

NeoCol: Standard Operating Procedure (SOP) for Neonatal Rectal Swabs v2.0

Purpose:

The purpose of this SOP is to describe the standard procedures involved in collecting Neonatal rectal 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.

Responsibility:

This SOP applies to any clinical staff who are taking rectal 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:

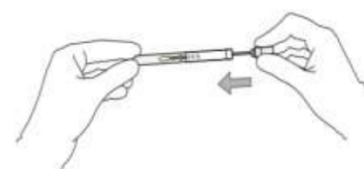
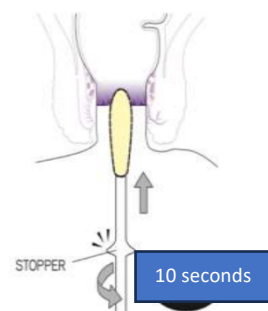
Gloves should be worn during swab collection. Standard clinical hand hygiene practices should be followed before, and after sample collection. Handle all specimens with care and treat them as potentially infectious material.

Materials:

- Non-Sterile gloves.
- 1x mini tipped sterile swab plus container with amies medium (*for culture*)
- 1x cryogenic label
- 1x dry swab (*for genetics*)
- Plastic zip lock bag for specimen transport

Procedure:

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 cryogenic tube.
 - b. With clean scissors, carefully cut the shaft of the swab, so that the swab is able to fit inside the cryogenic 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_SOP03).
12. Transport the swabs to the laboratory within 30 minutes.
13. Log the sample collection into the NeoCOL Sample Collection Log.
14. Dispose of any waste as per hospital policies.



Appendix 1: Neonatal Rectal Swab Timepoints

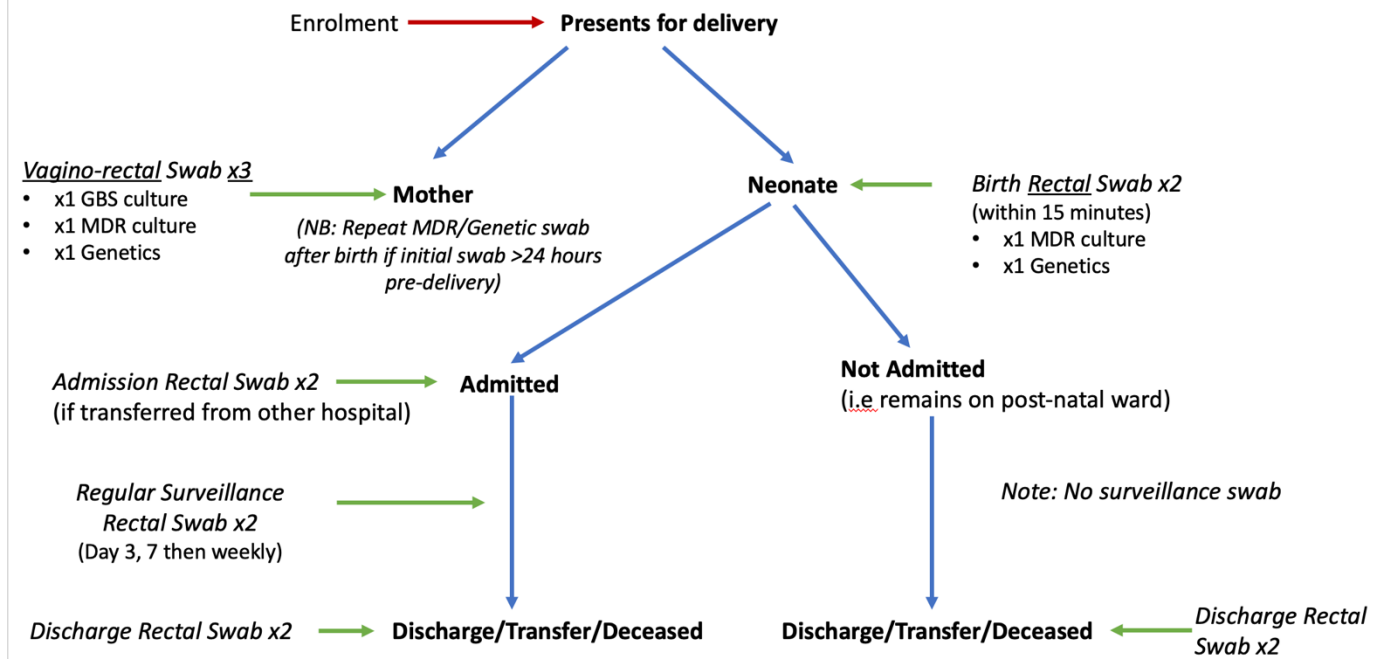


Figure 1. Swab time-points for participants

NOTE:

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

Appendix 2: Specimen Labelling Code

Site	Participant Number	Mother/Child	Timepoint (day)	Sample Type
A Philippine General	001 – 999	M Mother	00, 03, 07, 10, 14, 21...	B gBs swab (group B streptococcus)
B Cipto Mangunkusumo		C Child		M Mdr swab (multidrug resistant)
C Hasan Sadikin				G Genetic swab
D Soetomo				S Stool

Eg. B020C07M = Cipto Mangunkusumo Hospital, Participant 020, Child, Day 07, MDR swab

References

- Turner, P.; Pol, S.; Soeng, S.; Sar, P.; Neou, L.; Chea, P.; Day, N.P.; Cooper, B.S.; Turner, C. High prevalence of antimicrobial-resistant gram-negative colonization in hospitalized Cambodian infants. *The Pediatric infectious disease journal* 2016, 35, 856.
- 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.
- CHAIN Rectal Collection SOP v1.04 accessed on 5th May 2023. [Online](#).
- Roberts, T.; Limmathurotsakul, D.; Turner, P.; Day, N.; Vandepitte, W.; Cooper, B. Antimicrobial-resistant Gram-negative colonization in infants from a neonatal intensive care unit in Thailand. *Journal of Hospital Infection* 2019, 103, 151-155.

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

Site Training Record

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