

NeoCol: Standard Operating Procedure (SOP) for Neonatal Swabs v4.0

Purpose:

The purpose of this SOP is to describe the standard procedures involved in collecting Neonatal rectal swabs and neonatal skin swabs according to the NeoCOL study protocol.

Principal:

Rectal swabs collect a sample of the bacteria that colonise the lower gastrointestinal tract of a neonate. The bacterial samples can be analysed to determine which species are present and assess whether they carry antibiotic resistance genes. The collection of swabs at multiple time points over the course of the neonates' stay in hospital (see Appendix) will provide important information about if, and when the infant becomes colonised with these resistant types of bacteria. Two swabs are taken: one for culture and another for genetic testing.

Oral / Skin / Rectal swabs collect a sample of the fungi that colonise the neonate. The fungal samples can be analysed to determine which candida species are present and assess whether they carry antifungal resistance genes. The collection of swabs at multiple time points over the course of the neonates' stay in hospital will provide important information about if, and when the infant becomes colonised with different types of fungi. One swab will be taken: firstly, swabbing the mouth, groin and then rectum of the neonate. At a later date this may be extended to have an individual swab per site to investigate which sites are specifically colonised with *Candida* spp.

Responsibility:

This SOP applies to any clinical staff who are taking rectal and skin swabs from neonates for the NeoCOL study. It is the responsibility of those users to follow these guidelines when collecting rectal 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.
- x1 Sterile swab plus container with amies medium (for MDR culture) (*figure1*)
- x1 Sterile swab plus container with amies medium (for fungal culture) (*figure1*)
- x1 cryogenic label
- x1 2ml eNAT medium in tube & regular FLOQ swab in sachet (*for genetics*) (*figure 2*)
- Plastic zip lock bag for specimen transport



Figure 1: Sterile swab plus transport container with amies gel



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

Procedure:

Oral + Groin + Rectal swabs (Fungal):

1. Explain the procedure to the parent/guardian 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 infant
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 neonate in a comfortable position.
6. If available, provide the infant with sucrose for comfort for swabs taken on day 7 or later (not delivery swab), as per hospital guidelines.
7. Perform hand hygiene and put on gloves.
8. Open the sterile swab package and remove the swab, being careful not to touch the top of the swab to yourself or any other surfaces.
 - a. Oral:
 - i. When the neonate is comfortable and settled, introduce the swab between the cheek and the gum in one side of the mouth and gently rotate swab for 5 seconds. Move the swab tip to the other side of the mouth and rotate swab for another 5 seconds. Make sure the swab appears moistened when removed. Remove the swab from the mouth.
 - b. Groin:
 - i. Then, using the same swab, swipe all sides of swab tip back and forth 5 times over left groin skin surface (inguinal crease in the skin where the leg meets the pelvic region). Repeat on the right.
 - c. Rectal:
 - i. Position the neonate in a comfortable position on their side.
 - ii. Finally, using the same sterile swab, when the neonate is comfortable and settled, gently insert one sterile swab ~1cm into the anal sphincter. Gently rotate the swab for 10 seconds to ensure an adequate sample is collected. A visibly soiled sample is best. Remove the swab.
9. Place the swab into the respective labelled transport container and place into the plastic ziplock bag.
10. Transport the swabs to the laboratory within 30 minutes for storage pending transport to processing laboratory.
11. Log the sample collection into the NeoCOL Sample Collection Log.
12. Dispose of any waste as per hospital policies.
13. Note: The delivery swab must be taken within 15 minutes of birth to avoid detection of early horizontal transfer.
14. One fungal swab should be taken at each time-point for neonates.

Rectal Swabs (MDR / Genetics):

1. Explain the procedure to the parent/guardian and obtain verbal consent.
2. Label each of the specimen containers according to the label coding system (see appendix).
3. Position the neonate in a comfortable position on their side.
4. If available, provide the infant with sucrose for comfort, as per hospital guidelines.
5. Perform hand hygiene and put on gloves.
6. Open the sterile swab package and remove the swab, being careful not to touch the top of the swab to yourself or any other surfaces.
7. When the neonate is comfortable and settled, gently insert one sterile swab ~1cm into the anal sphincter. Gently rotate the swab for 10 seconds to ensure an adequate sample is collected. A visibly soiled sample is best. Remove the swab.
8. Place the swab into the respective labelled transport container and place into the plastic ziplock bag.
9. Repeat for the *second* swab (may be done in any order).
10. 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.
11. If the infant passes a stool during the procedure, collect the sample as per the Whole Stool Collection SOP (NeoCol_2.0_SOP03).
12. Transport the swabs to the laboratory via pneumatic tube systems in delivery ward within 30 minutes for storage in fridge (2–8°C) in hospital microbiology department pending transport to processing laboratory
13. Log the sample collection into the NeoCOL Sample Collection Log.
14. Dispose of any waste as per hospital policies.
15. Note: The delivery swab must be taken within 15 minutes of birth to avoid detection of early horizontal transfer.
16. Three rectal swabs should be taken at each time-point for neonates (one for MDR culture, one for Genetics and one for Fungal culture (see above)).

