MTN-016 Training

Specimen Labeling and Preparation for Entry into LDMS
Specimen Labeling

- Each *original* specimen collection container must be labeled with a SCHARP-provided PTID Label
  - Infant blood specimen
One PTID Label size is used in MTN-016

- Small PTID Labels for all blood specimens collected from infants

**PTID Label**

300-1234-5-2 V:__.__

**DATE:** __/______/___

(MTN-016) dd MMM yy
MTN-016 PTID Labels

- On the PTID label, write in the visit code and specimen collection date.
- To ensure adhesion, make sure the container/slide is clean, dry and at room temperature before affixing label.
- Use Word files (macros) to print PTID labels (PTID will need to be typed in before labels are printed).
- Use small label stock to print the PTID labels.
MTN-016 Label Supply

- SCHARP will provide blank label stock to be used for PTID Labels
- Sites can order more blank label stock by emailing the MTN-016 Project Manager, Corey Miller <corey@scharp.org>
- SCHARP will also provide Word files (macros) that can be used to create PTID Labels
MTN-016 LDMS Specimen Tracking Sheet

- A non-DataFax form (1 page) supplied by SCHARP and included in the “as needed” CRF supplies
- Documents specimens to be entered into LDMS
  - documents all specimens collected at a visit. Includes spaces to record PTID, visit code, specimen collection date, and for some specimens, time of collection
- Also has space to document number of tubes/specimens collected
MTN 016 Non-DataFax LDMS Specimen Tracking Sheet
For login of MTN 016 infant stored specimens into LDMS

<table>
<thead>
<tr>
<th>Participant ID</th>
<th>Visit Code</th>
<th>Specimen Collection Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site Number</td>
<td>Participant Number</td>
<td>Ctr</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th># of TUBES or SPECIMENS</th>
<th>PRIMARY SPECIMEN</th>
<th>PRIMARY ADDITIVE</th>
<th># of ALIQUOT TUBES or SPECIMENS</th>
<th>ALIQUOT DERIVATIVE</th>
<th>ALIQUOT SUB / ADDITIVE DERIVATIVE</th>
<th>NOTES FOR LAB</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Blood (BLL) for DNA/RNA</td>
<td>EDT (purple top)</td>
<td>Plasma (PL 1/2)</td>
<td>N/A</td>
<td>Store aliquots of at least 0.2 ml. Plasma must be frozen within 4 hours of collection.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>EDT (purple top)</td>
<td>Cell Pellet (CEL)</td>
<td>PER</td>
<td>Store at -70C until testing</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>EDT (purple top)</td>
<td>Dried Blood Spot (DBS)</td>
<td>N/A</td>
<td>Store at RT</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Blood (BLL) for resistance</td>
<td>EDT (purple top)</td>
<td>Plasma (PL 1/2)</td>
<td>N/A</td>
<td>Store in aliquots of at least 0.2 ml. Plasma must be frozen within 4 hours of collection.</td>
<td></td>
</tr>
</tbody>
</table>

Comments: __________________________________________

Initials: ____________________________

LDMS Data Entry Date: ___________ / ________

Version 1.0, 18 JUN-09
Clinic Staff Preparation of LDMS Specimens

- Gather all of the participant’s specimens that will be entered into LDMS
- Obtain the MTN-016 LDMS Specimen Tracking Sheet completed for the participant
- Review the Tracking Sheet to verify all specimens present are recorded properly on the sheet (verify that visit code, collection date, and collection time on labels match what is recorded on the Tracking Sheet)
- Deliver Tracking Sheet and specimens to the LDMS entry lab
LDMS Staff Entry of Specimens into LDMS

- Enter information as recorded on the LDMS Tracking Sheet into LDMS
- Contact clinic staff if you have questions about the Tracking Sheet and/or specimens
- Once the specimens are entered into LDMS, record the LDMS data entry date and LDMS staff entry initials on the tracking sheet
Questions???