THE REPUBLIC OF UGANDA
MINISTRY OF HEALTH

HIV DRUG RESISTANCE

Facility Job Aid

Section One
Basic Information

Section Two
Sample Management

Section Three
Commodity Management

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Basic Information

- Action Sites of Anti-retroviral drugs
- Viral load log drop
- Nomenclature of Mutations
- NNRTI Mutations
- Etravirine Weighting Score
- NRTI Resistance
- NRTI Mutations
- Protease Inhibitor Mutations
- Integrase Inhibitor Resistance

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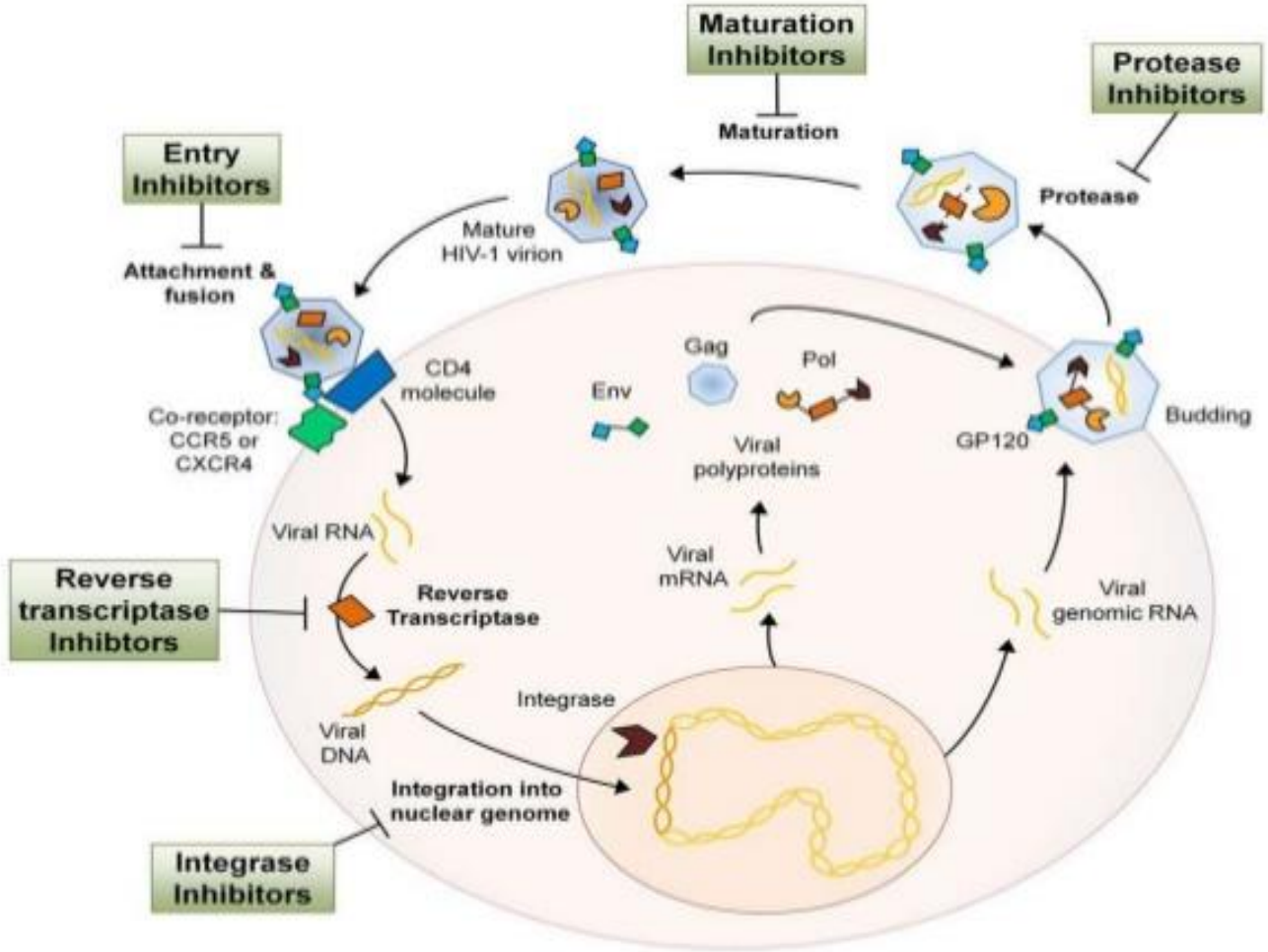
Action points for drugs

- Entry inhibitors
- Reverse transcriptase inhibitors
- Integrase inhibitors
- Protease inhibitors
- Maturation inhibitors

Anti-retroviral drugs- sites of action



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Viral load log drop & Genetic Barrier to resistance

Viral load log drop

For HIV positive patients on ART, significant viral reduction is considered after a log drop important after the three months adherence counselling sessions.

Further management after viral reduction less than a log drop will prevent further IV drug resistance.

Eg VL of 23000 copies/ml drops to 4500 copies /m l

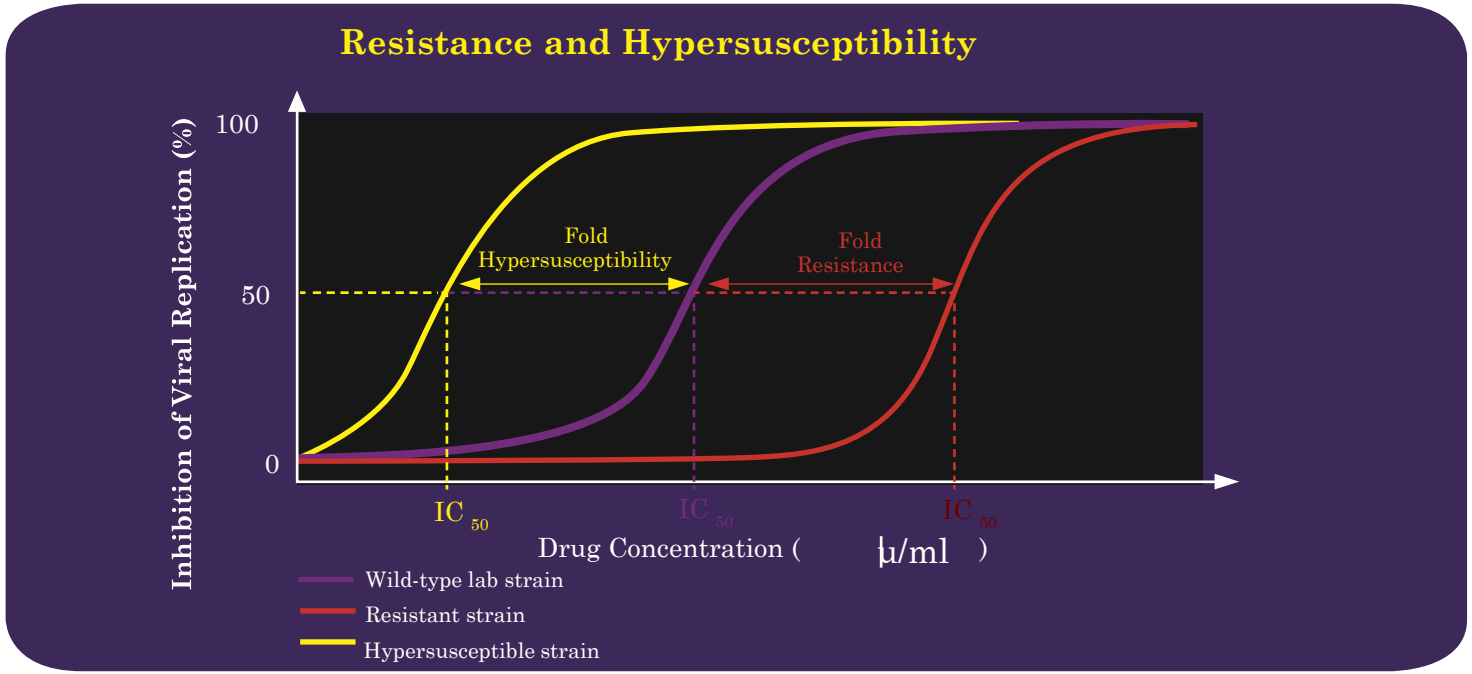
Genetic barrier to resistance

Is defined as the threshold above which resistance occurs. This is determined by Number of critical mutations required for drug resistance to develop the level of pre-existing resistance.

The rate of replication of these pre-existing resistant strains.

Low genetic barrier to resistance: NNRTI first generation

High genetic barrier to resistance: PI integrase inhibitors, triple class regimens.



