

SARS-CoV-2 Deceased Organ Donor Screening

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Summary of changes

- Inclusion of reference to TransplantPath specifically requirement for the SN to upload a completed copy of FRM6439 to DonorPath negating the need to email copy to Hub Operations, the National Referral Centre and Donor Family Care Service.
- Amendment to Lead Nurse / Regional Head of Nursing / Organ Donation Management Team on call.

N.B. This SOP must always be read in conjunction with the current version of POL304 SARs-CoV-2 Assessment and Screening in Organ Donors and Recipients. Users must refer to <https://www.odt.nhs.uk/covid-19-advice-for-clinicians/> for the most recent version of POL304 and all linked documents.

Useful Information

Severe Acute Respiratory Syndrome Coronavirus 2 also known as SARS-CoV-2 causes Coronavirus Disease 2019 (COVID-19). The transmission of COVID-19 is thought to occur mainly through respiratory droplets generated by coughing and sneezing, and through contact with contaminated surfaces (WHO 2020).

The COVID-19 pandemic has had a significant impact on organ donation and transplantation in the UK. Although fundamental questions still remain about the biology of the Severe Acute Respiratory Syndrome Coronavirus-type 2 (SARS-CoV-2), the natural history and optimal treatment of COVID-19, knowledge has evolved rapidly since early 2020. This document provides guidance on the SARS-CoV-2 assessment and screening of potential solid organ donors and must be read in conjunction with POL304.

Key to COVID-19 Testing:

- **Collect sample in correct specimen transport container + check labelling**
- **Contact Donor Testing Laboratory before sending samples**
- **Request laboratory confirm arrival of samples**
- **Agree and note ETA of results**
- **Where results are not negative send FRM6439 to Donor Testing Virologist**
- **Await final NHSBT SARS-CoV-2 results**

Which samples should be taken?

SCREENING OF POTENTIAL ORGAN DONOR FOR COVID-19

1. Upper respiratory tract sample options:

- individual nose and throat swabs in separate collection tubes OR
- combined nose and throat swab in one collection tube containing universal transport medium OR
- single swab used for throat then nose

2. Lower respiratory tract sample in universal container

ENDOTRACHEAL ASPIRATE

N.B. Some patients who cannot have nose swab taken (i.e. extensive trauma or bleeding); very rarely, neither nose – or throat swab can be obtained so an oral swab can be taken instead.

It should be noted that failure of internal control amplification invalidates the test – no result available (system failure). The test needs to be repeated on the same or another sample. This is not an indeterminate result.

Glossary

Roles

SN - Specialist Nurse Organ Donation. For the purposes of this document the term SN will apply to a Specialist Nurse with the relevant knowledge, skills, and training in organ donation, working within NHSBT Organ Donation Services Teams (ODST), including SNOD-Specialist Requester, SNOD-Family Care

LN – Lead Nurse

RHoN - Regional Head of Nursing

CLOD - Clinical Lead for Organ Donation

ICU Consultant – Intensive Care Unit Consultant

HO - Hub Operations

PID – Patient Identifiable Data

Donor Testing Virologist – Virologist undertaking deceased donor testing either within regional laboratory or on occasion within donor hospital

ODST – Organ Donation Services Team

ODMT On call – Organ Donation Management Team on call 24/7 escalation.

Terminology

SARS-CoV-2 - Severe Acute Respiratory Syndrome Coronavirus-type 2

COVID-19 - Coronavirus disease

SARS-CoV-2 Ribonucleic Acid (RNA) - the test used to detect SARS-CoV-2 infection

NTS – Nose and Throat Swab

ETA – Endotracheal Aspirate

DonorPath - the secure electronic record that is utilised to upload clinical information about a patient.

NRC – National Referral Centre

Restrictions

This SOP is to be followed by a qualified, trained SN. In the event of a SN who is in training, this SOP is to be utilised under supervision.

