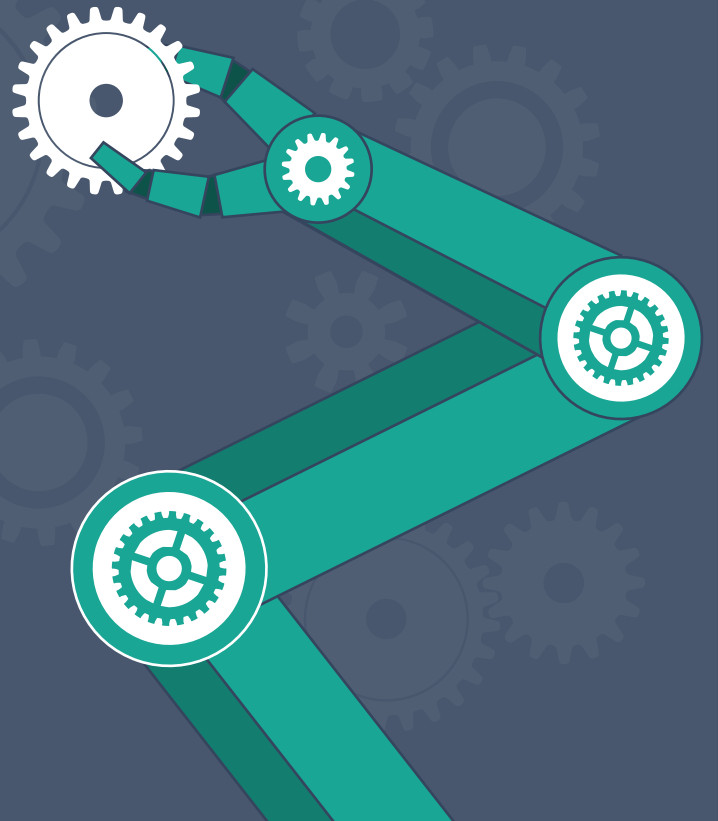
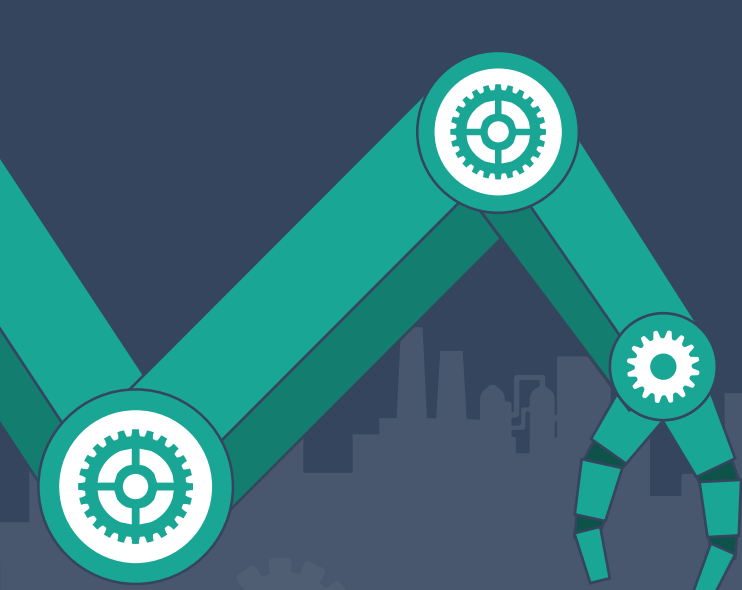




A5403

Panida Yodkeeree



A5403

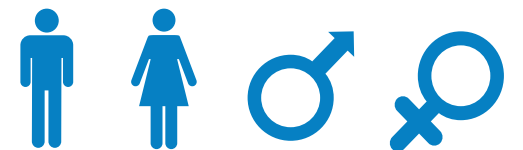
Giving Standardized Estradiol Therapy In Transgender Women to Research
Interactions with HIV Therapy: the GET IT RIgHT Study
A Multicenter Trial of the AIDS Clinical Trials Group (ACTG)