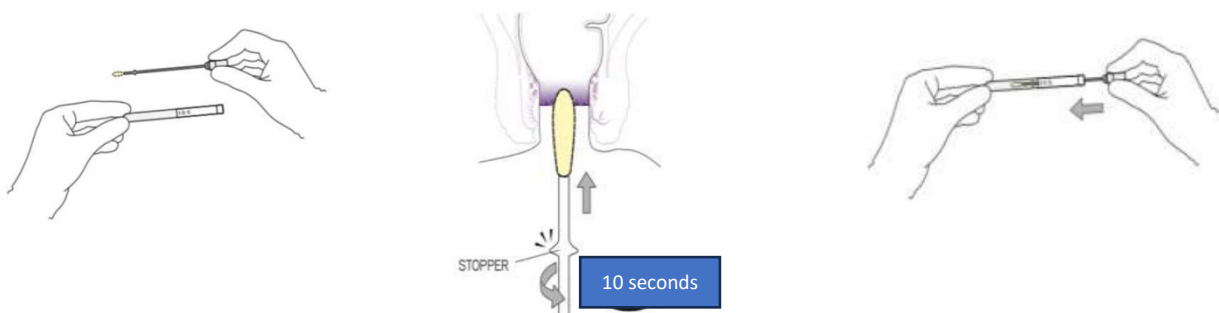
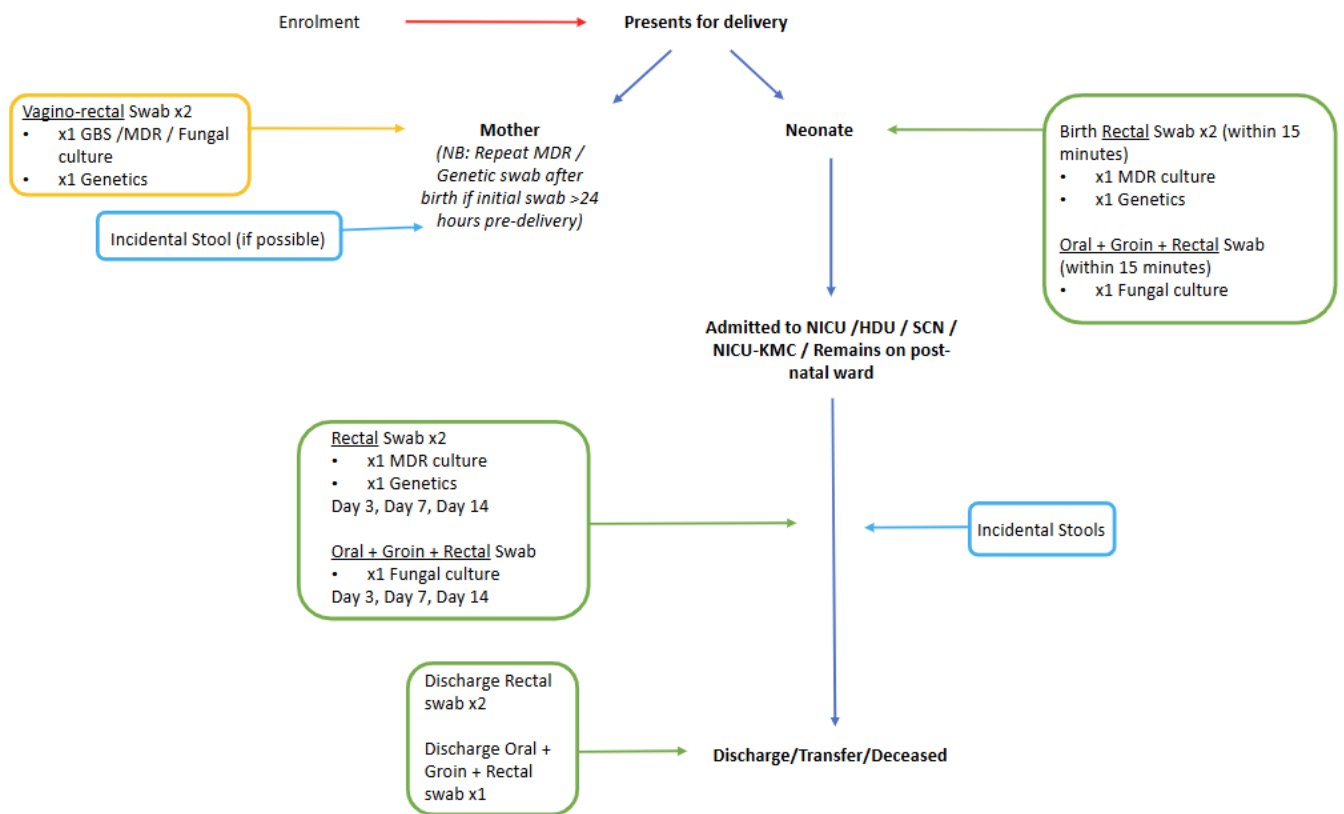


