RAPTOR – a general guide

Version 2, updated to reflect protocol v.6

01.03.2022

Video tutorial guide is available here.

Contents

STEP 1 – identify eligible patients

Eligibility:

- Patients with covid-like symptoms (any symptoms associated with covid that may lead the clinician to suspect a covid infection) can be recruited (protocol v.6, p16-7)
- Patients must be exhibiting covid-like or flu-like symptoms to be eligible. Within 12 days of symptom onset for Lumira
- Patients with recurring covid-like symptoms can be recruited into the study, but can only participate once

- Patients who have tested positive for covid and are no longer symptomatic, or have not developed symptoms, are not eligible for the study at the moment
- Patients who have come into contact with someone who has tested positive can only be included if they also develop symptoms (but this may be a useful avenue to identify potential participants)
- Patients who are in immediate need of hospitalisation, or who are unable to understand and consent to the study, are not eligible
- In all cases, if in doubt please refer to the product Information For Use (IFU form), and follow the product guidelines

- Children can be included in the study, with parental/guardian consent

- Patient information sheets for the different age groups can be found here

Identification:

- Opportunistic recruitment: patients who report covid-like symptoms to the practice could trigger research prompts (e.g. pop-up on patient record)
- Searching patient records for recent positive covid rest results
- Patient self-identification: provide information about the study on practice website, social media, posters within the practice, on the practice recorded telephone message
- See here for tips on maximising recruitment

STEP 2 – patient consent

Steps:

- Add patient to uMed platform
    - Note: write +44 at the beginning of the contact phone number, not 44, for UK numbers

- Ensure the patient has read and understood the patient information leaflet, relevant to their age group (available on the RAPTOR website)

- Run through all steps of the eCRF
    - recorded uMed training webinar
    - written guide

Training:

- uMed training guide

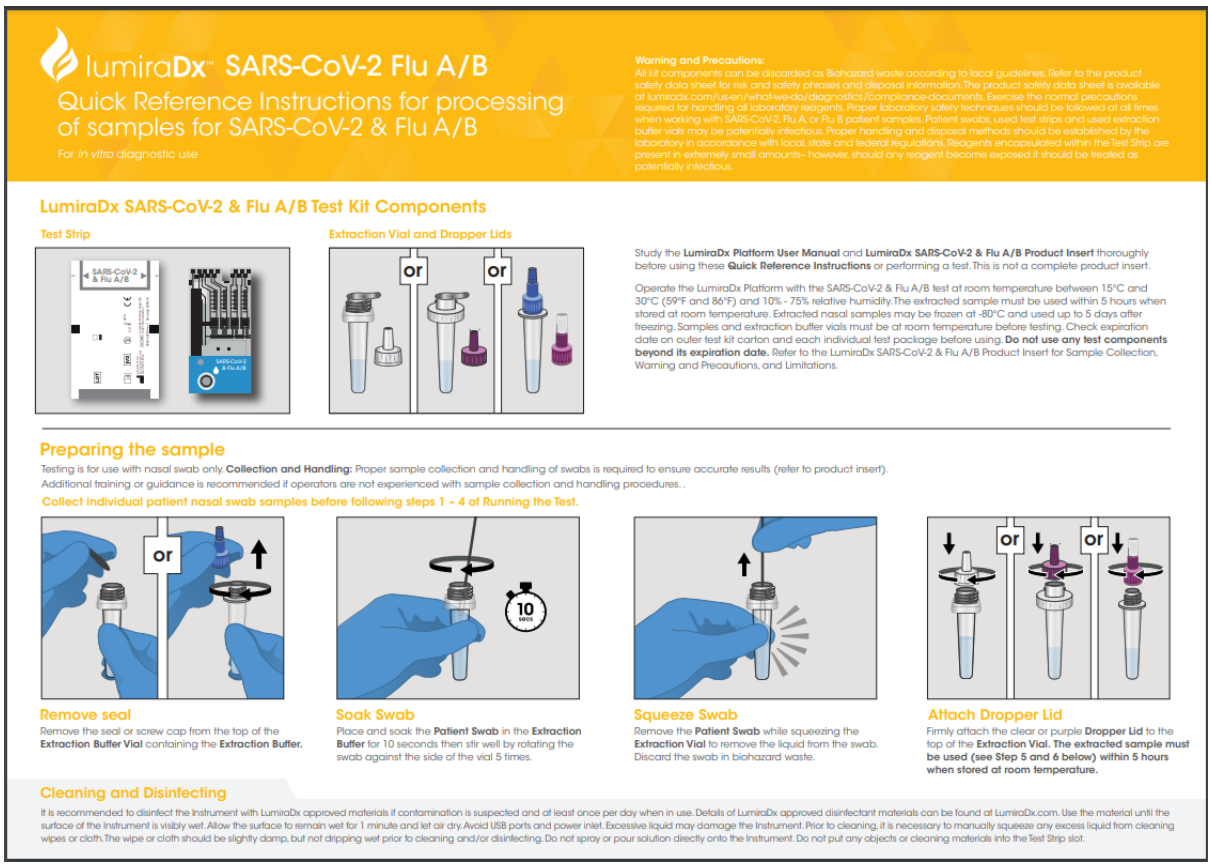
STEP 3 – Point of care tests (POCTs)