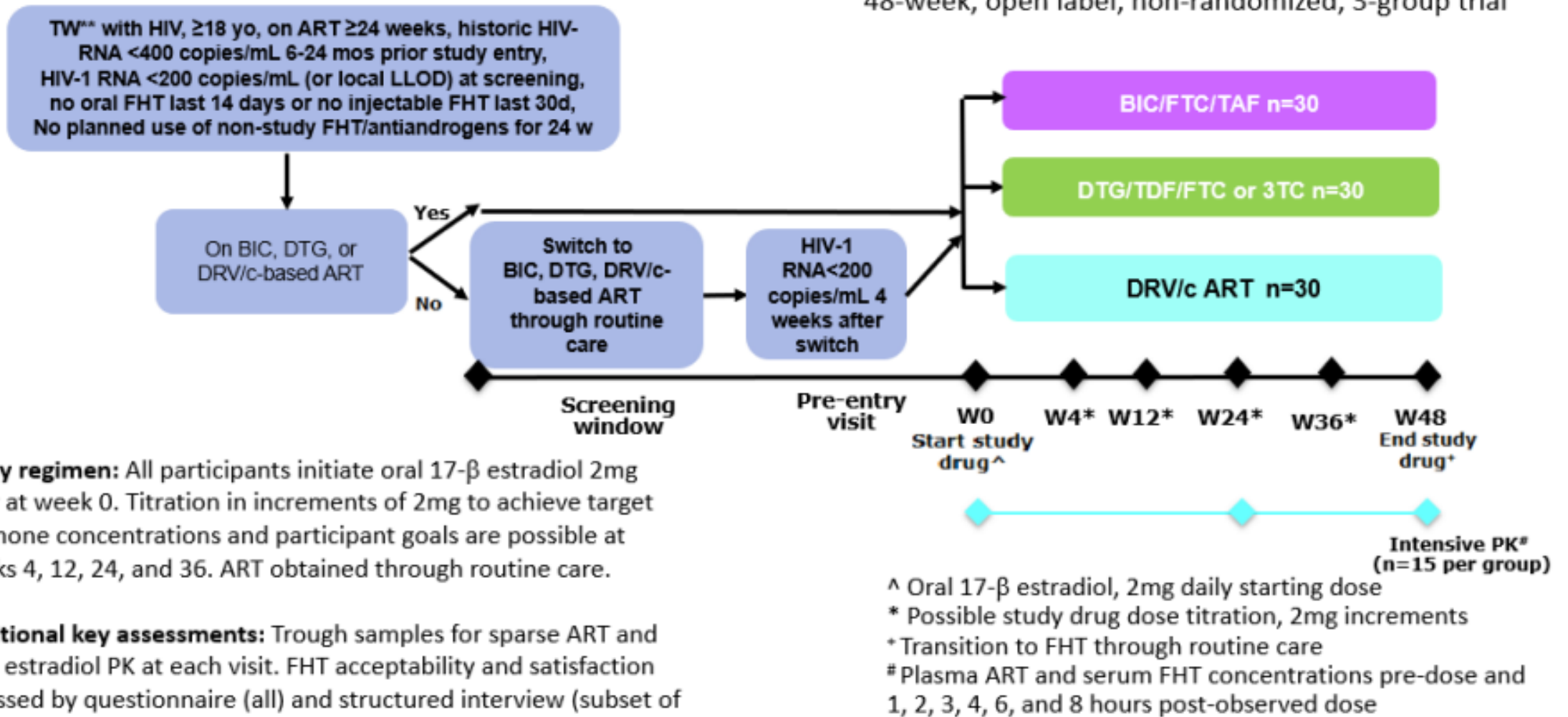
Study design

adult transgender women (TW) and other individuals identifying as female or transfeminine but with male sex assigned at birth (henceforth referred to in aggregate as TW) living with human immunodeficiency virus-1 (HIV-1)

- phase II b
- 48-week
- open-label
- non-randomized
- three-group (90 participants (30 per group)).