Related Documents/References

SOPs

SOP3649 – Voice Recording of Organ Donor Clinical Conversations

SOP4938 – Sharing Clinical Information

FRMs

FRM6445 - COVID-19 Swab and Endotracheal Aspirate Request Form

FRM6439 – SARS-CoV-2 Assessment and Screening (in deceased organ donors)

FRM6634 – Result Table

INFs

INF1549 – Business Continuity Deceased Donation Assessment Tool

POLs

POL304 - SARS-CoV-2 Assessment and Screening in Organ Donors and Recipients

DATs

DAT3906 – COVID-19 Guidance for OTDT Specialist Nurse Colleagues

DAT4077 – Virology Laboratory Email Address List

NHSBT Covid 19 advice for clinicians

<https://www.odt.nhs.uk/covid-19-advice-for-clinicians/>

Example Video Endotracheal Aspirate

<https://www.odt.nhs.uk/covid-19-advice-for-clinicians/example-of-eta-sampling/>

Example Video Throat and Nose Swab

<https://www.odt.nhs.uk/covid-19-advice-for-clinicians/nose-and-throat-sampling/>


SOP5869/6 – SARS-CoV-2 Deceased Organ Donor Screening

1. Referral of a Potential Deceased Organ Donor

Information	<p>SARS-CoV-2 RNA positivity alone does not define infectiousness and cannot be interpreted in a binary fashion. POL304 sets out the circumstances where organ donation from selected donors with positive (or indeterminate) SARS-CoV-2 RNA test results may be reasonable aligning donor and recipient assessments with the evolving pandemic situation and the growing evidence on the use of organs from SARS-CoV-2 positive donors.</p> <p>Permissiveness for clinical teams to assess particular donor/recipient circumstances is important so that safe donation and transplantation procedures are not avoided solely on the basis of a positive screening SARS-CoV-2 result.</p>				
Action	<p>Assess for donation referring to POL304 SARS-CoV-2 Assessment and Screening in Organ Donors and Recipients.</p>				
Notes	<p>If SARS-CoV-2 (RNA) samples have already been taken and sent in advance by the ICU, the SN must check with the processing lab that the samples have arrived and expected time of results.</p> <p>Any concerns regarding the testing or any implications of results to be discussed with local donor testing virologist to determine risk.</p>	<p>If Critical Care Capacity is stretched, explore ways to mitigate.</p> <p>Refer to INF1549 - Business Continuity Deceased Donation Criteria Assessment Tool.</p> <p>If unable to facilitate report via https://safe.nhsbt.nhs.uk/in-cidentSubmission/Pages/IncidentSubmissionForm.aspx</p>	<p>If the decision is finely balanced then consider using an ethical decision-making framework e.g. www.moralbalance.org</p>	<p>SNs must adhere to local donor hospital policies on the use of Personal Protective Equipment (PPE) when caring for patients with positive or indeterminate SARS-CoV-2 RNA test results referring to DAT3906 Guidance for SNs.</p>	<p>On referral to the ODST, the SN/TM taking the referral should document in Sequence of Events on DonorPath the level of PPE that is currently in use.</p>

SOP5869/6 – SARS-CoV-2 Deceased Organ Donor Screening

2. Organ Donation is being Assessed

Information	Deceased Organ Donation is being Assessed			
				
Action	<p>England, Wales + NI If opt in on ODR send tissue typing, microbiology bloods and SARS-CoV-2 RNA samples, process tissue typing but do not process other samples until family consent. If not opt in on ODR send and process samples after discussion with family.</p> <p>Scotland samples cannot be taken without discussion and authorisation from nearest relative after duty to inquire and checking unwillingness or change of mind.</p>			
Notes	<p>England, Wales + NI</p> <p>If opt in on the ODR send tissue typing, microbiology, and SARS-CoV-2 samples, process tissue typing but do not process other samples until family consent.</p> <p>If not opt in on ODR do not send samples until family consent as per SOP3630 Diagnostics-blood tests.</p> <p>There is no requirement to wait for COVID-19 results before processing tissue typing samples.</p>	<p>Scotland</p> <p>As per SOP3630 Diagnostics - Blood tests samples cannot be taken without discussion and authorisation from nearest relative after duty to inquire and checking unwillingness or change of mind.</p>	<p>As per POL304 – SARS-CoV-2 Assessment and Screening in Organ Donors and Recipients SARS-CoV-2 RNA nose and throat and endotracheal aspirate samples must be preferably within 24 hours (and no longer than 48 hours) of organ retrieval.</p>	<p>The SN should oversee the taking of the throat and nose swab and endotracheal aspirate to ensure they are in the correct sample transport container and correctly labelled using 3 PID.</p>