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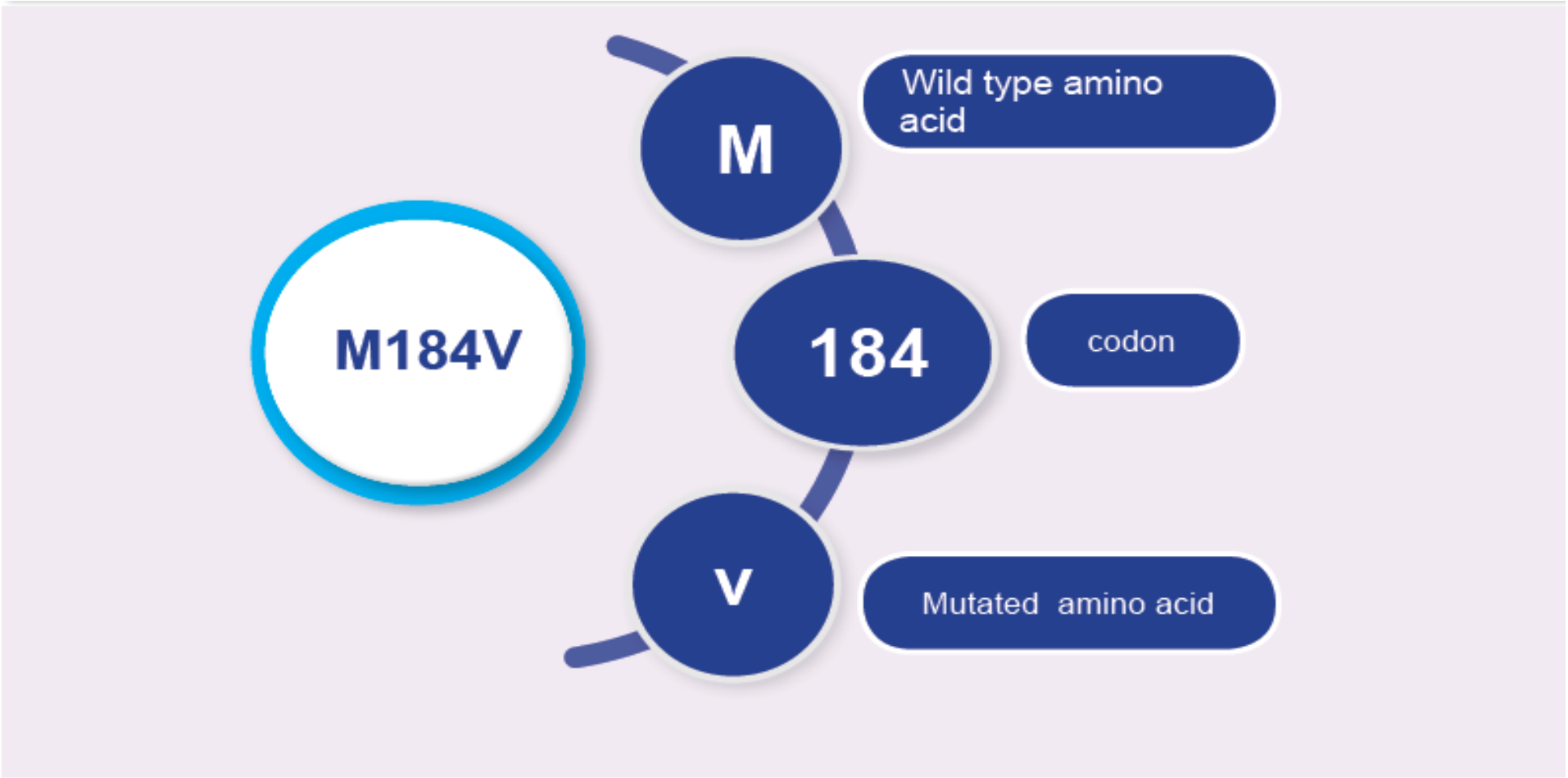
Nomenclature of Mutations



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NNRTI mutations

Consensus	100 L	101 K	103 K	106 V	138 E	181 Y	188 Y	190 G	230 M
DOR	I	EP		**AMI**		CIV	**L**HC	**SE**	**L**
EFV	**I**	E**P**	**NS**	**AM**		CIV	**L**HC	**ASE**	**L**
ETR	**I**	E**P**			AGKQ	**CIV**	L	ASE	**L**
NVP	**I**	**EP**	**NS**	**AM**		**CIV**	**L**HC	**ASE**	**L**
RPV	**I**	**EP**			**AGKQ**	**CIV**	**L**	**ASE**	**L**

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Etravirine weighting score

1	1.5	2.5	3
V901	V106I	L100I	Y181I
A98G K101E	E138A V179F	K101P Y181C	Y181V
K101H	G190S	M230L	Ad
E138G			
E138K			
E138Q			
V179D			
V179T			
G190A			

Add together

Total weighted genotypic score

0-2	**Highest response**
2.5-3.5	**Intermediate response**
≥4	**Reduced response**

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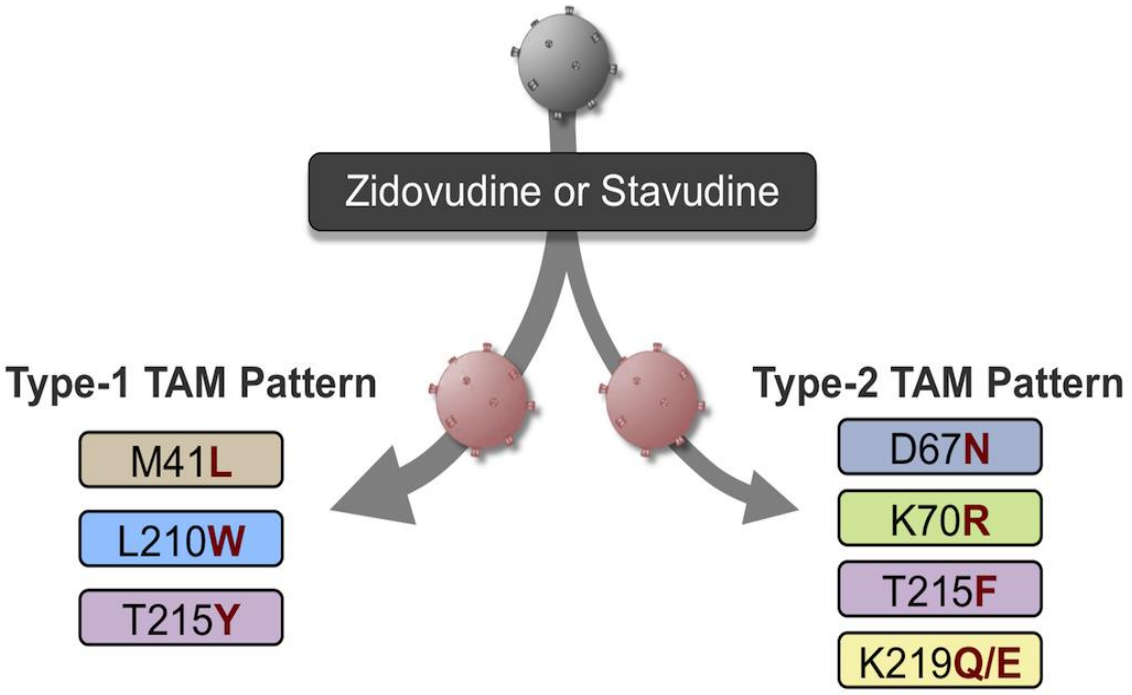
NRTI resistance

TAMS

- Selected by AZT and D4T
- The greater the number of TAMS, the greater the degree of resistance and cross resistance.

Point / discriminatory mutations eg
M184V and K65R

Multi-nucleoside resistance mutations
Q151M Complex
69 insertion
Deletions



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NRTI mutations

Consensus	184 M	65 K	70 K	74 L	115 Y	41 M	67 D	70 K	210 L	215 T	219 K	69 T	151 Q
3TC	VI	R										Ins	M
FTC	VI	R										Ins	M
ABC	VI	R	E	VI	F	L			W	FY		Ins	M
DDI	VI	R	E	VI		L			W	FY		Ins	M
TDF	***	R	E		F	L		R	W	FY		Ins	M
D4T	***	R	E			L	N	R	W	FY	QE	Ins	M
ZDV	***	***	*	*		L	N	R	W	FY	QE	Ins	M

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Protease Inhibitor mutations

Consensus	30 D	32 V	33 L	46 M	47 I	48 G	50 I	54 I	76 L	82 V	84 I	88 N	90 L
ATV/r		I	F	IL	V	V M	L	VTALM		ATFS	V	S	M
DRV/r		I	F		VA		V	LM	V	F	V		
FPV/r		I	F	IL	VA		V	VTALM	V	ATSF	V		M
IDV/r		I		IL	V			VTALM	V	AFTS	V	S	M
LPV/r		I	F	IL	VA	V M	V	VTALM	V	AFTS	V		M
NFV	N		F	IL	V	V M		VTALM		AFTS	V	DS	M
SQV/r						V M		VTALM		AT	V	S	M
TPV/r		I	F	IL	VA								