- RAPTOR website with links
- Always please read the IFU for product use and for more information

Lumira Dx

- Patient must be exhibiting covid-like or flu-like symptoms, ideally within 12 days of symptom onset

Training video	Lumira product documents for flu and covid tests	Lumira product documents in full	Lumira quick test guide



lumiraDx™ SARS-CoV-2 Flu A/B

Quick Reference Instructions for processing of samples for SARS-CoV-2 & Flu A/B

For *in vitro* diagnostic use

Warning and Precautions:
All kit components can be discarded as Biohazard waste according to local guidelines. Refer to the product safety data sheet for risk and safety phrases and disposal information. The product safety data sheet is available at lumiradx.com/us-en/what-we-do/diagnostics/compliance-documents. Exercise the normal precautions required for handling all laboratory reagents. Proper laboratory safety techniques should be followed at all times when working with SARS-CoV-2, Flu A, or Flu B patient samples. Patient swabs, used test strips and used extraction buffer vials may be potentially infectious. Proper handling and disposal methods should be established by the laboratory in accordance with local, state and federal regulations. Reagents encapsulated within the Test Strip are present in extremely small amounts– however, should any reagent become exposed it should be treated as potentially infectious.

LumiraDx SARS-CoV-2 & Flu A/B Test Kit Components

Test Strip

Extraction Vial and Dropper Lids

Study the **LumiraDx Platform User Manual** and **LumiraDx SARS-CoV-2 & Flu A/B Product Insert** thoroughly before using these **Quick Reference Instructions** or performing a test. This is not a complete product insert.

Operate the LumiraDx Platform with the SARS-CoV-2 & Flu A/B test at room temperature between 15°C and 30°C (59°F and 86°F) and 10% - 75% relative humidity. The extracted sample must be used within 5 hours when stored at room temperature. Extracted nasal samples may be frozen at -80°C and used up to 5 days after freezing. Samples and extraction buffer vials must be at room temperature before testing. Check expiration date on outer test kit carton and each individual test package before using. **Do not use any test components beyond its expiration date.** Refer to the LumiraDx SARS-CoV-2 & Flu A/B Product Insert for Sample Collection, Warning and Precautions, and Limitations.

Preparing the sample

Testing is for use with nasal swab only. **Collection and Handling:** Proper sample collection and handling of swabs is required to ensure accurate results (refer to product insert). Additional training or guidance is recommended if operators are not experienced with sample collection and handling procedures. .

