

NeoCol: Standard Operating Procedure (SOP) for Maternal Swabs v3.0

Purpose:

The purpose of this SOP is to describe the standard procedures involved in obtaining Maternal Vagino-rectal swabs according to the NeoCOL study protocol.

Principal:

Vagino-rectal swabs collect a sample of the bacteria and fungi that colonise the vagina & lower gastrointestinal tract of a mother at birth at time of delivery. The samples can then be analysed to determine which species are present and assess whether they carry antimicrobial resistance genes. This information can then be compared to the colonisation information from their infants to better understand transmission dynamics. Recto-vaginal should be ideally collected <u>prior to birth and any healthcare worker physical examination</u>. *Two* swabs will be collected: one for multidrug resistant organism culture (ESBL/CRE), for GBS culture and fungal culture and one for genetics.

We are aiming to understand how maternal colonisation with bacteria and yeast may impact the colonisation of an infant, and how this may alter clinical outcomes.

Responsibility:

This SOP applies to any clinical staff who are taking vagino-rectal and skin swabs from mothers for the NeoCOL study. It is the responsibility of those users to follow the guidelines when collecting swabs for the study.

Safety Requirements:

Gloves should be worn during swab collection. Standard clinical hand hygiene practices should be followed before, and after sample collection. Handle all specimens with care and treat them as potentially infectious material.

Materials:

- Non-Sterile gloves
- 1x Flocculated sterile swab plus container with amies medium (GBS culture / MDR / fungal culture) (figure 1)
- 1x 2ml eNAT medium in tube & regular FLOQ swab in sachet (for genetics) (figure 2)
- 2x Cryogenic specimen labels
- Plastic zip lock bag for specimen transport



Figure 1: Flocculated Sterile swab plus amies medium



Figure 2: Genetic Swab (2ml eNAT medium in tube & regular FLOQ swab in sachet)

Procedure:

Vagino-Rectal Swabs (MDR / GBS /Fungal and Genetics):

- 1. Explain the procedure to the mother and obtain verbal consent. (see NeoCOL_2.0_SOP11 for process for consent)
- 2. Get pre-made sample pack containing swabs and Sample Request Forms required per mother.
- 3. Label each of the specimen containers according to the label coding system (see appendix 2).
- 4. Complete Sample Request form (see appendix 3).
- 5. Position the mother in the lithotomy position.
- 6. Perform hand hygiene and put on gloves.
- 7. Open the sterile swab packages and remove the swab, being careful not to touch the top of the swab to yourself or any other surfaces.
- 8. Insert the tip of the swab 4 cm into the lower vagina first and rotate for 10 seconds without use of a speculum.
- 9. Then insert the same swab 1 cm into the anus and rotate for 10 seconds. Note: A visibly soiled swab is
- 10. Remove the swab and place the swab into the appropriate labelled transport container, and place into the plastic ziplock bag.
- 11. For the genetic swabs:
 - a. After collection, place the tip of the swab directly into the supplied eNAT tube.
 - b. Break the swab at the red line as indicated on the packaging so that the swab is able to fit inside the eNAT tube and the lid can be closed. Be careful not to touch the tip of the swab on yourself or any surface.
- 12. If the mother passes a stool around the time of delivery, collect the sample as per the Whole Stool Collection SOP (NeoCol_2.0_SOP03).
- 13. Transport the swabs to the laboratory via pneumatic tube systems within 30 minutes for storage in fridge (2–8°C) in hospital microbiology department pending transport to processing laboratory
- 14. Document the samples in the NeoCOL Sample Collection Log.
- 15. Dispose of any waste as per hospital guidelines.
- 16. Note: The samples must be taken 15 minutes prior / after delivery or at delivery for accurate detection of vertical transfer. If sample collected >24 hours pre-delivery, the swabs must be repeated.
- 17. Two vagino-rectal swabs should be taken from mothers (one for MDR / GBS / Fungal culture and one for genetics (see above)).