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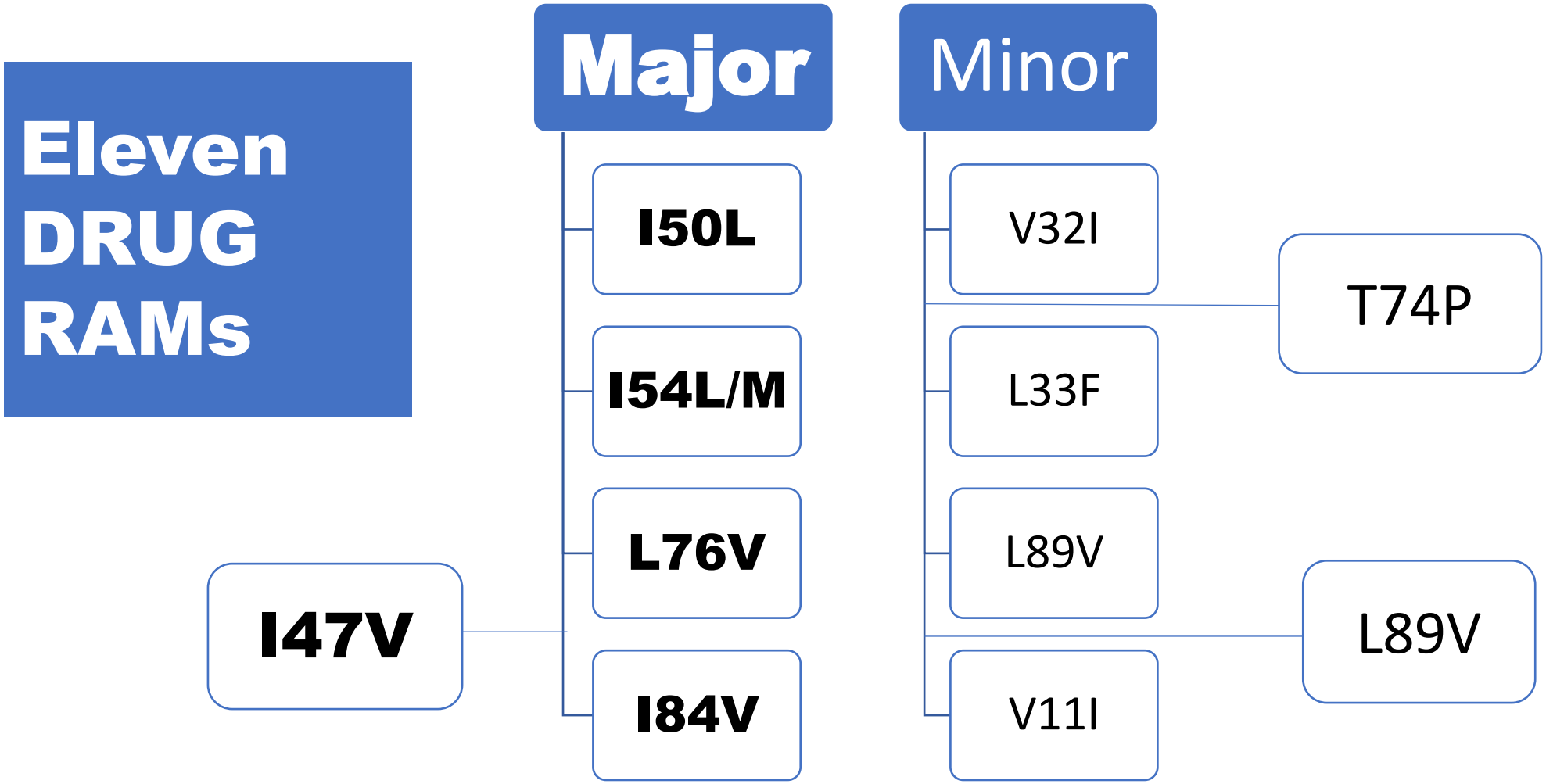
Protease Inhibitor mutations



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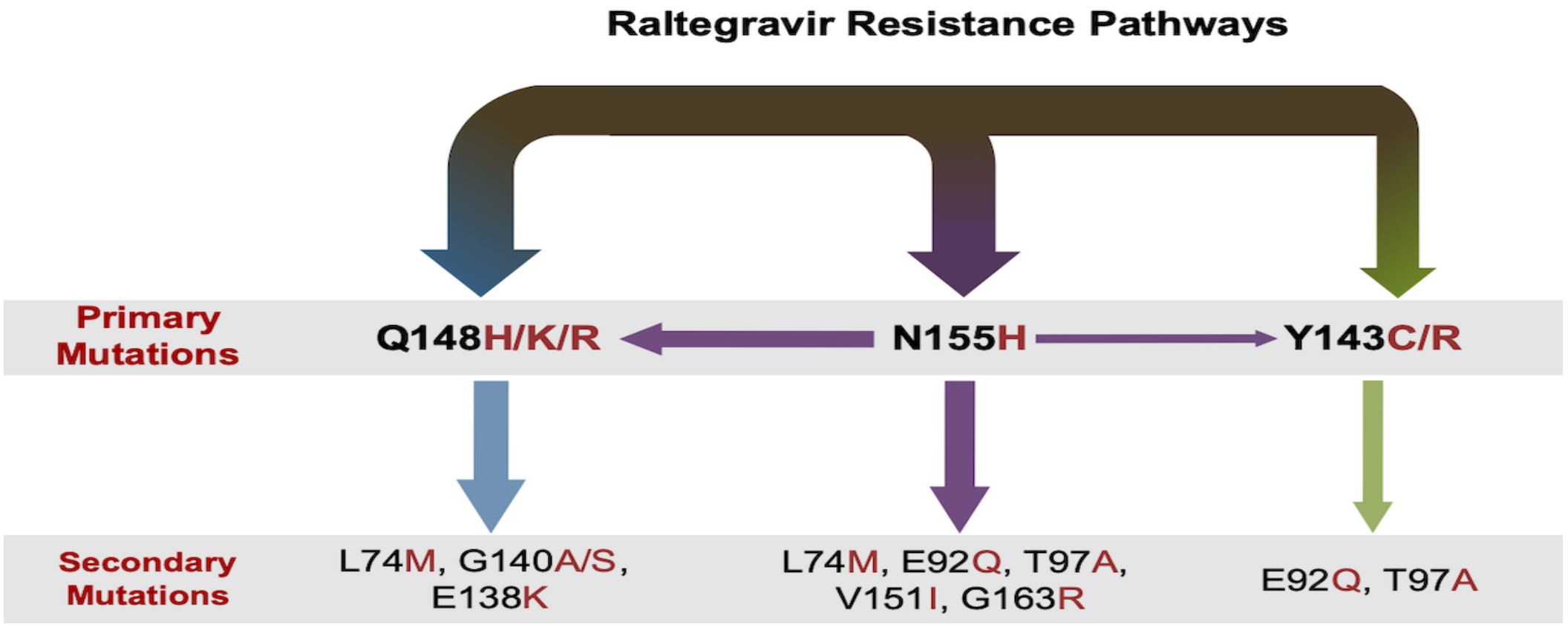
Integrase Inhibitor resistance



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Integrase Inhibitor resistance

Consensus	66 T	92 E	118 G	138 E	140 G	143 Y	147 S	148 Q	155 N	263 R
Bictegravir (BIC)	K	Q	R	KAT	SAC			HRK	H	K
Dolutegravir (DTG)	K	Q	R	KAT	SAC			HRK	H	K
Elvitegravir (EVG)	AIK	Q	R	KAT	SAC		G	HRK	H	K
Raltegravir (RAL)	AIK	Q	R	KAT	SAC	RCH		HRK	H	K

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Sample Management

- Eligibility Criteria
- HIV Drug Resistance Cascade
- Completion of the VL/DR lab forms
  - Key Parameter
  - Treatment line and Regimen code
  - Indication for Viral load testing
  - Revised Form (August 2021 Version)
- Sample Integrity
  - Phlebotomy
  - Processing
  - Storage and Transportation
  - Triple Packaging

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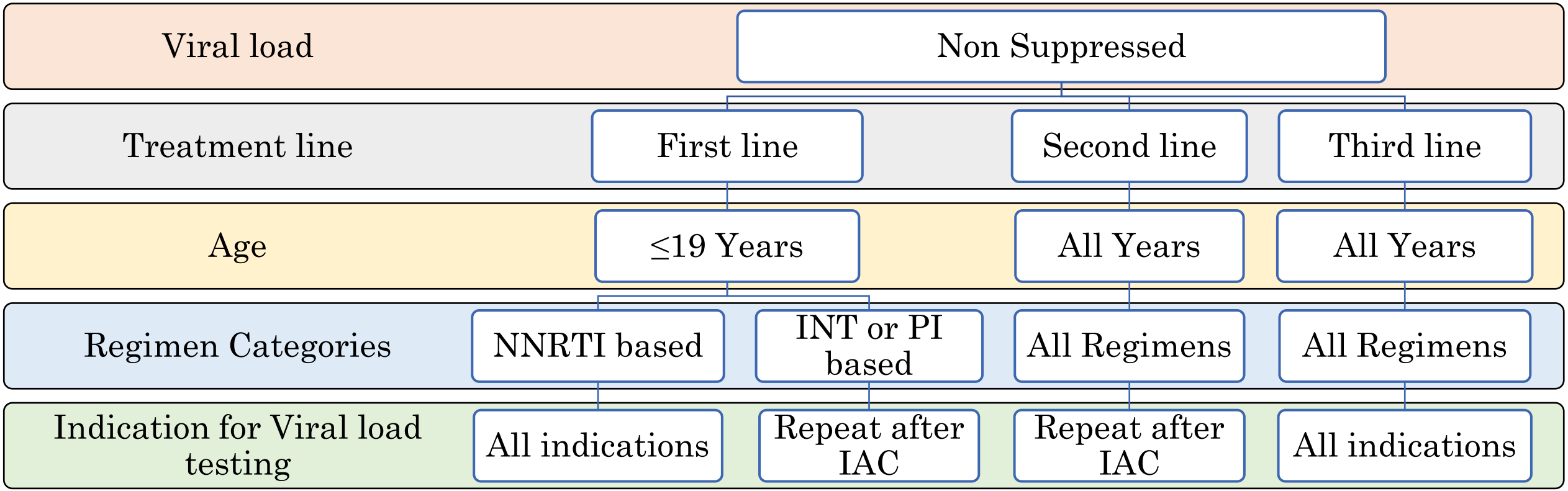
Who is Eligible???