48-week, open label, non-randomized, 3-group trial



**Identifies as a trans woman or identifies as female or transfeminine but was assigned male sex at birth

Schema Figure 1

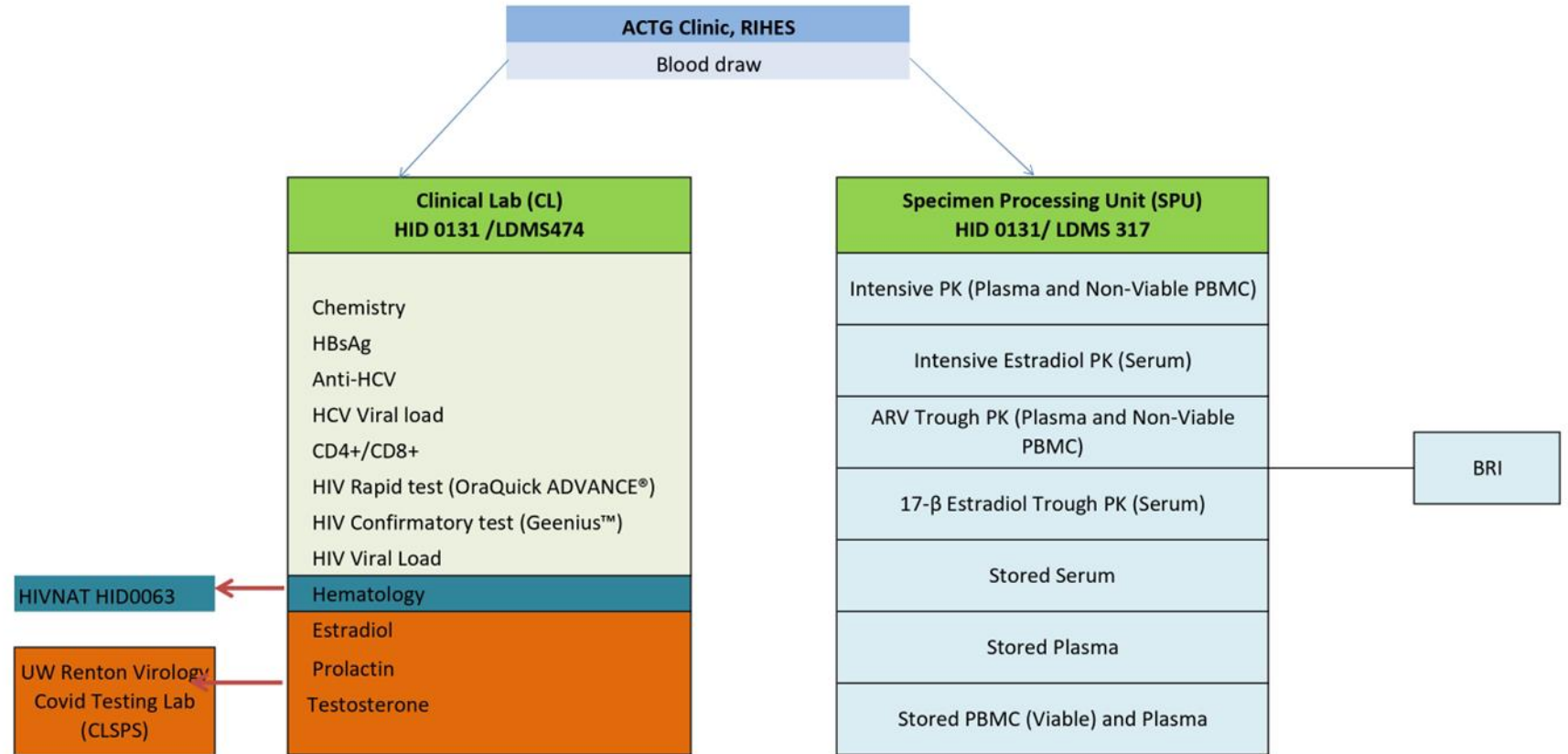
Specimen Flow Chart

HIVNAT (Hematology)