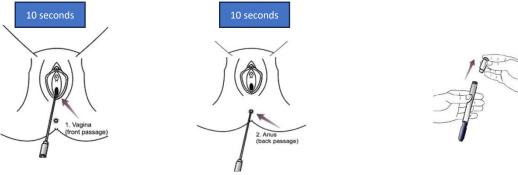
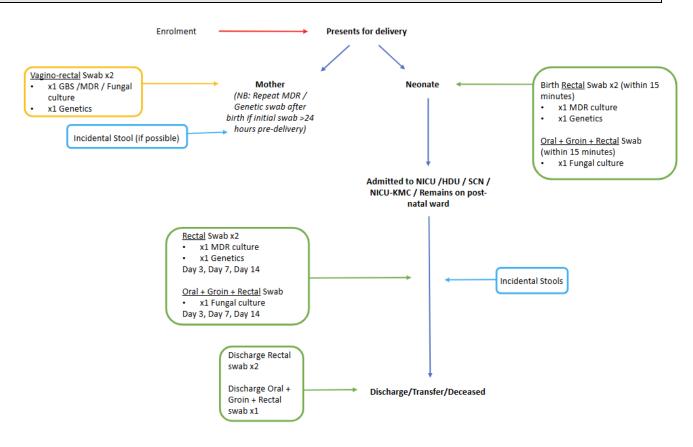


Figure 2: Procedure for collection of maternal vagino-rectal swabs



Figure 3: Pneumatic tube system for sending mother and infant delivery samples

Appendix 1: Maternal Swab Timepoints



Appendix 2: Specimen Labelling Code

| Site | | Participant Number | Mother/Child | | Timepoint (day) | Sample Type | | HMU Lab |
|------|---------------------------|-----------------------|--------------|--------|---------------------------|-------------|--|--|
| E | Hung Vuong Hospital | 001 – 999 | М | Mother | 00 | С | Culture: -gBs swab (group B streptococcus) -Mdr swab (multidrug resistant -Fungal swab | C changed to: -B for gBs plates -M for MDR plates -F for Fungal plates |
| | | | | | | G | G enetic swab | |
| | | | С | Child | 00, 03, 07, 14, DIS | М | M dr swab (multidrug resistant) | |
| | | | | | | G | G enetic swab | |
| | | | | | | S | S tool | |
| | | | | | | F | F ungal swab | |

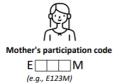
Eg. E020M00C: Hung Vuong Hospital, Participant 020, Mother, Day 00, Culture Swab

Appendix 3: Laboratory Test Request form for mother



NeoCOL Study





LABORATORY TEST REQUEST FOR MOTHER

| Sample collection time |
|----------------------------|
| □ Day 0 |
| ☐ Other day (specify)/2025 |

Fill in the Sample ID on the samples that have been taken.

Note: These samples ID must match the id affixed to the submitted test sample.

| | MDR swab | Genetic swab | GBS swab | Fungal swab | Stool |
|----------------|----------|--------------|----------|-------------|-------|
| | Mxx | xxG | xxB | xxF | xxS |
| Sample ID | ШМ | □□G | □□В | □F | □S |
| | | | | | |
| | | | | | |
| Notes (if any) | | | | | |
| | | | | | |

References

- Monash Women's Hospital: GBS Screening Information Sheet. Online.
- Filkins L, Hauser J, Robinson-Dunn B, Tibbetts R, Boyanton B, Guidelines for the Detection and Identification of Group B Streptococcus, American Society for Microbiology, (2021),
- CHAIN Rectal Collection SOP v1.04 accessed on 5th May 2023. Online.
- CDC *C. auris* Screening: Patient Swab Collection accessed on 21st February 2025. Online.

Document History

| Version | Author(s) | Approved by | Update Reason | Date | SOP No: |
|---------|-----------------|-------------|--|-------------|------------------|
| 1.0 | B. Dickson | P. Williams | New document | 11 JUL 2023 | NeoCOL_SOP02 |
| 2.0 | R. | P. Williams | Adapted for | 07 MAR 2025 | NeoCOL_2.0_SOP02 |
| | Kelleghan | | NeoCOL 2.0 | | |
| 3.0 | R. Kelleghan | P. Williams | Updated swab amounts, flowchart and specimen labelling | 04 JUN 2025 | NeoCOL_2.0_SOP02 |
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Site Training Record

| Trainee Name | Read/Understand SOP (Tick) | Access to SOP (Tick) | Trainee Signature | Date | Trainers Initials |
|--------------|-------------------------------|-------------------------|-------------------|------|----------------------|
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