HIV Drug Resistance Testing Eligibility Criteria



Note: Samples will only proceed for HIV drug resistance testing if all the above apply

CONSOLIDATED GUIDELINES FOR THE PREVENTION AND TREATMENT OF HIV AND AIDS IN UGANDA, MOH(2020)

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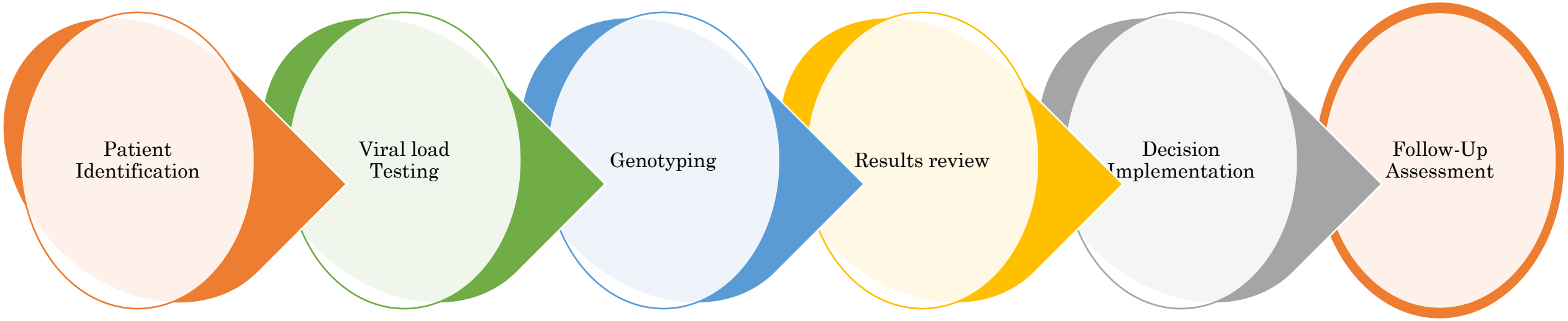
HIV Drug Resistance Cascade



Factors that affect Optimal Patient Identification

Management of Non-Suppressed Clients

Completion of the VL/DR Lab Request Form

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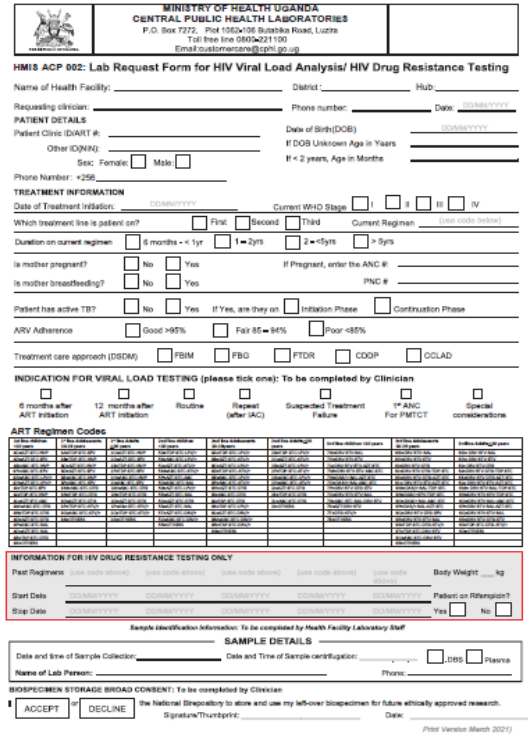
Key parameter on the Form for HIV DR testing

Completion of the VL/DR lab forms



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CENTRAL PUBLIC HEALTH LABORATORIES
P.O. Box 7272, Plot 1062×106 Butabika Road, Luzira
Toll free line 0800-221100
Email:customercare@cphl.go.ug

HMIS ACP 002: Lab Request Form for HIV Viral Load Analysis/ HIV Drug Resistance Testing

Name of Health Facility: _____ District: _____ Hub: _____

Requesting clinician: _____ Phone number: _____ Date: DD/MM/YYYY

PATIENT DETAILS

Patient Clinic ID/ART #: _____ Date of Birth(DOB) DD/MM/YYYY

Other ID(NIN): _____ If DOB Unknown Age in Years _____

Sex: Female ☐ Male ☐ If < 2 years, Age in Months _____

Phone Number: +256_____

TREATMENT INFORMATION

Date of Treatment Initiation: DD/MM/YYYY Current WHO Stage ☐ I ☐ II ☐ III ☐ IV

Which treatment line is patient on? ☐ First ☐ Second ☐ Third Current Regimen _____ (use code below)

Duration on current regimen: ☐ 6 months - < 1yr ☐ 1 – 2yrs ☐ 2 – <5yrs ☐ > 5yrs

Is mother pregnant? ☐ No ☐ Yes If Pregnant, enter the ANC #: _____

Is mother breastfeeding? ☐ No ☐ Yes PNC #: _____

Patient has active TB? ☐ No ☐ Yes If Yes, are they on ☐ Initiation Phase ☐ Continuation Phase

ARV Adherence ☐ Good >95% ☐ Fair 85 – 94% ☐ Poor <85%

Treatment care approach (DSDM) ☐ FBIM ☐ FBG ☐ FTDR ☐ CDDP ☐ CCLAD

INDICATION FOR VIRAL LOAD TESTING (please tick one): To be completed by Clinician

☐ 6 months after ART initiation ☐ 12 months after ART initiation ☐ Routine ☐ Repeat (after IAC) ☐ Suspected Treatment Failure ☐ 1st ANC For PMTCT ☐ Special considerations

ART Regimen Codes

1st line Children <10 years	1st line Adolescent >10 years	2nd line Children <10 years	2nd line Adolescent >10 years	3rd line Children <10 years	3rd line Adolescent >10 years	1st line Children <10 years	1st line Adolescent >10 years
3A (ABC/3TC/AZT)	3A (ABC/3TC/AZT)	2A (ABC/3TC/LPV/r)	2A (ABC/3TC/LPV/r)	3A (ABC/3TC/AZT)	3A (ABC/3TC/AZT)	3A (ABC/3TC/AZT)	3A (ABC/3TC/AZT)
3B (ABC/3TC/NVP)	3B (ABC/3TC/NVP)	2B (ABC/3TC/ATV/r)	2B (ABC/3TC/ATV/r)	3B (ABC/3TC/NVP)	3B (ABC/3TC/NVP)	3B (ABC/3TC/NVP)	3B (ABC/3TC/NVP)
3C (ABC/3TC/EFV)	3C (ABC/3TC/EFV)	2C (ABC/3TC/DRV/r)	2C (ABC/3TC/DRV/r)	3C (ABC/3TC/EFV)	3C (ABC/3TC/EFV)	3C (ABC/3TC/EFV)	3C (ABC/3TC/EFV)
3D (ABC/3TC/DTG)	3D (ABC/3TC/DTG)	2D (ABC/3TC/DTG)	2D (ABC/3TC/DTG)	3D (ABC/3TC/DTG)	3D (ABC/3TC/DTG)	3D (ABC/3TC/DTG)	3D (ABC/3TC/DTG)
4A (ABC/3TC/AZT/LPV/r)	4A (ABC/3TC/AZT/LPV/r)	4A (ABC/3TC/AZT/LPV/r)	4A (ABC/3TC/AZT/LPV/r)	4A (ABC/3TC/AZT/LPV/r)	4A (ABC/3TC/AZT/LPV/r)	4A (ABC/3TC/AZT/LPV/r)	4A (ABC/3TC/AZT/LPV/r)
4B (ABC/3TC/AZT/ATV/r)	4B (ABC/3TC/AZT/ATV/r)	4B (ABC/3TC/AZT/ATV/r)	4B (ABC/3TC/AZT/ATV/r)	4B (ABC/3TC/AZT/ATV/r)	4B (ABC/3TC/AZT/ATV/r)	4B (ABC/3TC/AZT/ATV/r)	4B (ABC/3TC/AZT/ATV/r)
4C (ABC/3TC/AZT/DRV/r)	4C (ABC/3TC/AZT/DRV/r)	4C (ABC/3TC/AZT/DRV/r)	4C (ABC/3TC/AZT/DRV/r)	4C (ABC/3TC/AZT/DRV/r)	4C (ABC/3TC/AZT/DRV/r)	4C (ABC/3TC/AZT/DRV/r)	4C (ABC/3TC/AZT/DRV/r)
4D (ABC/3TC/AZT/DTG)	4D (ABC/3TC/AZT/DTG)	4D (ABC/3TC/AZT/DTG)	4D (ABC/3TC/AZT/DTG)	4D (ABC/3TC/AZT/DTG)	4D (ABC/3TC/AZT/DTG)	4D (ABC/3TC/AZT/DTG)	4D (ABC/3TC/AZT/DTG)

INFORMATION FOR HIV DRUG RESISTANCE TESTING ONLY

Past Regimens (use code above) (use code above) (use code above) (use code above) (use code above) (use code above) Body Weight ___ kg

Start Date DD/MM/YYYY DD/MM/YYYY DD/MM/YYYY DD/MM/YYYY DD/MM/YYYY DD/MM/YYYY Patient on Rifampicin?