- ❖ แจ้งคลินิกขอตารางนัด
อาสาสมัคร เพื่อจอง shipment
- ❖ ใบ Hematology Report ส่ง
email แบบมี password

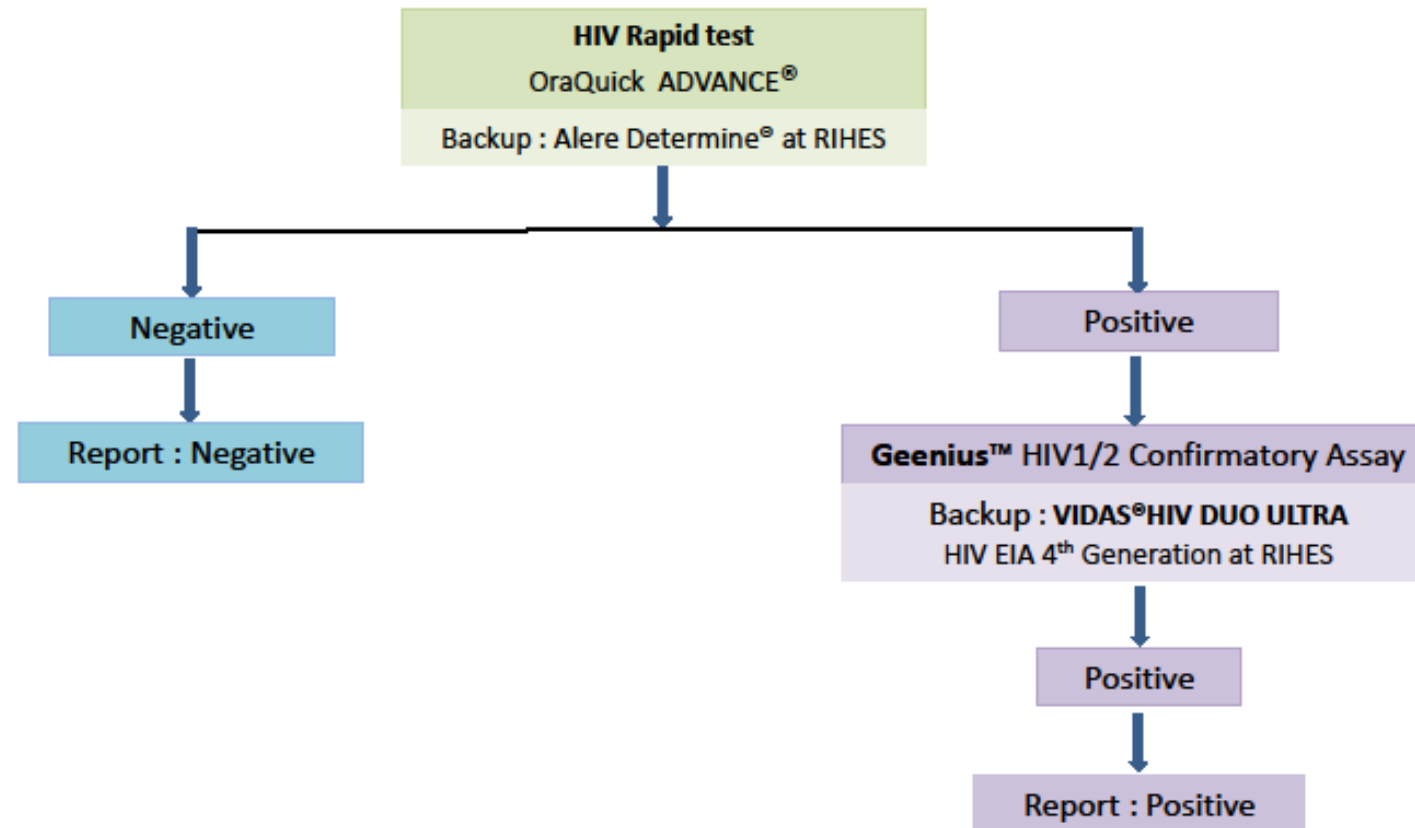
UW Renton Virology Covid Testing Lab (CLSPS)

