



MTN 017 Laboratory Training

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Objectives

- ◆ Overview of Follow-up Lab testing
- ◆ Specimen Management
- ◆ LDMS Tracking Sheet
- ◆ Plasma PK results
- ◆ Q&A

Overview of Lab Testing by Visit

	VST 1 SCR	VST 2 ENR	VST 3 MID	VST 4 END	VST 5 PD2	VST 6 MID	VST 7 END	VST 8 PD3	VST 9 MID	VST 10 END
Rectal HSV detection	★	★	★	★	★	★	★	★	★	★
Anal HPV		X								
Rectal GC/CT	X	X	★	X	★	★	X	★	★	X
Rectal sponge for PK			X	X	X	X	X	X	X	X
Rectal sponge for PD		X	X	X	X	X	X	X	X	X
Rectal sponge immuno*		X		X			X			X
Rectal biopsy Proteomics*		X		X			X			X
Rectal biopsy Histology*		X		X			X			X
Rectal biopsies Pheno*		X		X			X			X
Rectal biopsy Gene Array*		X		X			X			X
Rectal biopsies PD*		X		X			X			X
Rectal biopsies PK*				X			X			X

*Tissue subset only



Overview of Lab Testing

Blood Specimens

- ◆ Plasma for PK (EDTA tube)
 - ◆ Process and store at $\leq -70^{\circ}\text{C}$ within 8 hours of collection.
 - ◆ Drug regimen must be reported as ORAL or GEL on LDMS TS for result interpretation.
- ◆ Blue Tiger top CPT (Na Citrate) x3
 - ◆ Blood PK – PBMCs
 - ◆ Keep specimens upright at RT and process within 8 hours of collection.

Collection of Rectal Specimens

◆ Biopsies for PK*

If at anytime collection of biopsies are limited submit testing in order of priority. Refer to section 10.7 Testing of Rectal Specimens of the MTN 017 SSP.

- ◆ 2-5 biopsies delivered to lab within 2 hours of collection.
- ◆ Weigh each biopsy by weighing empty cryovial and subtracting it from weight of biopsy in cryovial. Document weight on TS.
- ◆ Flash freeze in LN₂ or dry ice bath. Store each biopsy separately at ≤70°C. Document freeze time.
- ◆ Batch ship on dry ice to JHU CPAL.



Specimen Management

- ◆ All specimens must be tracked according to site Chain of Custody.
- ◆ CRFs are required for specimens reported to SCHARP.
- ◆ Specimens to be shipped to the MTN LC or JHU CPAL must be accompanied by an LDMS tracking sheet or LC approved equivalent and entered into LDMS.

MTN 017

LDMS Specimen Tracking Sheet

For login of MTN 017 stored specimens into LDMS

Participant ID <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small>Site Number Participant Number Chk</small>			Visit Code <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small>dd MMM yy</small>		Specimen Collection Date <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small>dd MMM yy</small>		
# of TUBES or SPECIMENS	PRIMARY SPECIMEN	PRIMARY ADDITIVE	ALIQOT DERIVATIVE	ALIQOT SUB ADDITIVE/ DERIVATIVE	INSTRUCTIONS FOR PROCESSING		
<input type="checkbox"/>	Blood – Plasma Archive / Storage (BLD)	EDT (purple top)	PL1/2	N/A	Store in aliquots of 1.0 ml. If held at room temperature, plasma must be frozen within 4 hours of collection. If refrigerated or on ice, plasma must be frozen within 24 hours of collection.		
<input type="checkbox"/>	Blood – Plasma PK (BLD) Collection Time: ____ : ____ Hour : Min	EDT (purple top)	PL1	N/A	Product Use: GEL or ORAL (circle one) Store in 1.0 ml aliquots and freeze within 8 hours of collection. Enter PK GEL (gel use) or PK ORAL (oral use) into Other Spec ID field of LDMS.		
<input type="checkbox"/>	Blood – PBMC PK (BLD) Collection Time: ____ : ____ Hour : Min	CPS (CPT tube)	CIO	MET	Keep upright at RT and process within 8 hours.		
<input type="checkbox"/>	Anal Swab – HPV (PAN)	VTM	SWB	N/A	Wrap cap with parafilm and store at ≤-70°C within 4 hours of collection.		
<input type="checkbox"/>	Rectal Sponge – PK (REC) Collection Time: ____ : ____ Hour : Min	NON	SPG	N/A	____ - ____ = ____ mg Post-weight Pre-weight Net weight Time Frozen: ____ : ____ Hour : Min Freeze at ≤-70°C within 2 hours of collection. Enter PK into Other Spec ID field of LDMS.		
<input type="checkbox"/>	Rectal Sponge – PD (REC) Collection Time: ____ : ____ Hour : Min	NON	SPG	N/A	____ - ____ = ____ mg Post-weight Pre-weight Net weight Time Frozen: ____ : ____ Hour : Min Freeze at ≤-70°C within 4 hours of collection. Enter PD into Other Spec ID field of LDMS.		