Stop Date DD/MM/YYYY DD/MM/YYYY DD/MM/YYYY DD/MM/YYYY DD/MM/YYYY DD/MM/YYYY Yes ☐ No ☐

Sample Identification Information: To be completed by Health Facility Laboratory Staff

SAMPLE DETAILS

Date and time of Sample Collection: _____ Date and Time of Sample centrifugation: _____ ☐ DBS ☐ Plasma

Name of Lab Person: _____ Phone: _____

BIOSPECIMEN STORAGE BROAD CONSENT: To be completed by Clinician

ACCEPT or DECLINE the National Biorepository to store and use my left-over biospecimen for future ethically approved research.

Signature/Thumbprint: _____ Date: _____

Print Version March 2021

Main parameters for selection

- Patient Details
  - ❖The Age must correspond with the Date of Birth especially *for children and adolescent on First-line ART*
- Treatment Information
  - ❖The **treatment line** ticked must correspond with the **regimen code** used i.e., *4M (ABC/3TC/DTG) for Firstline <10 yrs.*
- Indication for Viral load Testing
  - ❖Cautiously tick the **indication for VL testing** to depict the reason for ordering a viral load test i.e., *Repeat Viral load after Intensive Adherence Counseling (IAC)*

Note:
Data *Accuracy* is key to Patient Identification. Therefore, lab personnel must *Verify* data filled by the clinician

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Which treatment line is the Patient on???

Treatment line and Regimen code

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7456200

HMIS ACP 002: Lab Request Form for HIV Viral Load Analysis/ HIV Drug Resistance Testing

Name of Health Facility: _____ District : _____ Hub: _____

Requesting clinician: _____ Phone number: _____ Date: DD/MM/YYYY

PATIENT DETAILS

Patient Clinic ID/ART #: _____ Date of Birth (DOB) DD/MM/YYYY

Other ID(NIN): _____ If DOB Unknown Age in Years _____

Sex: Female: ☐ Male: ☐ If < 2 years, Age in Months _____

Phone Number: +256 _____

TREATMENT INFORMATION

Date of Treatment Initiation: DD/MM/YYYY Current WHO Stage ☐ I ☐ II ☐ III ☐ IV

Which treatment line is patient on? ☑ First ☐ Second ☐ Third Current Regimen *4M* (use code below)

Duration on current regimen ☐ 6 months - < 1yr ☐ 1 – 2yrs ☐ 2 - <5yrs ☐ > 5yrs

Caution:
Always refer to the table to choose a code in relation to; Age, Treatment line and Regimen. For example in the above scenario, the code “4M” indicates; A child below <10 years on ABC+3TC+DTG as their Firstline Regimen

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What is the reason for ordering a Viral load test???

Indication for VL testing

Treatment care approach(DSDM) ☐ FBIM ☐ FBG ☐ FTDR ☐ CDDP ☐ CCLAD

INDICATION FOR VIRAL LOAD TESTING (please tick one): To be completed by Clinician

☐ 6 months after ART initiation ☐ 12 months after ART initiation ☐ Routine ☑ Repeat (after IAC) ☐ Suspected Treatment Failure ☐ ANC For PMTCT ☐ Special considerations

ART Regimen Codes

1st line children <10 years	1st line Adolescents 10-19 years	1st line Adults ≥20 years	2nd line children <10 years	2nd line Adolescents 10-19years	2nd line Adults ≥20 years	3rd line children <10 years	3rd line Adolescents 10-19 years	3rdline Adults ≥20 years
4C=AZT-3TC-NVP	3A=TDF-3TC-EFV	1C=AZT-3TC-NVP	5D=TDF-3TC-LPV/r	8A=TDF-3TC-LPV/r	2B=TDF-3TC-LPV/r	7B=DAR/r-RAL-AZT-3TC	9A=DAR/r-RAL-TDF-3TC	6A= DAR/r-RAL-TDF-3TC
4D=AZT-3TC-EFV	3B=ABC-3TC-NVP	1D=AZT-3TC-EFV	5K=ABC-3TC-LPV/r	8B=AZT-3TC-ATV/r	2C=AZT-3TC-ATV/r	7F=DAR/r-RAL-ABC-3TC	9B=DAR/r-RAL-AZT-3TC	6B=DAR/r-RAL-AZT-3TC
4E=ABC-3TC-NVP	3C=AZT-3TC-NVP	1E=TDF-3TC-NVP	5L=AZT-3TC-ATV/r	8C=AZT-3TC-LPV/r	2E=AZT-3TC-LPV/r	7G=DRV+RTV+RAL	9C=DAR/r-ETV-TDF-3TC	6C=DAR/r-RAL-ABC-3TC
4F=ABC-3TC-EFV	3D=AZT-3TC-EFV	1F=TDF-3TC-EFV	5M=ABC-3TC-ATV/r	8D=TDF-3TC-ATV/r	2F=TDF-3TC-ATV/r	7H=DRV+RTV+ETV	9F=DAR/r-RAL-ABC-3TC	6E=DAR/r-ETV-TDF-3TC
4G=ABC-3TC-LPV/r	3E=ABC-3TC-NVP	1H=ABC-3TC-NVP	5P=AZT-3TC-ABC	8E=ABC-3TC-LPV/r	2G=ABC-3TC-LPV/r	7L=DRV+RTV+ETV+AZT/3TC	9G=DRV+RTV+RAL	6G= DRV+RTV+RAL
4H=AZT-3TC-LPV/r	3F=ABC-3TC-EFV	1I=ABC-3TC-EFV	5Q=ABC-3TC-RAL	8F=ABC-3TC-ATV/r	2H=ABC-3TC-ATV/r	7M=DRV+RTV+ETV+ABC/3TC	9H=DRV+RTV+ETV	6H= DRV+RTV+ETV
4I=TDF-3TC-EFV	3M=ABC-3TC-DTG	1M=ABC-3TC-DTG	50=AZT-3TC-LPV/r	8G=OTHERS	2I=OTHERS	7E=OTHERS	9I=DRV+RTV+DTG	6I= DRV+RTV+DTG
4J=TDF-3TC-NVP	3N=TDF-3TC-DTG	1N=TDF-3TC-DTG	5R=AZT-3TC-RAL				9J=DRV+RTV+DTG+TDF/3TC	6J=DRV+RTV+DTG+TDF/3TC
4L=AZT-3TC-ABC	3K=OTHERS	1G=OTHERS	5N=OTHERS				9K=DRV+RTV+DTG+AZT/3TC	6K=DRV+RTV+DTG+AZT/3TC
4M=ABC-3TC-DTG							9L= DRV+RTV+ETV+AZT/3TC	6L= DRV+RTV+ETV+AZT/3TC
4N=TDF-3TC-DTG							9E=OTHERS	6D=OTHERS
4K=OTHERS								

Caution:
Always indicate the reason for ordering a viral load test adhering to the testing algorithm; the above scenario indicates a viral load test ordered following completion of an intensive adherence counseling (IAC)

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REVISED FORM (AUGUST 2021 VERSION)

INDICATION FOR VIRAL LOAD TESTING (please tick one): To be completed by Clinician

6 Months after ART initiation	12 Months after ART initiation	Routine	Repeat (after IAC)	Suspected Treatment Failure	1st ANC For PMTCT	Special considerations
☐	☐	☐	☑	☐	☐	☐

TREATMENT LINE AND CURRENT REGIMEN (please use tick or a cross ☒)

☑ **First Line** write ticked code here: 4M

1st line children <10 years	1st line Adolescents 10-19 years	1st line Adults ≥20 years
☐ 4C=AZT-3TC-NVP	☐ 3A=TDF-3TC-EFV	☐ 1C=AZT-3TC-NVP
☐ 4D=AZT-3TC-EFV	☐ 3B=TDF-3TC-NVP	☐ 1D=AZT-3TC-EFV
☐ 4E=ABC-3TC-NVP	☐ 3C=AZT-3TC-NVP	☐ 1E=TDF-3TC-NVP
☐ 4F=ABC-3TC-EFV	☐ 3D=AZT-3TC-EFV	☐ 1F=TDF-3TC-EFV
☐ 4G=ABC-3TC-LPV/r	☐ 3E=ABC-3TC-NVP	☐ 1H=ABC-3TC-NVP
☐ 4H=AZT-3TC-LPV/r	☐ 3F=ABC-3TC-EFV	☐ 1I=ABC-3TC-EFV
☐ 4I=TDF-3TC-EFV	☐ 3M=ABC-3TC-DTG	☐ 1M=ABC-3TC-DTG
☐ 4J=TDF-3TC-NVP	☐ 3N=TDF-3TC-DTG	☐ 1N=TDF-3TC-DTG
☐ 4L=AZT-3TC-ABC	☐ 3O=AZT-3TC-DTG	☐ 1O=AZT-3TC-DTG
☑ 4M=ABC-3TC-DTG	☐ 3P=TDF-3TC-ATV/r	☐ 1P=ABc-3TC-ATV/r
☐ 4N=TDF-3TC-DTG	☐ 3Q=ABC-3TC-ATV/r	☐ 1Q=TDF-3TC-ATV/r
☐ 4O=AZT-3TC-DTG	☐ 3K=OTHERS	☐ 1G=OTHERS
☐ 4P=ABC-3TC-RAL	☐	
☐ 4Q=AZT-3TC-RAL	☐	
☐ 4R=TAF-3TC-DTG	☐	
☐ 4K=OTHERS	☐	