- ❖ รับเลือดจาก ACTG แล้วนำส่ง
ห้อง SPU โดย SPU จะมี
แบบฟอร์มรับเลือด เราจะเก็บตัว
copy ไว้ 1 ใบ
- ❖ ทาง SPU จะ ship to UW
Renton แบบ batch โดยจะอิง
ตามตารางนัดหมาย
- ❖ ผลแลป จะส่ง email ไปที่ clinic
เลยไม่ผ่านห้อง CL

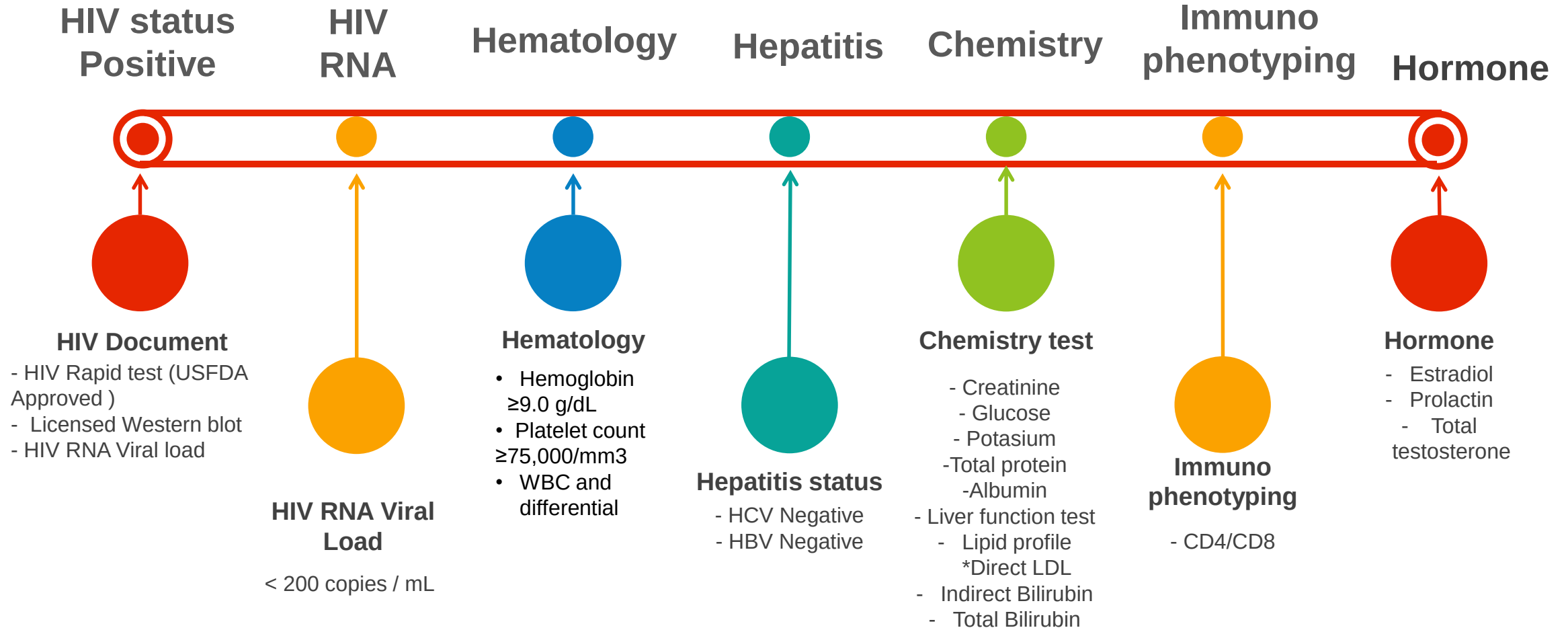


Updated by PAY 30NOV23, CKK 15DEC2023, PAY11MAR24_WJ17APR24

HIV algorithm for A5403



Inclusion Criteria



Toxic Grade

[Grade from ACTG Clinic](#)

* Drive Y → Folder ACTG Study → A5403 ____ 09 Lab Report

A5403 Requisition form

1. Clinical Lab 2. SPU 3. Office



A5403 Clinical Laboratory & SPU Requisition Form

RIHES Chiang Mai University ,P.O. Box 80 CMU , Chiang Mai, Thailand Tel 66-5393-6148 ext.469

PID _____
SID _____
Institution _____

Group 1/2/3

Visit _____ DOB (DD/MM/YYYY) ____/____/____ SEX ☐ Male ☐ Female Last food / drink (DD/MM/YYYY) ____/____/____ Time (24 Hrs Clock) ____:____

Fasting ☐ Yes ☐ No Weight (kg) _____

Collection Date (DD/MM/YYYY) ____/____/____ Time Blood (24 Hrs Clock) ____:____ Collector Initial _____ QC Initial _____ Transporter Initial _____

Laboratory category		Collection Tube	Extra	Pre-entry	Screen- ing	Entry/ Day 0	Week 4	Week 12	Week 24	Week 36	Week 48	Premature study / Treatment Discont
Clinical Lab (LIMS 474)	Hematology (Hb, Hct, RBC, WBC, WBC differential ,ANC, Plt)	1x3 ml Spray Dried EDTA tube			X	X			X		X	X
	CD4+ Cell Count (if HIV+)					X				X	X	
	HIV testing (if no document)				X							
	Chemistry (GLU, K, Cr ,TP, ALB)	1x5 ml SST tube			X	X	X	X	X	X	X	X
	LFT (ALT(SGPT),AST(SGOT), ALP, TBIL ,IBIL)				X	X	X	X	X	X	X	
	Lipid panel (Fasting) (TG, CHOL , Direct-LDL (LDLD), HDL)				X		X	X		X	X	
	HBsAg (if not have available in the medical record)				X							
