SOP-006 – Release to Outside Agency

Table of Contents

SOP Name: Release to Outside Agency		SOP #: 006
North Carolina Office of the Chief Medical Examiner Toxicology Laboratory	**Revision:** 6 – Major revision to Virology testing procedure 2.1 – Updated syntax	**Revision Date/Initials:** SCBF – 02/27/2017 REW – 08/21/2017

Approving Authority Name	Approving Authority Signature	Approval Date
Ruth E. Winecker, Ph.D.		04/14/2015
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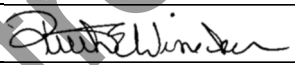
Ruth E. Winecker, Ph.D.		08/21/2017

1. Principle of Protocol

1.1. This procedure is designed to provide instructions for the release of specimens and evidence to different outside agencies.

1.2. The SOP will provide rationale and basic instructions regarding the currently approved outside laboratories and outside agencies

1.3. This is intended to be used as a guide and any questions should be directed to Senior Staff and the Chief Toxicologist.

2. Procedure for Toxicology Subcontracting (OCME directed)

2.1. In accordance with Policy TOX-P15, specimens are sent to an outside lab by OCME in order to complete testing needed to establish cause and manner of death that is currently unavailable in-house. For a majority of analytes, NC-OCME sends specimens to NMS Labs http://www.nmslabs.com/. Expenses for this type of testing is the responsibility of the state of North Carolina.

2.1.1. Toxlog

2.1.1.1. Worklist, New Worklist, Assay name NMS

2.1.1.2. Complete Electronic Chain of Custody

2.1.2. Specimen Requirements

2.1.2.1. If frozen, thaw under hood during vial/paperwork preparation

2.1.2.2. Prepare Scintillation Vials with T#, S#, specimen type (e.g. blood, liver, urine)

2.1.2.3. Transfer 5 mL of specimen (or more if you have more than 3 required tests, consult NMS catalog)

2.1.2.4. If a headspace specimen is required, prepare with T# and S# on vial

2.1.3. Paperwork

2.1.3.1. Consult NMS Catalog for test code

2.1.3.2. Fill out required NMS testing form found in the accessioning room

2.1.3.3. Fill out NMS FedEx label (pre-printed at Evidence Tech desk)

2.1.4. Shipping

2.1.4.1. Package a cardboard box with the paperwork and a Styrofoam box inside with an icepack and the specimen(s) (boxes found in the accessioning room by hood, more cardboard and Styrofoam boxes available from supplies coming into laboratory, see staff for availability)

2.1.4.2. Deliver downstairs to the FedEx table in the mailroom

3. **Procedure for Tryptase testing**

3.1. Viracor-IBT laboratories (http://www.viracoribt.com/) performs OCME directed Total Tryptase analysis. Tryptase testing measures the amount of tryptase in the blood, which is an enzyme that is released along with histamine and other chemicals from mast cells when they are activated, often as part of an allergic immune response.

3.1.1. Toxlog

3.1.1.1. Worklist, New Worklist, Outside lab, tryptase

3.1.2. Specimen Requirements

3.1.2.1. If frozen, thaw under hood during vial/paperwork preparation

3.1.2.2. Prepare Scintillation Vials with T#, S#, decedent name

3.1.2.3. Transfer 5 mL of specimen

3.1.2.4. Laboratory would prefer if the specimen is < 30 days old

3.1.3. Paperwork

3.1.3.1. Fill out required Viracor forms found in the accessioning room

3.1.4. Shipping

3.1.4.1. Package Viracor Box found in the accessioning room with the specimen and paperwork inside a FedEx large envelope (address available on requisition form)

3.1.4.2. Deliver downstairs to the FedEx table in the mailroom

3.1.5. Chain of Custody

3.1.5.1. Complete Electronic Chain of Custody

4. Procedure for Insulin Testing

4.1. ARUP laboratories (http://www.aruplab.com/) perform OCME directed Insulin analysis.

4.1.1. Toxlog

4.1.1.1. Worklist, New Worklist, Outside lab, insulin

4.1.2. Specimen Requirements

4.1.2.1. **Frozen antemortem serum** is the most ideal specimen for insulin analysis. Postmortem whole blood with a postmortem interval of ~12 hours or less may be spun into serum and frozen ASAP. Postmortem whole blood with a PMI of >12 hours should be reported as "Specimen Unsuitable" on the final toxicology report. Notify a senior chemist for reporting.