☐ **Second Line** write ticked code here

2nd line children <10 years	2nd line Adolescents 10-19years	2nd line Adults≥20 years
☐ 5D=TDF-3TC-LPV/r	☐ 8A=TDF-3TC-LPV/r	☐ 2B=TDF-3TC-LPV/r
☐ 5K=ABC-3TC-LPV/r	☐ 8B=AZT-3TC-ATV/r	☐ 2C=AZT-3TC-ATV/r
☐ 5L=AZT-3TC-ATV/r	☐ 8C=AZT-3TC-LPV/r	☐ 2E=AZT-3TC-LPV/r
☐ 5M=ABC-3TC-ATV/r	☐ 8D=TDF-3TC-ATV/r	☐ 2F=TDF-3TC-ATV/r
☐ 5P=AZT-3TC-ABC	☐ 8E=ABC-3TC-LPV/r	☐ 2G=ABC-3TC-LPV/r
☐ 5O=AZT-3TC-LPV/r	☐ 8F=ABC-3TC-ATV/r	☐ 2H=ABC-3TC-ATV/r
☐ 5R=ABC-3TC-RAL	☐ 8H=AZT-3TC-DTG	☐ 2J=AZT-3TC-DTG
☐ 5Q=AZT-3TC-DTG	☐ 8I=ABC-3TC-DTG	☐ 2K=TDF-3TC-DTG
☐ 5S=AZT-3TC-RAL	☐ 8J=TAF-3TC-DTG	☐ 2L=ABC-3TC-DTG
☐ 5T=AZT-3TC-DRV/r	☐ 8K=TAF-3TC-LPV/r	☐ 2I=OTHERS
☐ 5U=ABC-3TC-DRV/r	☐ 8L=AZT-3TC-DRV/r	
☐ 5N=OTHERS	☐ 8M=ABC-3TC-DRV/r	
	☐ 8N=TAF-3TC-DRV/r	
	☐ 8G=OTHERS	

☐ **Third Line** write ticked code here

3rd line children <10 years	3rd line Adolescents 10-19 years	3rdline Adults≥20 years
☐ 7G=DRV-RTV-RAL	☐ 9G=DRV-RTV-RAL	☐ 6G= DRV-RTV-RAL
☐ 7H=DRV-RTV-ETV	☐ 9H=DRV-RTV-ETV	☐ 6H= DRV-RTV-ETV
☐ 7L=DRV-RTV-ETV-AZT-3TC	☐ 9I=DRV-RTV-DTG	☐ 6I= DRV-RTV-DTG
☐ 7M=DRV-RTV-ETV-ABC-3TC	☐ 9J=DRV-RTV-DTG-TDF-3TC	☐ 6J=DRV-RTV-DTG-TDF-3TC
☐ 7N=DAR/r-RAL-AZT-3TC	☐ 9K=DRV-RTV-DTG-AZT-3TC	☐ 6K=DRV-RTV-DTG-AZT-3TC
☐ 7O=DAR/r-RAL-ABC-3TC	☐ 9L= DRV-RTV-ETV-AZT-3TC	☐ 6L= DRV-RTV-ETV-AZT-3TC
☐ 7P=DRV-RTV-DTG-ETV	☐ 9M=DRV-RTV-RAL-TDF-3TC	☐ 6M= DRV-RTV-RAL-TDF-3TC
☐ 7Q=DRV-RTV-ETV-RAL	☐ 9N=DRV-RTV-EFV-TDF-3TC	☐ 6N=DRV-RTV-EFV-TDF-3TC
☐ 7R=ABC-3TC-RAL-DRV-RTV	☐ 9O=DRV-RTV-RAL-ABC-3TC	☐ 6O=DRV-RTV-RAL-ABC-3TC
☐ 7S=AZT-DRV-RTV	☐ 9P=DRV-RTV-RAL-AZT-3TC	☐ 6P=DRV-RTV-RAL-AZT-3TC
☐ 7T=DTG-ATV/r	☐ 9Q=DRV-RTV-DTG-EFV	☐ 6Q=DRV-RTV-ETV-RAL
☐ 7E=OTHERS	☐ 9R=DRV-RTV-ETV-RAL	☐ 6R=DRV-RTV-DTG-ETV
	☐ 9S=TDF-3TC-DTG-ATV/r	☐ 6S=TDF-3TC-DTG-ATV/r
	☐ 9T=TDF-3TC-DRV-RTV	☐ 6D=OTHERS
	☐ 9U=ABC-3TC-DRV-RTV	
	☐ 9E=OTHERS	

Note:
In the August 2021 Version; the treatment-line and current regimen are filed with a tick or cross as shown above. The above scenario indicates; a child below <10 years on ABC+3TC+DTG as their Firstline Regimen with a viral load test ordered following completion of an intensive adherence counseling (IAC)

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What shows a Good Sample???

Sample integrity indicators

Container

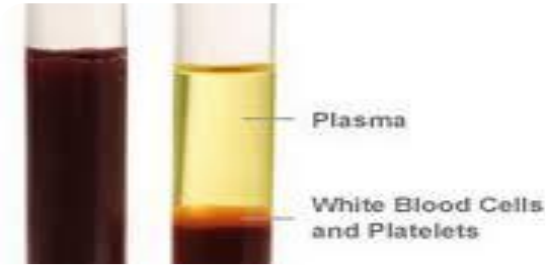
PPT™ Plasma Preparation Tubes with an inert Gel

State

Non-hemolyzed Plasma

Volume

At-least 3ml of Plasma per tube



Type

100% Plasma for HIV Drug Resistance Testing

Factors that affect Sample integrity

Phlebotomy

Aseptic techniques

Sample Mixing

Processing

Time on Bench

Centrifugation

Storage

Cold Chain

Freeze-Thaw Effect

Transportation

Time in Transit

Cold Chain

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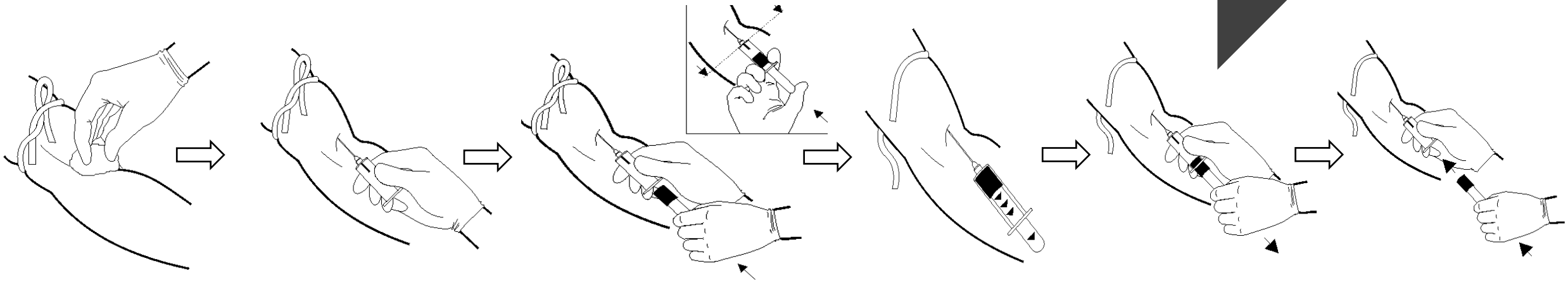
What to Consider during Sample Collection???

Phlebotomy

1. Verify patient request form
2. Select a suitable site for venipuncture
3. Prepare the equipment, patient and venipuncture site observing universal precautions and infection control
4. Label the PPT tubes with patient Art no., Serial Form no. as a minimum
5. Perform the venipuncture following the SOPs while observing universal precautions and aseptic techniques
6. Collect 5 – 8 ml of blood in Two (2) BD PPT™ Tubes



What to Consider during Sample Processing???

