



MTN 017 Real-Time PK Testing

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Objectives

- ◆ Specimen Handling
- ◆ Specimen Management
- ◆ Specimen Shipping
- ◆ Test Results
- ◆ Q&A



MTN Network Lab Contacts

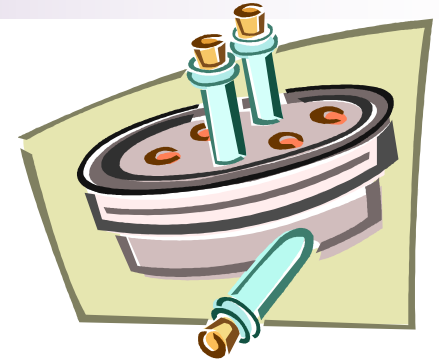
- ◆ MTN Network lab

- ◆ Pam Kunjara 412-641-6393
pkunjara@mwri.magee.edu

- ◆ MTN Pharmacology Core Lab

- ◆ James Johnson jjohnso6@jhmi.edu
 - ◆ Mark Marzinke mmarzin@jhmi.edu
 - ◆ Craig Hendrix chendrix@jhmi.edu

Specimen Handling



◆ Plasma for PK

- ◆ Collected at every Mid Period and End Period visit (Visits 3, 4, 6, 7, 9, and 10)
- ◆ Whole blood (EDTA) will be spun down to obtain plasma and stored at -80°C within 8 hours of collection.
- ◆ Specimens will be accompanied by an LDMS Tracking sheet and logged into LDMS.

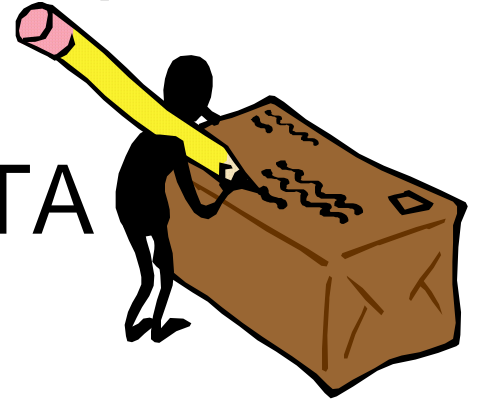


Specimen Management

- ◆ All specimens must be tracked according to site Chain of Custody.
- ◆ CRFs are required for specimens reported to SCHARP.
- ◆ All collected samples will be reported from SCHARP to the MTN NL to assure that samples are being shipped for testing in a timely manner.

Specimen Shipping

- One month after the first participant enrolls **biweekly** shipments of plasma for PK should be initiated.
- All shipping staff must be IATA certified.
- All shipments must be accompanied by an LDMS Shipping Manifest.





Specimen Shipping cont.

- Specimens will be shipped on dry ice to the MTN Pharmacology Core to arrive by **Thursday** for testing on Friday.
- Prior to shipping sites must notify the MTN NL and Pharmacology Core by e-mail with tracking details along with LDMS generated and excel batch files.

Specimen Shipping cont.

- Shipping costs will be billed directly to the MTN NL. World Courier and FedEx accounts numbers will be available.
- Please reference MTN-017-9231 for all PK shipments

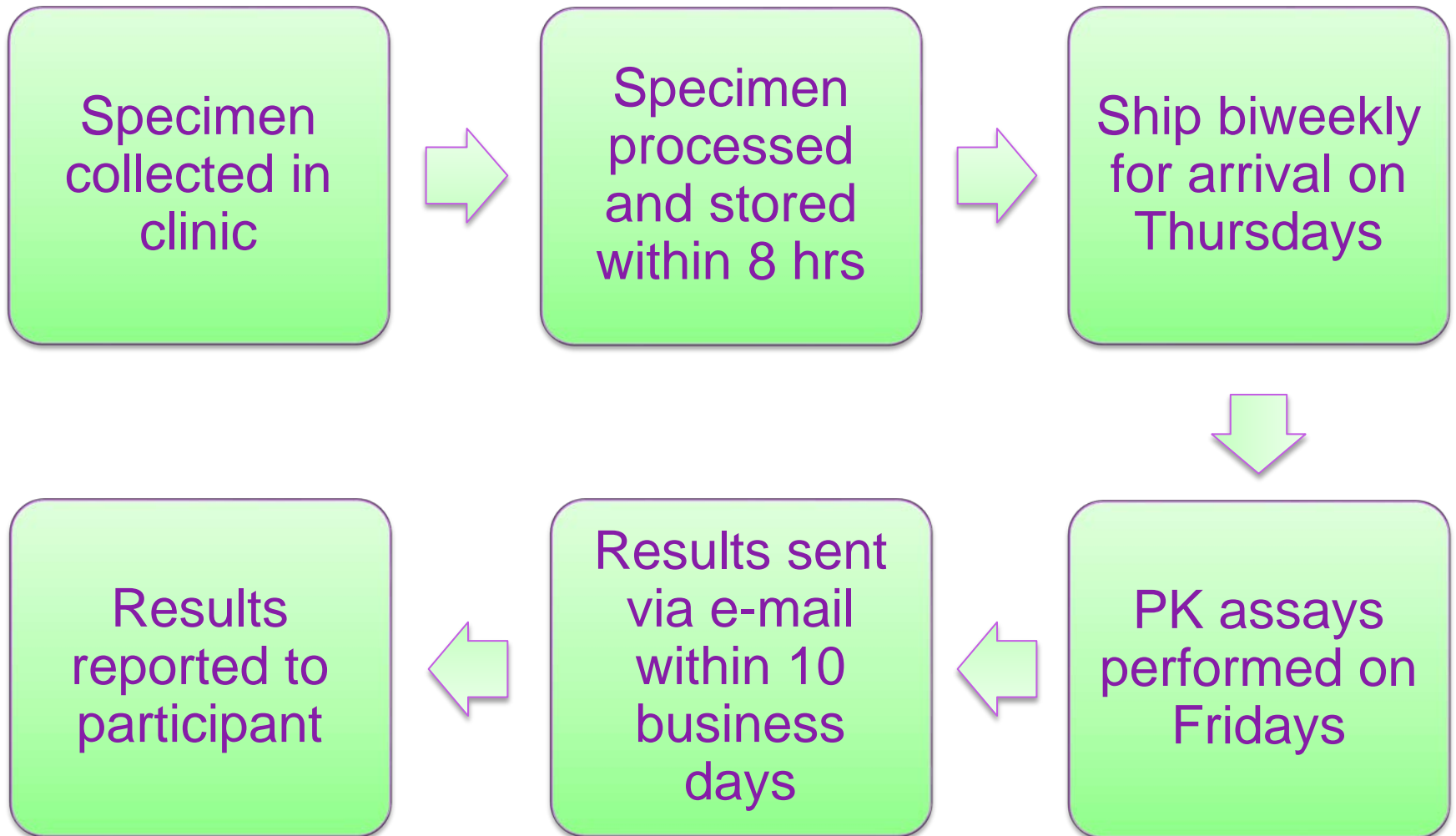


PK Test Results



- Results will be available within **10 business days** of specimens being received at the Pharmacology Core.
- The MTN Pharmacology Core will report qualitative results to the sites on a **spreadsheet in pdf format via e-mail**. Quantitative results will be sent to SCHARP.

Specimen Flow Chart



Any Questions?