	Anti-HCV (if not have available in the medical record)				X							
	HCV RNA * (if not have available in the medical record)	1x6 ml Spray Dried EDTA tube			X							
	HIV-1 RNA	1x6 ml Spray Dried EDTA tube		X	X	X		X	X	X	X	X
	Estradiol (Ship to UW Renton via 317)	1x5 ml SST Tube			X	X	X	X	X	X	X	X
	Prolactin (Ship to UW Renton via 317)				X							
Total testosterone (Ship to UW Renton via 317)				X	X	X	X	X	X	X		
SPU (LIMS 317)	Store Plasma	6 ml Spray Dried EDTA tube				X***	1T	1T	X***	1T	X***	X***
	Store Serum	6 ml SST tube				1T	1T	1T	1T	1T	1T	
	Store PBMC and Plasma (1A for Intensive PK subgroup)	10 ml Spray Dried EDTA tube				3T			3T		3T	
	Store PBMC and Plasma (1B for ARV trough PK subgroup)	10 ml Spray Dried EDTA tube				7T			7T		7T	
	ARV Trough PK (wrapped in fold within 5 minutes of collection until centrifugation)	4 ml Spray Dried EDTA tube				2T**	1T	2T	2T**	2T	2T**	2T**
	17beta Estradiol Trough PK	5 ml SST tube (Collect only 4 ml blood)				1T	1T	1T	1T**	1T	1T**	1T**
	Intensive ARV PK for a subset of 15 participants per group (see PK collection requisition form)	4 ml Spray Dried EDTA tube				10T			10T		10T	
	Intensive Estradiol PK for a subset of 15 participants per group (see PK collection requisition form)	5 ml SST tube (Collect only 4 ml blood)							7T		7T	

Remark: *For HCV antibody testing is positive **For participants who are completing an intensive PK visit on the same day as the study visit, an additional trough sample is not required
*** Stored Plasma :Will be shared with stored plasma and viable PBMC collection on the following visits: Entry , Week 24 ,Week 48 , and at Discontinuation.