SOP5869/6 – SARS-CoV-2 Deceased Organ Donor Screening



Blood and Transplant
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<p>Information</p>	<p>If ICU has not already tested for SARS-CoV-2 RNA, inclusive of endotracheal aspirate OR If previously tested negative but new symptoms or further respiratory deterioration OR time of previous samples would be outside the preferable 24 hours (and no longer than 48 hours) to potential organ retrieval:</p>			
<p>Action</p>	<p>ICU team to take throat/nose swab and endotracheal aspirate. SN to complete FRM6445 and label with 3 points of PID.</p>	<p>Send samples to virology laboratory as per local agreement as early as possible in the process communicating clearly.</p>	<p>Throat/Nose swab and endotracheal aspirate are to be tested on the next available run.</p>	<p>Record dates and times of sample collection on FRM6439.</p>
<p>Notes</p> <p>1</p>	<p>There is no requirement for a broncho-alveolar lavage to be performed with a bronchoscope. Example videos of how to take a throat and nose swab and an endotracheal aspirate from a ventilated patient in a close circuit manner are provided in the following links: https://www.odt.nhs.uk/covid-19-advice-for-clinicians/nose-and-throat-sampling/ https://www.odt.nhs.uk/covid-19-advice-for-clinicians/example-of-eta-sampling/ Healthcare professionals should always follow their own local hospital infection guidelines and protocols.</p>		<p>COVID-19 Regional SN arrangements for sending samples is available see file director or in the regional handbooks. SN to liaise with processing laboratory to agree correct specimen transport container. Care must be taken to ensure that sample pots are suitable for testing viral PCR.</p>	

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Paediatrics:

Where a maternal assessment is required, there is no requirement to additionally complete a maternal COVID-19 screen, donor screening is sufficient.