Processing

After collection of whole blood in the BD PPT™ Tube, immediately and gently invert the BD PPT™ Tube 8–10 times

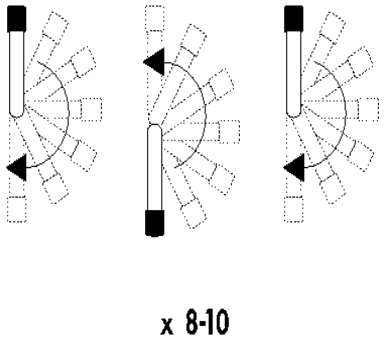
Label the PPT tubes with patient Art no., Serial Form no. as a minimum

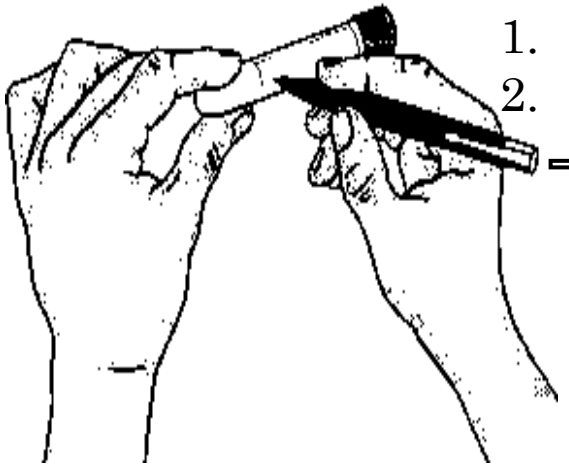
After mixing, the whole blood specimen may be stored up to six (6) hours at room temperature until centrifugation

Centrifuge BD PPT™ Tube in a balanced, swing-out rotor type centrifuge at room temperature at 1500 RCF(xg) for a minimum of 10 minutes

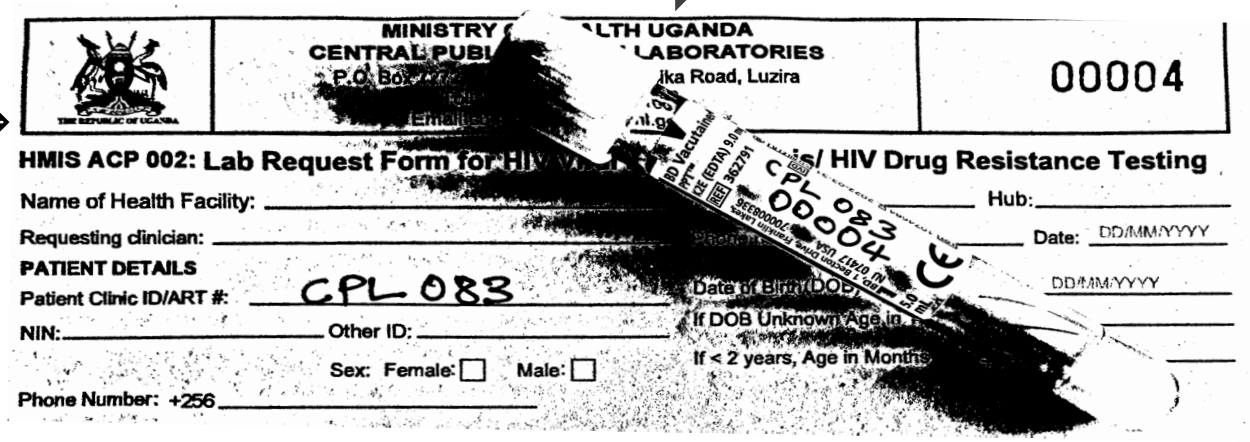
Note: Use the following formula to convert to RPM (revolutions per minute):

RCF = 1.12 x Radius of rotor(mm) x (rpm / 1000)2





1. Art No.
2. Form No.



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What to Consider during Sample Storage and Transportation???

Storage and Transportation

- Store processed Plasma at 4-8°C until picked for transportation
- **Note**: Avoid storing at -20°C and -80Cto prevent a freeze-thaw effect that affects viral load results
- Always follow-up with Hub riders to pick sample within two(2) days
- Transfer the BD PPT™ Tube with the plasma into the cooler boxes utilizing the triple packaging system
- Place ice packs at the bottom of the samples within in the cooler box
- Samples should reach CPHL between 1-3 days from collection
- Always accompany the samples with fully filled requisition forms

Note:
Facilities without a refrigerator and/or a centrifuge should adopt batched collection of whole blood samples in PPT tubes. These are encouraged to schedule visits of eligible patients on the day a Hub rider visits the site or whenever scheduled. With support from the Implementing partners, the Hub coordinators should support such lower-level facilities with collection materials and mentorship on ensuring sample integrity is maintained. These facilities can always use DBS cards for other clients as per the viral load testing algorithm. A similar approach should be adopted for community based sample collection. The goal is to ensure samples are processed within six (6) hours from collection. Thereafter, stored at 4-8 °C storage conditions awaiting transportation.

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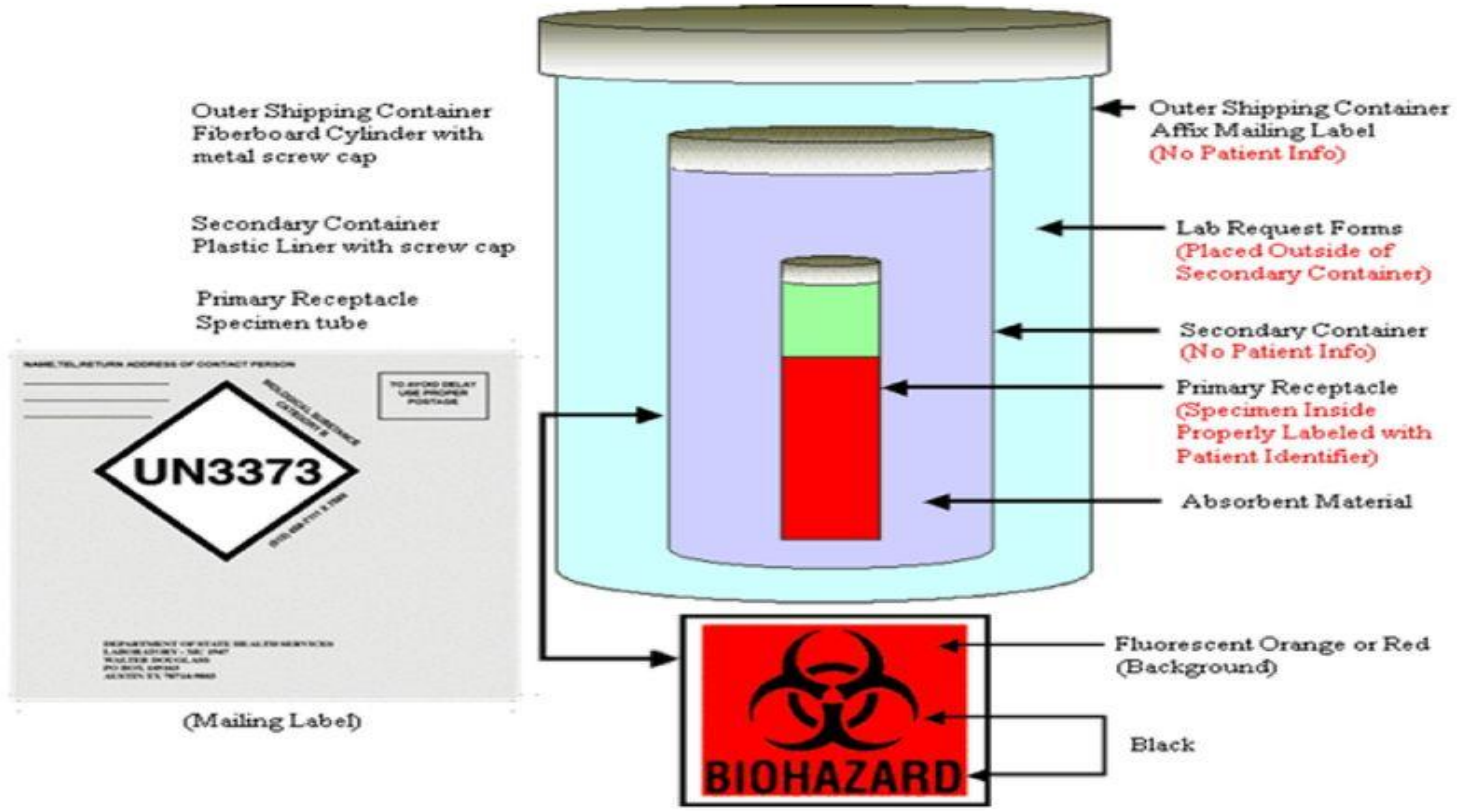
What to Consider during Sample Storage and Transportation???

Storage and Transportation

Triple Packaging



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Commodity Management

- TDF+3TC+DTG
- Raltegravir
- Dolutegravir tablets
- Darunavir
- Ritonavir
- Etravirine
- TAF+3TC

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TDF+3TC+DTG

Drug Name: TDF+3TC+DTG
Formulation: Tablet (film coated)
Strength: 300/300/50mg

Description: This is a fixed-dose combination containing 2 nucleoside reverse transcriptase inhibitor (Tenofovir and Lamivudine) and 1 Integrase Inhibitor (Dolutegravir).

Administration:

- Given once a day; preferably in the morning
- Should not be crushed or chewed
- Can be taken on an empty or full stomach

Drug-drug interactions:

- Double the dose of DTG if given with Rifampicin
- If co-administering with antacids (e.g Magnesium Trisilicate), give the TDF+3TC+DTG 2 hours before or 6 hours after the antacid.
- Avoid giving DTG with carbamazepine, phenobarbital, and phenytoin. If co-administered, adjust the dose of anticonvulsant, or consider alternative agents (Sodium Valproate) or consider alternative anchor ARV.

Side effects:

Counsel patient or caregivers about the following side effects:

- Dizziness, faintness
- Difficulty falling asleep
- Nausea, vomiting, diarrhea and abdominal cramping or discomfort
- Decrease in appetite.
- Skin itching (localized or diffuse),
- Bone aches

Ask patient or caregiver to return to the health facility in case any symptoms on the left worsen or persist or in case they develop the following:

- Excessive drinking/eating, excessive urination: Hyperglyacaemia
- Lower back pain, change in urine volume
- Spontaneous fractures
- Exhaustion or extreme fatigue, muscle cramps or pain, headache
- Right upper quadrant abdominal pain, yellow urine or eyes
- Abdominal pain or discomfort, decrease appetite difficulty breathing,
- Excessive weight gain

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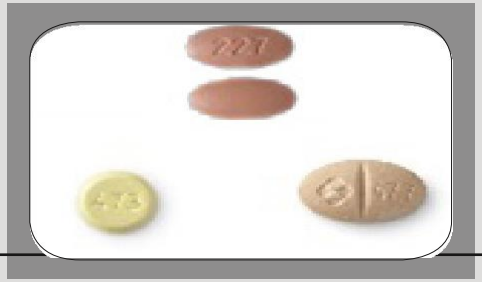
Raltegravir

Drug Name: Raltegravir

Formulation and strength. Film-coated tablets: 400 mg

Chewable tablets: 25 mg, 100 mg (scored, dividable)



Description:

Raltegravir is an integrase inhibitor indicated in the treatment of PLHIV.