Physician / Nurse comment _____

Clinical Lab Use Only ☐ Accept ☐ Reject

Specimen received :

☐ 5 ml. SST tube(s) ☐ 3 ml. Spray Dried EDTA tube(s)
☐ 6 ml. Spray Dried EDTA tube(s)

Received by _____

Date (DD/MM/YYYY) ____/____/____ Time (24 Hrs Clock) ____:____

Comment _____

SPU Use Only ☐ Accept ☐ Reject

Specimen received : ☐ 5 ml. SST tube(s) ☐ 6 ml. SST tube(s)

☐ 4 ml. Spray Dried EDTA tube(s) ☐ 6 ml. Spray Dried EDTA tube(s)
☐ 10 ml. Spray Dried EDTA tube(s)

Received by _____

Date (DD/MM/YYYY) ____/____/____ Time (24 Hrs Clock) ____:____

Comment _____

Nurse Use Only

Whole process checked by _____

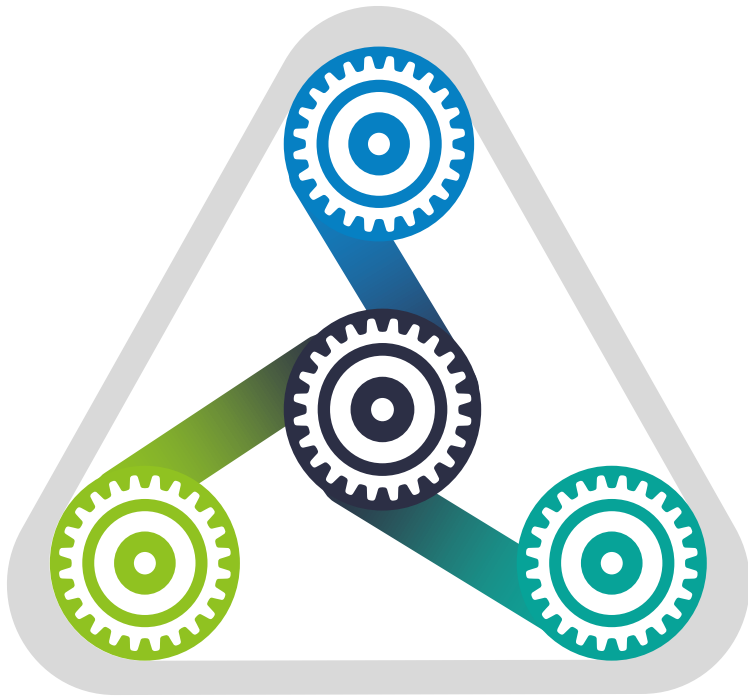
Date (DD/MM/YYYY) ____/____/____

Time (24 Hrs Clock) ____:____

Comment _____

Sticker
PID
Visit
Date collection
Date of Birth

Turn Around Time



HIV Rapid Test (OraQuick® Advance Rapid HIV1/2 Ab Test) = **1 Days**

HIV EIA 4th Generation (VIDAS® HIV Duo Ultra BioMerieux) = **7 Days**

Chemistry = **3 Days**

Hematology = **3 Days**

CD4/CD8 = **3 Days**

Hepatitis Serology (HBsAg, Anti-HCV) = **7 Days**

HCV RNA Viral Load = **14 Days**

HIV Viral Load = **14 Days**



Thank You