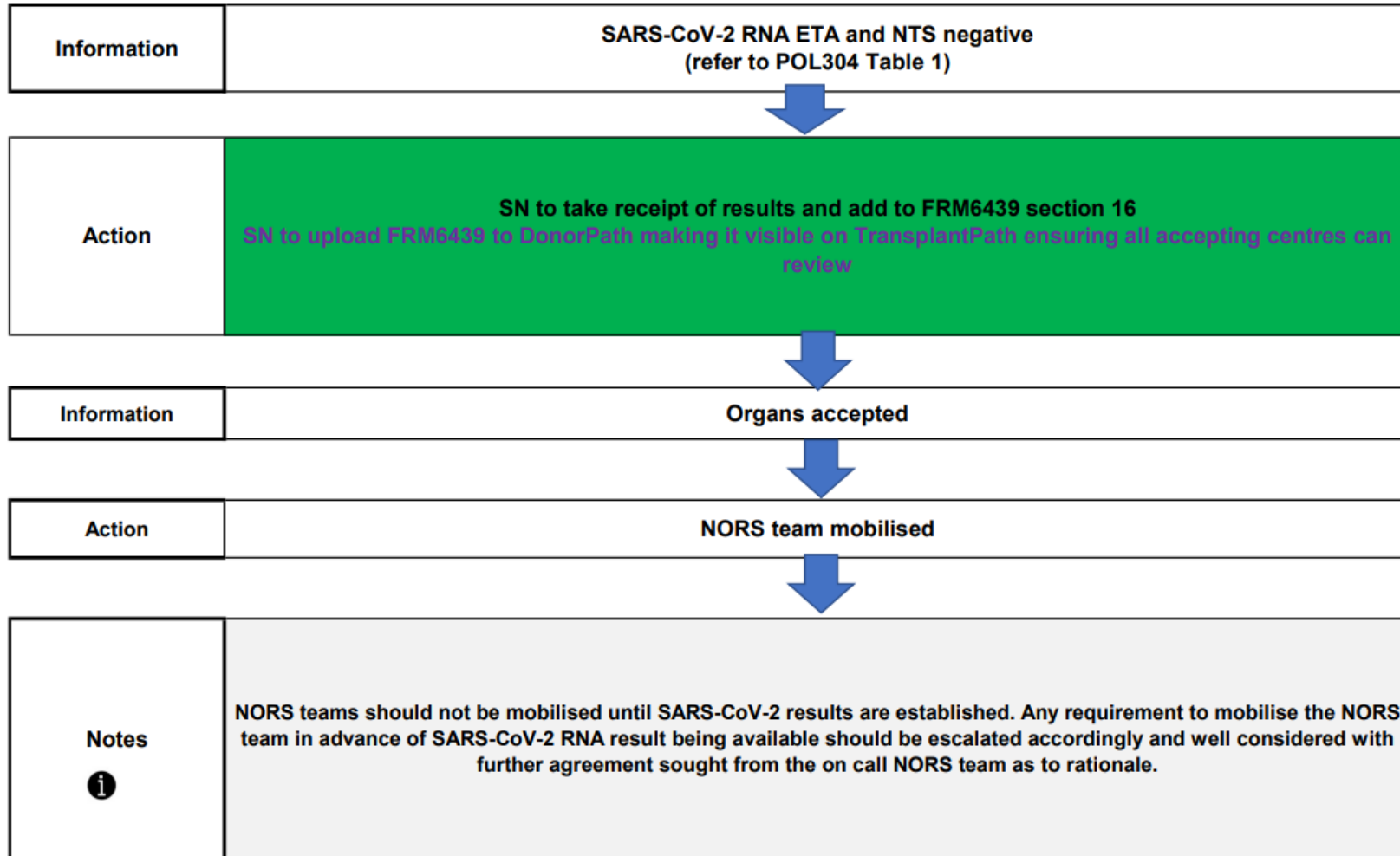
If a paediatric patient does not have an ETT, a nasopharyngeal aspirate may be a more appropriate sample. Nasopharyngeal aspirates are a common occurrence in paediatrics.

Paediatric Unit policy should be followed for ET/nasopharyngeal sampling including volume of saline installation.

- 2.1 SNs must complete FRM6439 SARS-CoV-2 Assessment and Screening (in deceased organ donors) sections 1 – 15 inclusive as soon as practically possible. SNs should commence section 16 noting admission SARS-CoV-2 testing and await results of NHSBT deceased donor screen.
- 2.2 Best practice indicates where possible SNs should have all SARS-CoV-2 results and any necessary interpretation, [attaching FRM6439 to DonorPath making it visible on TransplantPath](#) ahead of registering with Hub Operations. Regional laboratory variations may not make this possible on all occasions.

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3. Results and Interpretation



