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Purpose

To obtain and aliquot saliva specimens from LCBRN subjects.

Responsibility

Personnel associated with the LCBRN Biospecimen Resource Sites are responsible for carrying out the sample collection, processing and aliquoting procedures competently and safely. Data entry into the LCBRN online database may be carried out by different personnel than those entering data onto the LCBRN Biofluid Collection Form at the time of procurement.

All personnel handling human biosamples must have training in, and adhere to, universal biohazard precautions and human subject research ethics/confidentiality principles.

Equipment/Reagents

1. LCBRN saliva collection package containing sterile Salivette®-Cortisol collection device (Sardstedt, Cat # 51.1534.500), four sterile 1.8 mL cryovials (Thermo Scientific – NUNC, Cat.# 377267) with brown caps (Thermo Scientific – NUNC, Cat.# 375868), duplicate strips of labels, a Salivette® subject instruction sheet, and a blank copy of the LCBRN Biofluid Collection Form.
2. Protective gear (biosafety cabinet, eye/faceshield, disposable gloves, appropriate lab attire).
3. Clinical centrifuge capable of delivering 1000 x g centrifugal force, with appropriate rotors and adaptors to fit the tubes.
4. Pipettors and sterile disposable pipet tips capable of transferring 0.2 mL volumes. Pipette tips must be purchased with sterile certification or steam autoclaved (121oC x 30 minutes).

Note: Pipettors must be manufactured to have performance characteristics of no more than 1% systemic error (e.g. for 500 uL, dispensing error must be within +/-5 uL of this volume). Pipettors require annual calibration, with maintenance records kept on file.

Procedure

*Samples must be processed within 4 hours after collection.*

1. From the LCBRN subject enrollment package, obtain duplicate saliva sample identification adhesive labels for the subject and affix one to the Biofluid Collection Form. Enter date, subject status and sample type on the form.
2. Place the duplicate label on the Salivette® tube.
3. Provide subject with Salivette® collection device and instruction sheet.
4. The subject chews on the swab provided in the kit for at least 45 seconds to induce salivation, then places the moist swab back into the collection tube and replaces the top.
5. Record time of saliva collection on Biofluid Collection Form.
6. Transport sealed tube, Biofluid Collection Form, cryovials and aliquot labels to specimen processing lab. Use appropriate biohazard labeling and outer packaging.
7. Centrifuge the Salivette® tube at 1000 x g for 2 minutes at ambient room temperature (range 68-82 oF, 20-28 oC). The saliva collects at the bottom of the tube.
8. Transfer the tube(s) to a stable tube rack. Remove lid and inner section of the Salivette® device.
9. Aliquot saliva into labeled cryovials (0.2 mL aliquots) using a pipettor and sterile-filter pipette tips (up to 6 aliquots). Observe sterile technique during transfer and discard pipette tip(s) into appropriate biohazard waste container.
10. Label the cryovials with the LCBRN saliva aliquot labels. **Affix the duplicate labels onto the Biofluid Collection Form.**
11. Transfer biospecimens to -80oC freezer or in vapor phase of a liquid nitrogen freezer.
12. Record time of aliquot freezing on Biofluid Collection Form.
13. Enter data from the Biofluid Collection Form into the online LCBRN database (see separate procedure). A barcode reader should be used to enter sample container identification using the duplicate labels affixed to the Biofluid Collection Form.
14. Store the Biofluid Collection Form with other subject study data paper documents in a secured location.

**Change History**

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| Version # | Significant change(s) | Author | Effective Date |
| 1 |  | Moskaluk | 12/1/2010 |
| 2 | Minor additions | Moskaluk | 8/15/2011 |