Collect individual patient nasal swab samples before following steps 1 – 4 of Running the Test.

Remove seal
Remove the seal or screw cap from the top of the **Extraction Buffer Vial** containing the **Extraction Buffer.**

Soak Swab
Place and soak the **Patient Swab** in the **Extraction Buffer** for 10 seconds then stir well by rotating the swab against the side of the vial 5 times.

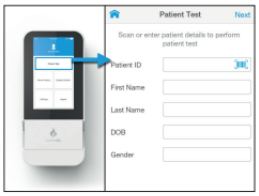
Squeeze Swab
Remove the **Patient Swab** while squeezing the **Extraction Vial** to remove the liquid from the swab. Discard the swab in biohazard waste.

Attach Dropper Lid
Firmly attach the clear or purple **Dropper Lid** to the top of the **Extraction Vial. The extracted sample must be used (see Step 5 and 6 below) within 5 hours when stored at room temperature.**

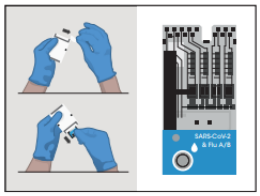
Cleaning and Disinfecting

It is recommended to disinfect the Instrument with LumiraDx approved materials if contamination is suspected and at least once per day when in use. Details of LumiraDx approved disinfectant materials can be found at LumiraDx.com. Use the material until the surface of the Instrument is visibly wet. Allow the surface to remain wet for 1 minute and let air dry. Avoid USB ports and power inlet. Excessive liquid may damage the Instrument. Prior to cleaning, it is necessary to manually squeeze any excess liquid from cleaning wipes or cloth. The wipe or cloth should be slightly damp, but not dripping wet prior to cleaning and/or disinfecting. Do not spray or pour solution directly onto the Instrument. Do not put any objects or cleaning materials into the Test Strip slot.

Running the Test

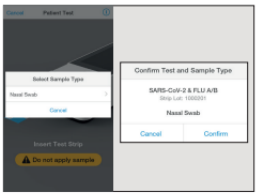


1. Select *Patient Test* from the **Instrument** *Home Screen* and enter the unique patient identifier information in the Patient ID details using the **Keyboard**.

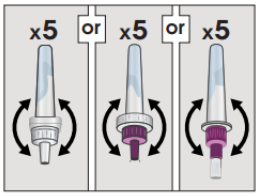


2. Remove the **Test Strip** from its pouch and hold by gripping only the blue portion. **Do not touch the Test Strip Sample Application Area. Do not bend the Test Strip or touch any part other than the blue portion.**

3. When prompted, open the **Instrument** door and gently insert the **Test Strip** as far as it will go. The thick black alignment rib on the **Test Strip** should be on the left and line up with the black line on the **Instrument. Do not apply the sample until prompted.** Install the Lot Calibration file if using a new **Test Strip Lot** for the first time. See the **Platform User Manual** for further details.

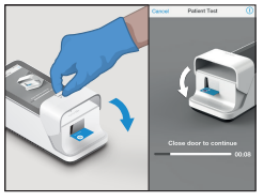


4. Confirm the test type.



5. Gently invert the **Extraction Vial** five times just before applying the sample to the **Test Strip.**

6. Apply **one whole drop** of the sample onto the **Test Strip Sample Application Area** when prompted by the **Instrument.**



7. Close the door when prompted to continue the test.

⚠ **Example of an error screen:**
If the On Board Control (OBC) fails, an error message will be shown, and no test result will be returned. Follow the on screen instructions to dispose of the Test Strip and start a new test. If the problem persists, contact LumiraDx Customer Services.

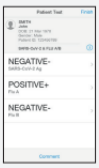
Interpretation of Results

Results are displayed within 12 minutes of applying the sample. Tap Finish to complete testing or tap Comment to leave a comment or to reject the Test, then follow prompts to return to the Home Screen. All test results must be read using the Lumiradx Instrument.