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Information	SARS-CoV-2 RNA ETA and/or N+T Swab indeterminate/positive/discordant (refer to POL304 Table 1 + Figure 1)
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Action	<p>SN to liaise with Donor Testing Virology - discuss collection of additional samples where considered to be of benefit (analysis of consecutive results can help with interpretation of the likely stage of infection). If interpretation available following prior agreement, SN to send a copy of FRM6439 to Donor Testing Laboratory securely as per DAT4077. Virologist can add results and assays to FRM6439 or SN can add on their behalf. As per POL304 it is not essential to have a written, signed interpretation of test results in all potential donors with positive SARS-CoV-2 screening results.</p> <p>SN to upload completed FRM6439 to DonorPath making it visible on TransplantPath to all centres.</p>
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Information	Organs accepted
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Action	NORS team mobilised
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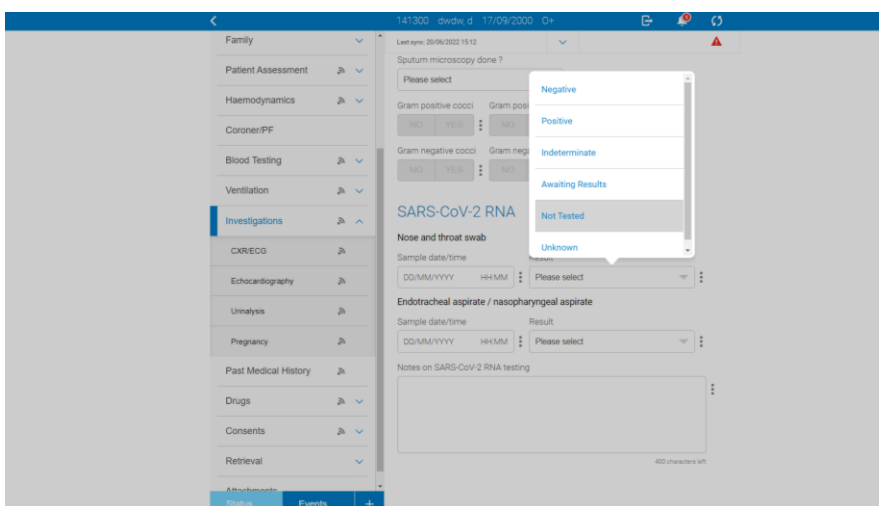
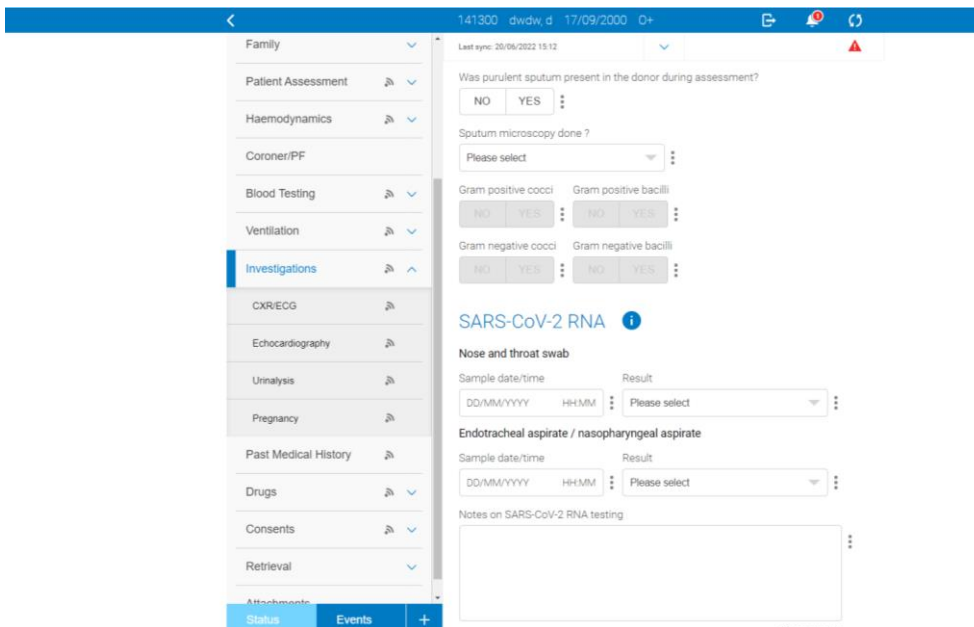


Notes 	NORS teams should not be mobilised until the SARS-CoV-2 RNA results are available.	In circumstances where the SN seeks advice of the Donor Testing Virologist they must ensure they are fully briefed on patient's medical and social history ahead of any call.	All clinical conversations MUST be voice recorded as per SOP3649