Product Use: Circle the regimen that represents the last product dispensation that occurred prior to specimen collection.

Comments: _____

Initials: _____ / _____
Sending Staff Receiving Staff

LDMS Data Entry Date: /
dd MMM yy LDMS Staff

MTN 017 – Tissue Subset LDMS Specimen Tracking Sheet

For login of MTN 017 stored specimens into LDMS

Participant ID <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small>Site Number Participant Number Chk</small>			Visit Code <input type="text"/> <input type="text"/> <input type="text"/>		Specimen Collection Date <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small>dd MMM yy</small>		
# of TUBES or SPECIMENS	PRIMARY SPECIMEN	PRIMARY ADDITIVE	ALIQUOT DERIVATIVE	INSTRUCTIONS FOR LAB			
<input type="checkbox"/>	Rectal Sponge – Mucosal Immuno (REC) Collection Time: _____ Hour : Min	NON	SPG	_____ - _____ = _____ mg <small>Post-weight Pre-weight Net weight</small> Time Frozen: _____ Hour : Min Freeze at ≤-70°C within 2 hours of collection. Enter MI into Other Spec ID field of LDMS.			
<input type="checkbox"/>	Rectal Biopsies – PK (FSR) Collection Time: _____ Hour : Min	NON	BPS	1 _____ - _____ = _____ mg 2 _____ - _____ = _____ mg 3 _____ - _____ = _____ mg 4 _____ - _____ = _____ mg 5 _____ - _____ = _____ mg <small>Post-weight Pre-weight Net weight</small> Time Frozen: _____ Hour : Min Freeze at ≤-70°C within 2 hours of collection. Enter PK into Other Spec ID field of LDMS.			
<input type="checkbox"/>	Rectal Biopsies – Gene expression microarrays (FSR) Collection Time: _____ Hour : Min	RNL	BPS	Store at 4°C overnight then transfer to ≤-70°C. Must be stored at ≤-70°C for a minimum of 24 hours prior to shipping.			

Comments: _____

Initials: _____ / _____
Sending Staff Receiving Staff

LDMS Data Entry Date: /
dd MMM yy LDMS Staff

MTN 017 – Tissue Subset LDMS Specimen Tracking Sheet

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Participant ID <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small>Site Number Participant Number Chk</small>			Visit Code <input type="text"/> <input type="text"/> <input type="text"/>		Specimen Collection Date <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small>dd MMM yy</small>		
# of TUBES or SPECIMENS	PRIMARY SPECIMEN	PRIMARY ADDITIVE	ALIQUOT DERIVATIVE	INSTRUCTIONS FOR LAB			
<input type="checkbox"/>	Rectal Biopsy – Histology (FSR) Collection Time: _____ Hour : Min	FOR	BPS	Store at room temperature and batch ship to MTN NL quarterly.			
<input type="checkbox"/>	Rectal Biopsies – PD (FSR) Collection Time: _____ Hour : Min	BTM	BPS	1 _____ - _____ = _____ mg 2 _____ - _____ = _____ mg 3 _____ - _____ = _____ mg 4 _____ - _____ = _____ mg <small>Post-weight Pre-weight Net weight</small> Transport biopsies to processing lab within 15-30 minutes of collection for processing. Enter PD into Other Spec ID field of LDMS.			
<input type="checkbox"/>	Rectal Biopsies – T Cell Phenotyping (FSR) Collection Time: _____ Hour : Min	BTM	BPS	Transport on ice to lab for testing. Enter PHENO into Other Spec ID field of LDMS.			
<input type="checkbox"/>	Rectal Biopsy – Proteomics (FSR) Collection Time: _____ Hour : Min	NON	BPS	Freeze at ≤-70°C within 2 hours of collection. Enter PRO into Other Spec ID field of LDMS. Time Frozen: _____ Hour : Min			