4.1.3. Paperwork

4.1.3.1. Fill out required ARUP forms found in the accessioning room

4.1.4. Shipping

4.1.4.1. Sample must ship overnight frozen on dry ice

4.1.4.1.1. Package a cardboard box with a Styrofoam box inside with dry ice and the specimens (boxes found in the accessioning room by hood, more cardboard and Styrofoam boxes available from supplies coming into laboratory, see staff for availability). Address is available on the requisition form

4.1.4.1.2. Dry Ice is available from the Dry Ice Container located in Vestibule L145 (lower level of SLPH side of the building).

4.1.4.1.3. Deliver downstairs to the FedEx table in the mailroom

4.1.5. Chain of Custody

4.1.5.1. Complete Electronic Chain of Custody

5. Procedure for Newborn/Genetic Screening (including Sickle Cell Trait)

5.1. A Hemoglobin (Hgb) Electrophoresis Test measures the different types of hemoglobin in the bloodstream. Normal hemoglobin carries and releases oxygen efficiently, while abnormal hemoglobin does not.

5.1.1. Toxlog

5.1.1.1. Worklist, New Worklist, Outside lab, Hgb

5.1.2. Specimen Requirements

5.1.2.1. If frozen, thaw under hood during vial/paperwork preparation

5.1.2.2. Prepare Scintillation Vials with T#, S#, Name

5.1.2.3. Transfer 4 mL of specimen

5.1.3. Specimen Handling

5.1.3.1. The Newborn Screening Laboratory is on the 2nd Floor of the State Laboratory of Public Health. The specimen can be walked over to the laboratory and handed to one of the Newborn Screening Technicians.

5.1.4. Chain of Custody

5.1.4.1. Complete electronic Chain of Custody

5.2. Newborn/Genetic Screening tests for a variety of conditions or disorders that are present from birth. This includes amino acid, fatty acid and organic acid disorders along with Congenital Adrenal Hyperplasia (CAH) and Cystic Fibrosis (CF). A complete list can be found at: http://slph.ncpublichealth.com/newborn/default.asp

5.2.1. Toxlog

5.2.1.1. Worklist, New Worklist, Outside lab, other agent

5.2.2. Specimen Requirements

5.2.2.1. Thaw on table in refrigerator if needed

5.2.2.2. Prepare Scintillation Vials with T#, S#, Name

5.2.2.3. Transfer 4 mL of specimen

5.2.3. Specimen handling

5.2.3.1. The Newborn Screening Laboratory is on the 2nd Floor of the State Laboratory of Public Health. The specimen can be walked over to the laboratory and handed to one of the Newborn Screening Technicians

5.2.4. Chain of Custody

5.2.4.1. Complete electronic Chain of Custody in MEIS (with a comment: State Lab Newborn Screening)

6. Procedure for Virology Testing

6.1. Human immunodeficiency virus (HIV) and hepatitis virus panel testing may be necessary in the case of exposure by first responders, medical examiners or good samaritans at the scene of a death or OCME personnel during the course of an autopsy or toxicological testing.

6.1.1. Testing request

6.1.1.1. Request typically made by interested parties (e.g physicians, patients , County Health Professionals, etc) via phone by indicating the name of the decedent, date and county of death.

6.1.1.2. It is imperative that the exposed individual be in coordination with their health care provider in order to receive both treatment advice and provide the services of a custodian of the testing record.

6.1.1.2.1. If the individual does not have a medical representative, please advise to acquire one immediately to have a qualified medical professional for the release of the results. **Testing may proceed during this interim; however results should only be released to the medical professional by the toxicology laboratory.**

6.1.1.3. Save a copy of either the documentation of the initial phone call (Telephone Contact Sheet policy TOX-P6) or copy of the initial email from a pathologist/medical examiner/interested party in the corresponding Tox folder.

6.1.2. Specimen Requirements

6.1.2.1. Prepare Scintillation Vials with T#, S#, Name

6.1.2.2. Transfer 4-5 mL of specimen

6.1.2.3. Perform electronic COC transaction in MEIS.

6.1.3. Paperwork

6.1.3.1. Two forms need to be submitted to the State Laboratory of Public Health along with the specimen.

6.1.3.1.1. HIV/HCV Paper form (DHHS-T1535): HIV Counseling & Testing Report Form is available at Evidence Technician's desk in a manila envelope.