Figure 2: Procedure for collection of neonatal rectal samples



Figure 4: Pneumatic tube system for sending mother and infant delivery samples

Appendix 1: Neonatal Swab Timepoints



NOTE:

- The delivery swab must be taken *within 15 minutes of birth* to avoid detection of early horizontal transfer.
- Two rectal swabs should be taken at each time-point for neonates.
- One oral + groin + rectal swab should be taken at each time-point for neonates.

Appendix 2: Specimen Labelling Code

Site		Participant Number	Mother/Child		Timepoint (day)	Sample Type		HMU Lab
E	Hung Vuong Hospital	001 – 999	M	Mother	00	C	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	Genetic swab	
						S	Stool	
			C	Child	00, 03, 07, 14, DIS	M	Mdr swab (multidrug resistant)	
						G	Genetic swab	
						S	Stool	
						F	Fungal swab	

E.g. E020C07M = Hung Vuong Hospital, Participant 020, Child, Day 07, MDR swab

E.g. E001CDISF = Hung Vuong Hospital, Participant 001, Child, Discharge, Fungal Swab

Appendix 3: Laboratory Test Request form for child



THE UNIVERSITY OF
SYDNEY

NeoCOL Study



Child's participation code

E C
(e.g., E123C)

LABORATORY TEST REQUEST FOR CHILD

Sample collection time		
☐ Day 0	☐ Day 21	☐ Day 48
☐ Day 3	☐ Day 28	☐ Day 55
☐ Day 7	☐ Day 35	☐ Other day (specify)/...../2025
☐ Day 14	☐ Day 42	☐ Discharge date (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 transferred test sample.

	MDR swab (Rectal swab)	Genetic swab (Rectal swab)	Fungal swab (Oral - inguinal - rectal samples)	Immunological sample (Blood Sample) (Collect only at birth, day 0, at discharge, and during infection)	Stool
	xxM	xxG	xxF	xxH	xxS
Sample ID	M	G	F	H	S
Notes (if any)					

References

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- Kagia, N.; Kosgei, P.; Ooko, M.; Wafula, L.; Mturi, N.; Anampiu, K.; Mwarumba, S.; Njuguna, P.; Seale, A.C.; Berkley, J.A. Carriage and acquisition of extended-spectrum β -lactamase-producing Enterobacterales among neonates admitted to hospital in Kilifi, Kenya. Clinical infectious diseases 2019, 69, 751-759.
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- CDC *C. auris* Screening: Patient Swab Collection accessed on 21st February 2025. [Online.](#)
- Johns Hopkins Medical Microbiology Specimen Collection Guidelines accessed on 28th March 2025. [Online.](#)

Document History

Version	Author(s)	Approved by	Update Reason	Date	SOP No:
1.0	B. Dickson	P. Williams	New document	11JUL2023	NeoCOL_SOP01
2.0	B. Dickson	P. Williams	Updated TP figure	4APR2024	NeoCol_SOP01
3.0	R. Kelleghan	P. Williams	Adapted for NeoCOL 2.0	7MAR2025	NeoCOL_2.0_SOP01
4.0	R. Kelleghan	P. Williams	Updated labelling sysem and flowchart	4JUN2026	NeoCOL_2.0_SOP01

Site Training Record

Trainee Name	Read/Understand SOP (Tick)	Access to SOP (Tick)	Trainee Signature	Date	Trainer Initials