | Negative Control | Result |
|---|---|---|
| Pink | Pink | Invalid |
| Yellow | Pink | Pass |
| Pink | Yellow | Invalid |
| Yellow | Yellow | Invalid |

If a valid result is obtained from the control tubes the samples can then be confirmed. Use the colour chart provided to ensure correct interpretation of colorimetric changes.

After reading results dispose of all test tubes and contaminated items associated with the test as clinical waste in the biohazard bag provided. Samples should be retained/disposed of in accordance with standard clinical procedure. All waste must then be treated in accordance with local guidelines regarding biohazardous waste. Take care when handling samples to ensure that bodily fluids to not leak from test tubes.

## ANALYTICAL PERFORMANCE

SENSITIVITY

The Oxsed RaVid Direct SARS-CoV-2 test has a limit of detection of 800 copies/mL. The LoD for this test was assessed at the Institute of Biomedical Engineering, University of Oxford by analysing simulated human swab samples spiked with a SARS-CoV-2 template (NIBSC SARS-CoV-2 RNA standard-Product code: 19/304) at a known copy number. The eluates were then serially diluted to 5 different concentration levels. The Oxsed RaViD Direct SARS-CoV-2 test detected 3/3 replicates at 20 copies/reaction from 3 different batches of test kits. Therefore 20 copies/reaction (800 copies/mL) was chosen as the tentative LoD value. Confirmation of the LoD value was then obtained by testing 20 replicates at 20 copies/reaction.

CLINICAL PERFORMANCE

The clinical performance of the Oxsed RaViD SARS-CoV-2 test was evaluated by the Department of Microbiology at Oxford University Hospitals. The study was conducted in a clinical laboratory with ISO 15189 accreditation by training clinical personnel.

The purpose therefore of this study was to perform measurements with Oropharyngeal Swab clinical samples (without RNA extraction procedure from different donors. All samples were retrospective Oropharyngeal swab clinical specimens in saline. Specifically, 39 individual negative Oropharyngeal specimens and a total of 30 positive samples were tested blindly to generate the Diagnostic Sensitivity also known as Positive Percentage Agreement (PPA); Diagnostic Specificity also known as Negative Percentage Agreement (NPA) and overall percentage agreement (OPA) as a measurement of estimated Diagnostic Accuracy:

| Sample Status | Oxsed RaVid SARS-CoV-2 Test | | Positive Percentage Agreement (PPA) | Negative Percentage Agreement (NPA) | Overall Percentage Agreement (OPA) |
|---|---|---|---|---|---|
| | + | - | | | |
| Positive | 22 | 0 | 73% | 100% | 88% |
| Negative | 8 | 39 | | | |

**Note:** *92% (PPA) for samples with CT<31; 82% (PPA) for samples with CT<33; 73% (PPA) for all samples (direct from swab)*

SPECIFICITY

The following cross-reactivity evaluation has been carried out by *In Vitro* and *In Silico* method in order to establish a specificity value of 100%.

| Pathogen | Interaction | Pathogen | Interaction |
|---|---|---|---|
| HCoV-NL63 | None | SARS_CoV2_Wuhan1 | Yes |
| CoV_HKU1 | None | HCoV-229E | None |
| SARS_CoV_Tor2 | None | EV68 | None |
| MERS_CoV | None | RSV | None |
| HCoV OC43 | None | Rhinovirus | None |
| Adenovirus | None | Chlamydia pneumoniae | None |
| hMPV | None | Haemophilus influenzae | None |
| HPIV-1 | None | Legionella pneumophila | None |
| HPIV-2 | None | Mycobacterium tuberculosis | None |
| HPIV-3 | None | Streptococcus pneumoniae | None |
| Influenza A | None | Streptococcus pyogenes | None |
| Influenza B | None | Bordetella pertussis | None |
| Pneumocystis jirovecii (PJP) | None | Mycoplasma pneumoniae | None |

## REFERENCES

1. Darnell, Miriam E.R and Taylor, Deborah R., Evaluation of inactivation methods for severe acute respiratory syndrome coronavirus in noncellular blood products. Wiley Public Health Emergency Collection, 46 (10): 1770-1777, 2006.

## EXPLANATION OF SYMBOLS

| Symbol | Explanation | Symbol | Explanation |
|---|---|---|---|
| IVD | In vitro diagnostics | REF | Catalogue number |
|  | Manufacturer |  | Temperature limit |
|  | Use by Date |  | Caution |
| CONTROL + | Positive Control | CONTROL − | Negative Control |
| LOT | Batch Code |  | Sufficient for |
|  | Keep away from sunlight (primer/probe mix) |  | Consult Electronic Instructions for Use |
|  | Single Use Only |  | Consult Instructions for Use |

## CONTACT US

For technical support, please contact our dedicated technical support team on:
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