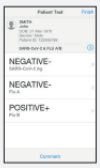
Negative

Positive SARS-CoV-2

Positive Flu A



Positive Flu B



Invalid results

If an issue occurs, a message will be displayed on the Instrument touch screen and a result will not be displayed. Alert messages include useful information and are highlighted by an orange banner. Error messages also include a ⚠ symbol. All messages will contain a description of the Instrument status or error and an instruction. Error messages contain an identifying code that may be used for further troubleshooting purposes.

Quality Controls

To complete Quality Control assessment of the LumiraDx Instrument and SARS-CoV-2 & Flu A/B test strips, you must use LumiraDx SARS-CoV-2 & Flu A/B Quality Controls which are available separately. If the Quality Controls do not perform as expected, do not report patient results. Retest using a new Test Strip – if problems persist contact LumiraDx Customer Services.

Customer Services
If the **LumiraDx SARS-CoV-2 & Flu A/B test** or the **LumiraDx Instrument** do not perform as expected, contact LumiraDx Customer Services via Lumiradx.com or customerservices@lumiradx.com

CE

Manufacturer Information
LumiraDx UK Ltd, Dumyat Business Park, Alloa, FK10 2PB, UK
Registration Number: 09206123

Authorized Representative in the European Union:
LumiraDx AB, Västra Vägen 5A, 16961 Solna, Sweden

S-COM-ART-01 803 I12

STEP 4 – virology reference swab

Swab processing:

- Take a nose and throat swab sample using the swab provided
- Insert the swab into the tube and break off the tip before securing the lid on
- Place the sample tube inside the packaging tube bottom first with the green lids on the same side:

- Place back in box with the completed form:
    - The **RCGP RAPTOR STUDY PHE Microbiology request form**, should be complete with the correct practice address (please check before continuing), project code and barcode.
    - Please complete the form IN FULL
    - Please take extra care to ensure that the **patient NHS number, name, DOB, RAPTOR ID, and date of sample collection** are complete and correct (the patient RAPTOR ID should be at the top of their consent form)

- Insert into envelope addressed to the Colindale lab in London and post in a priority post box:

Virus Reference Department

61 Colindale Avenue

London

NW9 5HT

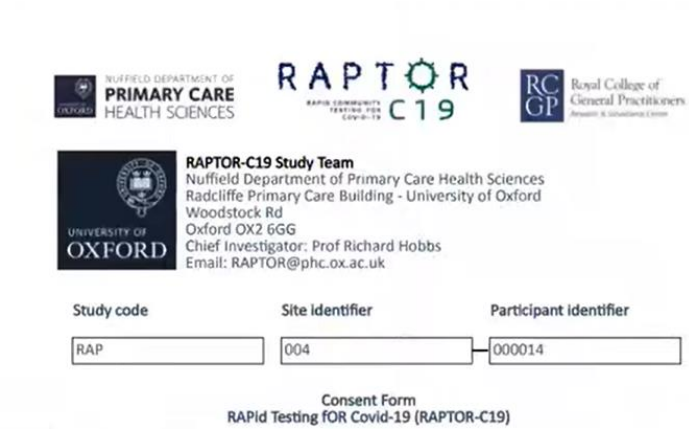
RAPTOR participant ID = the participant identifier number on the uMed participant record (see the top of the page when clicked in to a participant's records).

RAPTOR site ID = unique site code assigned by the RAPTOR project, NOT the practice code. The site ID can be found at the top of a completed participant consent form. Go to a participant record and click on:

'Form status' -> 'Study forms' -> ' View answers' -> 'download form'

The top of the form should have the study code, site identifier, and participant identifier at the top, e.g.:

RAP – [RAPTOR site ID] – [RAPTOR participant ID]



STEP 5 – check uMed

- Please check that all the correct information has been coded into uMed to complete the patient records
- This is extremely important as incomplete participant records may affect the funding that can be received for recruiting each participant