- 3.1. Best practice indicates where possible all donor characterisation information is available at the point of donor registration. In circumstances where the SARS-CoV-2 results have not been received and the SN is ready to register the donor with OTDT Hub operations, the SN should make contact with donor virology testing laboratory in order to assess timings. Where possible and feasible await the results if imminent.
- 3.2. In circumstances where the results are negative the SN must add the results to the completed FRM6439 SARS-CoV-2 Assessment and Screening (in deceased organ donors) in section 16. **The SN must upload FRM6439 to DonorPath making it visible on TransplantPath.**
- 3.3. As per POL304 it is not essential to have a written, signed interpretation of test results in all potential donors with positive SARS-CoV-2 screening results however, where this is available from the Donor Testing Virologist the SN should use DAT4077 and send a copy of FRM6439 to the Donor Testing Virologist via secure encrypted email. The SN should ask the Donor Testing Virologist to add the test results to section 16 and include any associated interpretation via secure email.
 - 3.3.1. In circumstances where the Donor Testing Virologist is able to provide interpretation but cannot do so via email the SN must voice record the clinical conversation (as per SOP3649 and usual clinical practice) with the virologist and add the results information to FRM6439 in section 16.
 - 3.3.2. In circumstances where the SN seeks the opinion of the Donor Testing Virologist with regards possible interpretation, it is essential that the SN is clear on the ask of the Donor Testing Virologist which is to help provide an interpretation of the results they have generated in the context of the patient history and information provided in FRM6439. The SN should note that if the Donor Testing Virologist feels there is not enough information to provide a valid interpretation that as per POL304, it is not essential to have written, signed interpretation of test results in all potential donors with positive SARS-CoV-2 screening results.
- 3.4. On all occasions the SN should agree with the Donor Testing Virologist requirements/benefits for additional testing where required in line with POL304.
- 3.5. Once all results have been tabled in chronological order and where applicable any written interpretation received from the Donor Testing Virologist the SN should proceed or stand down in line with POL304 (Table 1). Where required SNs can seek any additional advice via escalation to their **LN/RHoN/ODMT on call**.
- 3.6. For all proceeding donors **the SN must upload a copy of FRM6439 to DonorPath making it visible on TransplantPath.**
- 3.7. On all occasions where new clinical information is obtained post donor registration the SN must follow SOP4938 as per usual practice. Actions must be documented in sequence of events on DonorPath. **It is the SNs responsibility to ensure the most up to date version of FRM6439 is available to all centres on TransplantPath by uploading onto DonorPath.**

4. Recording Results on Donor Path

4.1 To ensure safe and consistent access to results by receiving centres the final SARS-CoV-2 results should be documented on DonorPath within the investigations section. A section entitled SARS-CoV-2 RNA is available as seen below. The SN can enter a date/time of sample and a result for nose and throat swab and endotracheal aspirate (nasopharyngeal in some paediatric cases). A free text field is available entitled 'Notes on SARS-CoV-2 RNA testing' (max 400 character). It is the responsibility of the SN to ensure results are recorded and visible to recipient centres. N.B. A blue bubble icon is associated with the field 'final result of deceased donor screening should be recorded'.



4.2 On occasions where there are multiple results which cannot be safely accommodated within FRM6439, FRM6634 can be used as an additional results table. On occasions where this additional table is used it must also be attached to DonorPath.

5. Useful links

NHSBT Covid 19 advice for clinicians

<https://www.odt.nhs.uk/covid-19-advice-for-clinicians/>

Clinical Governance reporting form

<https://safe.nhsbt.nhs.uk/incidentSubmission/Pages/Incident/SubmissionForm.aspx>

Ethical Framework www.moralbalance.org

Example Video Endotracheal Aspirate

<https://www.odt.nhs.uk/covid-19-advice-for-clinicians/example-of-eta-sampling/>

Example Video Throat and Nose Swab

<https://www.odt.nhs.uk/covid-19-advice-for-clinicians/nose-and-throat-sampling/>

WHO

[https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/naming-the-coronavirus-disease-\(covid-2019\)-and-the-virus-that-causes-it](https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/naming-the-coronavirus-disease-(covid-2019)-and-the-virus-that-causes-it)

WHO

https://www.who.int/health-topics/coronavirus#tab=tab_1