6.1.3.1.2. Hepatitis electronic form (DHHS-3722) is available on the State Laboratory Website: http://slph.ncpublichealth.com/Forms/3722-Hepatitis-20160823.pdf

6.1.4. Specimen handling

6.1.4.1. The Virology/Serology Laboratory is on the 3rd Floor of the State Laboratory of Public Health. The specimen can be walked over to the laboratory and handed to one of the Virology/Serology Technicians. The supervisor in the laboratory is currently Myra Brinson (7-8835) and direct contact is Laura Burkhart (7-8833). The main virology laboratory number 7-8625.

6.1.4.2. The following three analytes are tested for using the following methodology in all instances of exposure:

6.1.4.2.1. HIV Testing

6.1.4.2.1.1. HIV Ag/Ab combo by Chemiluminescent Microparticle Immunoassay (CMIA)

6.1.4.2.2. Hepatitis C Virus (HCV) Testing

6.1.4.2.2.1. Anti HCV (CMIA) and HCV RNA Nucleic Acid Amplification Test (NAAT)

6.1.4.2.3. Hep B Testing

6.1.4.2.3.1. Hep B Surface Ag (CMIA)

6.1.5. Chain of Custody

6.1.5.1. Complete electronic Chain of Custody in MEIS (with a comment: State Lab HIV/HEP testing)

6.1.6. Results

6.1.6.1. After the completion of the testing, the virology department will call the toxicology lab and/or provide a paper copy in our mailbox.

6.1.6.2. As long as a medical representative has been acquired by the exposed individual (in the case of non-OCME personnel) the report can be

communicated via fax or email. For OCME personnel, the report is communicated directly to the exposed employee.

6.1.6.3. Documentation that the report has been sent to a medical professional/ employee including date and name of both the sender/receiver should be recorded in the corresponding Tox folder and filed accordingly.

7. Procedure for Blood Spot cards

7.1. Law Enforcement may request a blood spot card be prepared for a decedent for DNA testing purposes. Typically, even though the card is requested in advance, it is prudent to have the individual call again **3 hours prior to arriving at our facility**. This will prevent cards sitting around, waiting for pick-up.

7.2. Preparation of the Blood Spot Card

7.2.1. The name, S# and T# should be written on a new blood spot card obtained in the accessioning area.

7.2.2. 5-6 drops of blood should be delivered on the card using a Pasteur pipette.

7.2.3. The card should remain in the hood until dry (~1 hour)

7.3. Chain of Custody

7.3.1. Complete Electronic Chain of Custody through MEIS

7.3.2. The OCME Toxicology Specimen COC should be filled out and signed by the receiver of the blood spot card

7.3.3. The receiver should get a copy of the COC along with the blood spot card in an envelope

8. Procedure for Evidence Transfer

8.1. Occasionally, a piece of physical evidence will be need to be forfeited or returned to law enforcement.

8.2. Chain of Custody

8.2.1. Complete Electronic Chain of Custody through MEIS

8.2.2. The OCME Toxicology Specimen COC should be filled out and signed by the receiver of the physical evidence.

8.2.3. The receiver should get a copy of the COC along with the sealed evidence

9. Procedure for Outside Testing Drugs/DNA (Next of Kin Directed)

9.1. In accordance with Policy TOX-P16, specimens are sent to an outside lab by OCME in order to satisfy testing directed by the next of kin, or courts in a civil suit. OCME is not responsible for the billing, expense or the interpretation of the results; we are merely the custodian of the specimen and will ship the sample to a laboratory of the next of kin/courts choosing.

9.1.1. NC-OCME Form and Letter DNA/Outside Testing

9.1.1.1. Upon phone or email request (provide documentation in the T folder via Telephone Contact Sheet or email), the requestor should be provided with a copy of the official Outside Testing form/letter.

9.1.1.2. When the official notarized copy is completed and mailed to our office, it should be filed in the T folder (either pending, "done" drawer).

9.1.1.3. It is important for the Evidence Technician to be aware of specimen volume if NC-OCME testing is still in progress. Consult with the Chief Toxicologist.

9.1.2. Chain of Custody

9.1.2.1.1. Complete Electronic Chain of Custody through MEIS

9.1.3. Specimen Requirements

9.1.3.1. The outside laboratory chosen by the requesting party should send a retrieval kit to our laboratory with complete instructions on specimen requirements

9.1.4. Shipping

9.1.4.1. Package specimen(s) and paperwork in materials sent from the outside laboratory (typically FedEx Box), include an ice-pack.

9.1.4.2. Deliver downstairs to the FedEx table in the mailroom