Administration:

- Oral twice daily for PLHIV
- You may take raltegravir with or without food.
- The raltegravir chewable tablet may be chewed or swallowed whole.
- Do not crush, chew, or break the film coated tablet. Swallow it whole.

Drug-drug interactions:

- No major drug to drug intereactions

Side effects:

- Common side effects nausea, headache, dizziness, excessive fatigue and sleep problems (insomnia).
- Serious side effects associated with **etravirine** are severe skin rash and allergic reactions.

When to Return:

Patients should come back to the health facility when they experience the following;

- Blistering or peeling skin including the areas around the mouth or eyes
- Blisters or sores in the mouth
- Yellowing of the skin or the white of the eyes
- Dark colored urine
- Pain, aching or tenderness on the right side of the stomach
- Redness or swelling of the eyes
- Trouble breathing
- Fever

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Dolutegravir tablets

Drug Name: Dolutegravir (DTG) **Formulation:** Tablet **Strength:** 10mg, 50mg

Description:

DTG is an integrase inhibitor indicated in the treatment of PLHIV. The 50mg tablet can be administred to children weighing 20kg and above while the 10mg tablet can be given to those weighing between 3kg and<20kg. DTG is the preferred anchor antiretroviral drug for ART naïve patients. It can also be used for 2nd and 3rd line regimen depending on their previous ART regimen.

Administration:

- Oral once daily, twice daily for PLHIV with TB coinfection.
- It can be taken with or without food.
- Administer 2 hours before or 6 hours after antacids or laxatives containing calcium, magnesium or aluminium and vitamin or mineral supplements that contain calcium or iron.

Drug-drug interactions:

- Antacids or laxatives that contain calcium, magnesium, or aluminum & vitamin or mineral supplements that contain calcium or iron can make DTG much less effective when taken at the same time. If they should be taken together, ask the patient to take DTG dose 2 hours before or 6 hours after taking the other medicine.
- Give cautiously in PLHIV on metformin for treatment of Diabetes. DTG may increase the dose of metformin when the 2 drugs are used together.
- Rifampicin- May decrease the serum concentration of DTG. Increase DTG dose to 50 mg twice daily in adults.
- Anticonvulsants-Phenobarbital- may decrease serum concentration of DTG (avoid combination), Carbamazepine may also decrease the concentration of DTG (Increase dolutegravir dose to 50 mg twice daily when used together with carbamazepine)
- Etravirine: May decrease the serum concentration of Dolutegravir. Avoid etravirine with dolutegravir. You can only give etravirine with DTG if coadministered with a boosted PI.

Side effects:

Dolutegravir is generally well tolerated. Common side effects include:

- Headache
- Insomnia
- Tiredness
- Fatigue.

When to Return:

Ask caregiver to return to the health facility in case any symptoms on the left worsen or persist or in case they develop the following:

- Fever
- Muscle or joint aches
- General ill feeling and Tiredness
- Swelling of your mouth, face, lips, or tongue
- Trouble breathing
- Blisters or peeling skin
- Redness or swelling of your eyes
- Signs and symptoms suggestive of **liver disease** such as yellowing of the skin or whites of the eyes (jaundice), dark-colored urine, light-colored bowel movement,nausea or vomiting, loss of appetite and pain, aching, or tenderness on the right side below the ribs)
- Signs & symptoms suggestive of **hyperglycaemia** : excessive drinking/eating, excessive urination, rapid weight gain/loss.

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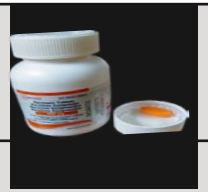
Darunavir

Drug Name: Darunavir
Formulation: Tablet
Strength: 75mg, 150mg and 600mg



Description:

Darunavir is a protease inhibitor that is always used in combination with ritonavir and other drugs to treat HIV.

Administration:

- Dose is dependent on weight for children and it is administered twice daily.
- It should be taken together with ritonavir at the same time every day.
- It works best when taken with food
- Darunavir should be taken whole and not crushed, chewed, or broken.
- Not recommended for patients with severe liver disease.

Drug-drug interactions:

- Co-administration of Darunavir/ritonavir with systemic corticosteroids (mainly dexamethasone) and rifampicin may result in loss of therapeutic effect and development of resistance to Darunavir.
- Darunavir may make the following birth control methods (pills, implants or vaginal rings) less effective. Patients using these birth control methods should use an alternative contraceptive method or an additional barrier method while taking Darunavir. as a single drug or combined with other drugs.

Side effects:

Darunavir has minimal side effects but in rare cases the following may occur.

- Liver injury: Nausea, vomiting, right upper quadrant abdominal pain, yellow eyes or urine
- Severe skin and hypersensitivity reactions: Skin itching (localized or diffuse), dizziness, faintness, difficulty breathing
- Hyperglycaamia.
- Fat redistribution

When to Return:

The patient should return to the health facility when they develop signs and symptoms suggestive of:

- livery injury
- hypersensitivity reactions
- hyperglycaemia as stipulated above.

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Ritonavir

Drug Name: Ritonavir
Formulation: Tablet
Strength: 100 mg

Description:
Ritonavir is a protease inhibitor usually given in combination with other PIs including Lopinavir, Atazanavir and Darunavir. It is given as a combined tablet with Lopinavir and Atazanivr but as a separate tablet with Darunavir.

Administration:

- Dose is dependent on weight for children and it is administered twice daily.
- It should be taken together with Darunavir at the same time every day.
- Ritonavir should be administered with meals.
- Ritonavir should be taken whole and not crushed, chewed, or broken.

Drug-drug interactions:

- The blood concentrations of combined oral contraceptives are reduced by ritonavir. Patients taking combined hormonal contraception should use an alternative contraceptive method or an additional barrier method while taking ritonavir. as a single drug or combined with other drugs.

Side effects:

- Common side effects include; diarrhea, nausea and vomiting, taste disturbance, abnormal skin sensations (burning, prickling and tingling), headache, weakness, and insomnia (difficulty sleeping).
- The more serious side effects may include liver failure, inflammation of the pancreas (pancreatitis) and severe allergic reactions.

When to Return:
The patient should return to the health facility when they develop signs and symptoms suggestive of livery injury, pancreatitis and severe allergic reactions.

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Etravirine

Drug Name: Etravirine **Formulation:** Tablet **Strength:** 25mg, 100mg , 200mg

Description:

Etravirine is a 2nd generation NNRTI used in the treatment of HIV positive ART experienced patients.

Administration:

- Dose is dependent on weight for children and it is administered twice daily.
- Don't take etravirine on an empty stomach.
- Swallow the tablets whole with a glass of water.
- If you are unable to swallow the etravirine tablet whole, place the tablets in a glass containing a teaspoon of water. (If needed add more water to cover the tablets). Do not put the tablets in other liquids.
- Stir well until the water looks milky. At this step you may add a little water, orange juice or milk to make the mixture easier to drink
- Dink the mixture right away. Rinse the glass with water, orange juice or milk several times and completely swallow the rinse each time to make sure you take the entire dose of the etravirine.
- Avoid using water or carbonated beverages while taking etravirine tablets.

Drug-drug interactions:

- Do not give etravirine with rifampicin as this may cause significant decreases in etravirine plasma concentrations leading to resistance to etravirine.
- Etravirine: May decrease the serum concentration of Dolutegravir. Avoid etravirine with dolutegravir. You can only give etravirine with DTG if in co-administered with a boosted PI.

Side effects:

- Etravirine is usually well tolerated with minor side effects such as nausea, diarrhoea and occasional dizziness.
- Serious side effects associated with etravirine are severe skin rash and allergic reactions.

When to Return:

Patients should come back to the health facility when they experience the following;

- Blisters or sores in the mouth
- Yellowing of the skin or the white of the eyes, Dark colored urine
- Pain, aching or tenderness on the right side of the stomach
- Redness or swelling of the eyes
- Trouble breathing
- Fever

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TAF/3TC

Name: TAF/3TC
Formulation: Fixed dose combination (FDC) tablet
Strength: 25/300 mg

Description: Nucleotide and Nucleoside Reverse Transcriptase Inhibitor respectively

Administration: Oral

Drug-drug interactions:

- TAF interacts with Rifampicin, carbamazepine, phenobarbitone and phenytoin; it is therefore not recommended for use with Rifampicin, phenobarbitone and phenytoin while its dose should be increased when used together with carbamazepine

Side effects:

Headache, diarrhea, nausea, decreased bone mineral density, lactic acidosis or severe hepatomegaly with steatosis for TAF.	**When to Return:** When symptoms related to side effects occur e.g. abdominal pain, headache, etc ; or 2 weeks after initiation