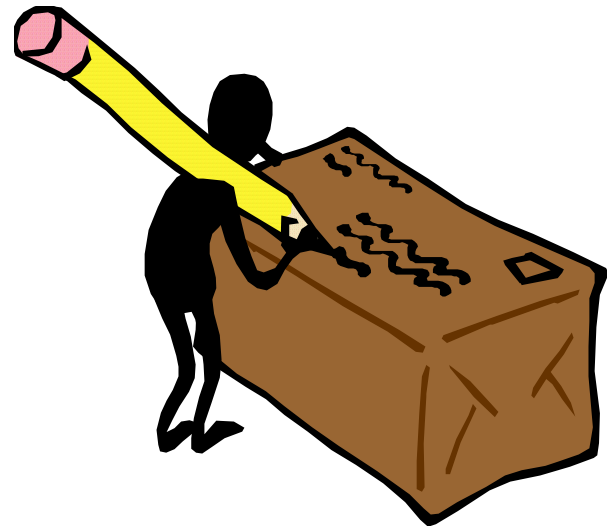
Comments: _____

Initials: _____ / _____
Sending Staff Receiving Staff

LDMS Data Entry Date: /
dd MMM yy LDMS Staff

Shipping Instructions

- ◆ Specimens to be batch shipped to MTN LC:
 - ◆ Plasma archive and Plasma storage
 - ◆ Anal Swab for HPV
 - ◆ Rectal Sponge for PD
- ◆ Specimens to be batch shipped to JHU CPAL:
 - ◆ Plasma for PK (every 2 weeks)
 - ◆ PBMCs for PK
 - ◆ Rectal Sponge for PK



Shipping Instructions



◆ Plasma for PK

- ◆ One month after the first participant enrolls shipments of plasma for PK should be initiated and scheduled approximately every other week.
- ◆ All shipments must be accompanied by an LDMS Shipping Manifest. Specimens will be shipped on dry ice to the JHU CPAL.
- ◆ Prior to shipping sites must notify the MTN LC and JHU CPAL by e-mail with tracking details along with **LDMS** generated and **EXCEL** batch files.

Shipping Instructions



◆ Plasma for PK (cont.)

- ◆ Shipping costs will be billed directly to the MTN LC. World Courier and FedEx accounts numbers will be available.
- ◆ Please reference MTN-017-9268 for all PK shipments
- ◆ Qualitative results will be reported to the site by fax or e-mail within **10 business days** of specimens being received by JHU CPAL. Please pay attention to US holidays.
- ◆ Quantitative results will be sent to SCHARP.



Shipping Instructions

- ◆ Ship according to IATA regulations
- ◆ For frozen specimens, ship on dry ice
- ◆ For specimens being shipped to the MTN LC notify Pam Kunjara by e-mail prior to shipping
 - ◆ pkunjara@mwri.magee.edu
 - ◆ Attach the LDMS batch file to e-mail
- ◆ For specimens being shipped to the JHU CPAL notify Craig Hendrix and Mark Marzinke by e-mail prior to shipping
 - ◆ chendrix@jhmi.edu
 - ◆ mmarzin1@jhmi.edu
- ◆ Do not ship on Friday unless courier can guarantee dry ice replenishment and business day delivery!

Any Questions?

