Nasal Mucus Collection
Infancy and Early Childhood

Collection, Processing and Storage Protocol
Site or Home Collection

Acknowledgements

The ECHO specimen Collection, Processing and Storage Protocols and associated forms were developed through the collaboration of multiple ECHO Components, Institutions and Affiliates. These documents would not have been possible without the expertise and support from the following individuals:

Augusto Litonjua
Carlos Camargo
Chris Siege
Christina Howell
Corette Parker

David Pegram
John Moye
Hirra Zahir
Holly Franklin
James Gern

Jim Zhang
Matt Koch
Rachel Kaufmann
Todd Robbins
ECHO Nasal Mucus Collection, Processing and Storage Protocol

Table of Contents

A. Overview .................................................................................................................................................... 3
B. Guidelines .................................................................................................................................................. 3
C. Collection Kit, Supplies and Kit Assembly .................................................................................................. 3
   1. Nasal Mucus Kit (Fisher Bioservices) ...................................................................................................... 3
   2. Supplies (Site) ........................................................................................................................................ 4
   3. Kit Assembly ........................................................................................................................................... 5
   4. Transport of specimen from participant home to site (home-visit collection)............................................ 5
D. Site Collection ............................................................................................................................................ 5
   1. Site Collection Instructions for the Study Staff ......................................................................................... 5
E. Home Collection ......................................................................................................................................... 6
   1. Home Pre-Collection Instructions for the Study Staff ................................................................................. 6
   2. Home Collection Instructions for the Staff ............................................................................................... 6
F. Processing .................................................................................................................................................  6
G. Storage ...................................................................................................................................................... 6
H. Shipping to the Biorepository ...................................................................................................................... 6
I. Supporting Documents ............................................................................................................................... 6
A. Overview

- The Nasal Mucus Collection procedures apply to children in infancy and early childhood lifestage.
- Due to the technical nature of this collection, specimen will be collected by trained study staff only and a caregiver must be present to assist with holding the child.
- Repeated sampling at 1 month and 6 months of age is recommended in infancy.
- Repeated sampling at 1 year and 3 years of age is recommended in early childhood.
- The collection can occur at the site or during a participant home visit.

B. Guidelines

- A nasal swab method will be used to collect the specimen from each nostril. The first specimen will be collected using a Becton Dickinson (BD) Universal Viral Transport (UVT) kit from one nostril. The second specimen will be collected using a COPAN Elution Swab (Eswab) kit from the other nostril.
- The nasal swab should be inserted no deeper than 2 centimeters inside each nostril in children less than 2 years of age and approximately 3 centimeters inside each nostril of older children.
- Since these are minimally invasive nasal swabs, there should be little to no discomfort for the child. The swabs may tickle and slightly irritate the nose but there should be no pain associated with the procedure.
- Specimen collected during a home-visit can be transported to the site on dry ice (preferred) or 3 freezer gel packs in an insulated shipper (details below).

C. Collection Kit, Supplies and Kit Assembly

1. Nasal Mucus Kit (Fisher Bioservices)
   - Becton Dickinson (BD) Universal Viral Transport (UVT) will include
     a. One (1) vial
     b. One (1) mini tip swab with scored plastic shaft
     c. One (1) triplet specimen ID labels
   - COPAN Elution Swab (ESwab)
     a. One (1) vial
     b. One (1) mini tip swab with scored plastic shaft
c. One (1) triplet specimen ID labels

2. Supplies (Site)
   - Gloves
   - −80°C Freezer
   - Cryobox for vial storage (5 x 5 x 3 in; 49 cell; 7 x 7 grid)
   - Nasal Mucus – Specimen Information Form (SIF)
   - Nasal Mucus – Specimen Tracking Form (STF)
   - Nasal Mucus – Collection Instruction Sheet (CIS)
   - Transport materials for home collection:
     b. Items can be ordered separately:
        i. Insulated Shipper: 608UPS [https://www.thermosafe.com/model/608UPS](https://www.thermosafe.com/model/608UPS)
        ii. Insulated shipper with outer cardboard box: 609UPS [https://www.thermosafe.com/subcategory/EPS+FOam+w/Corrugate](https://www.thermosafe.com/subcategory/EPS+FOam+w/Corrugate)
        iii. Biohazard Specimen Transport Bag: 01-800-00
ECHO Nasal Mucus Collection, Processing and Storage Protocol


v. 3 Gel packs: PP6 https://www.thermosafe.com/subcategory/Gel+Packs
OR
Dry ice

3. Kit Assembly

Follow the below steps to assemble the collection kit and prepare for the collection prior to meeting with the participant/caregiver.

- Confirm that the collection kit includes a UVT vial and swab, Eswab vial and swab, and two sets of triplet specimen ID labels.
  
  **Note:** Swabs and vials should not be mixed.

- Print SIF, STF, CIS.

- Fill out the headers on the SIF and STF.

- There are three identical labels for each specimen ID. Affix the first label to the Eswab. The second matching label to the **SPECIMEN LABEL** field on the STF and the third matching label to the **SPECIMEN LABEL** field on the SIF.

  Note: The swab in Eswab kit is not individually wrapped. Do not take out the swab until the time of collection and do not place the labeled vial back in the packaging.

- Repeat the labeling step for UVT vial.

- Have labeled Eswab vial and its swab, BD UVT vial and its swab, SIF and STF available during collection.

4. Transport of specimen from participant home to site (home-visit collection)

- Specimen must be transported to the site in an insulated shipper with 3 frozen gel packs or dry ice. Gel packs suggested in the supplies list must be placed in the freezer 24 hours prior to the home visit. Use manufacturer instructions in case a different model is used.

D. Site Collection

1. Site Collection Instructions for the Study Staff

- Refer to Nasal Mucus Collection Instruction Sheet (CIS).
E. Home Collection

1. Home Pre-Collection Instructions for the Study Staff
   • The collection kit materials should include labelled BD UTV and Eswab kits, gloves, CIS and labeled SIF and STF.
   • The transport materials should include a biohazard bag, 2 absorbent sleeves, 3 freezer gel packs or dry ice, an insulated shipper, and a cardboard box (if available).
   • Place gel packs or dry ice in the insulated shipper and close the lip completely.
     Note: Gel packs should be placed in the freezer 24 hours prior to the home visit.

2. Home Collection Instructions for the Staff
   • Refer to Nasal Mucus Collection Instruction Sheet (CIS).

F. Processing

• If specimen was collected at home, complete the STEP 2: TRANSPORT AND RECEIPT section of the STF once specimen is received at the site. If specimen was collected at the site, mark the section not applicable.

G. Storage

• Place the two specimen vials in a labeled cryobox (5 x 5 x 3 in; 49 cell; 7 x 7 grid)
• Store cryobox at −80°C as soon as possible.
• Complete STEP 3: STORAGE section of the STF.
• Data from the SIF and STF should be entered into Bio-Track immediately or within 48 hours of storing the specimen.
• Retain the SIF and STF at the site.

H. Shipping to the Biorepository

This information is available in the Laboratory Manual of the ECHO-wide Cohort Data Collection Protocol.

I. Supporting Documents

1. Nasal Mucus – Collection Instruction Sheet (CIS)
2. Nasal Mucus – Specimen Information Form (SIF)
3. Nasal Mucus – Specimen Tracking Form (STF)
4. Nasal Mucus – Specimen Tracking Form (STF) Completion Instructions