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Clinical HIV-2 Viral Load Testing of a Large Population of HIV-2 Infected Individuals

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**** The authors have no conflicts of interest to disclose ****

HIV-2 viral load uses real time HIV-2 RT-PCR assay with standards and a 'No RT' control

1. LYSIS

0.2 or 0.9 mL plasma

20ul internal control



2. EXTRACTION

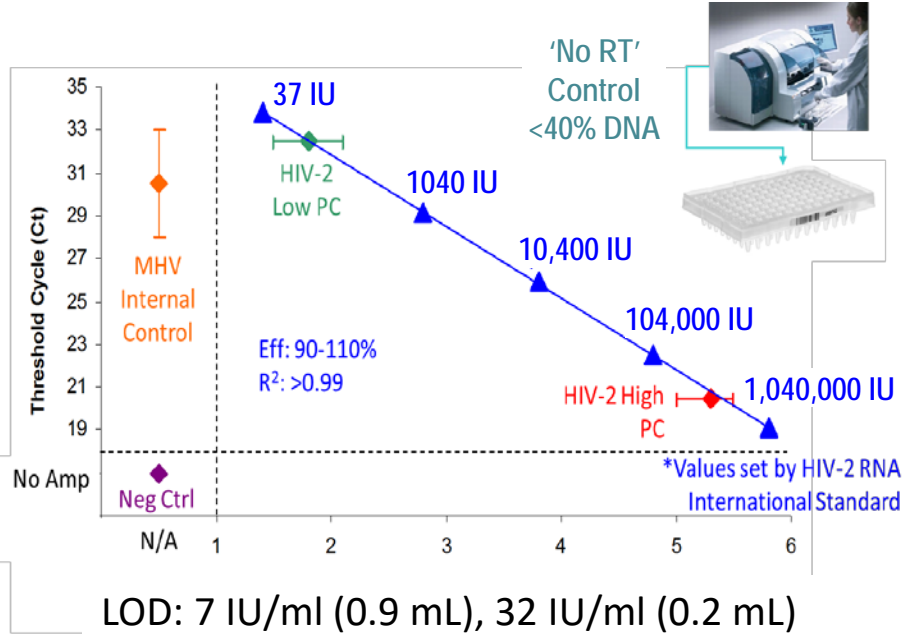
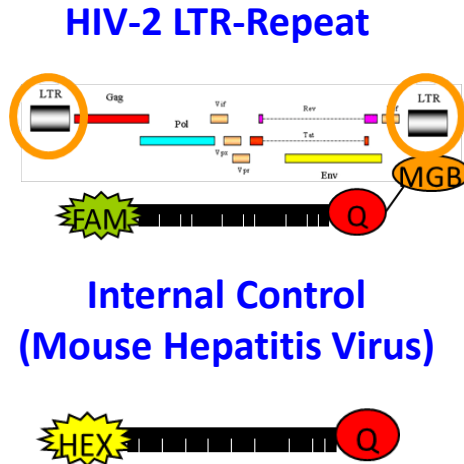


Total nucleic acid
Nuclisens
EasyMAG

3. REVERSE TRANSCRIPTION

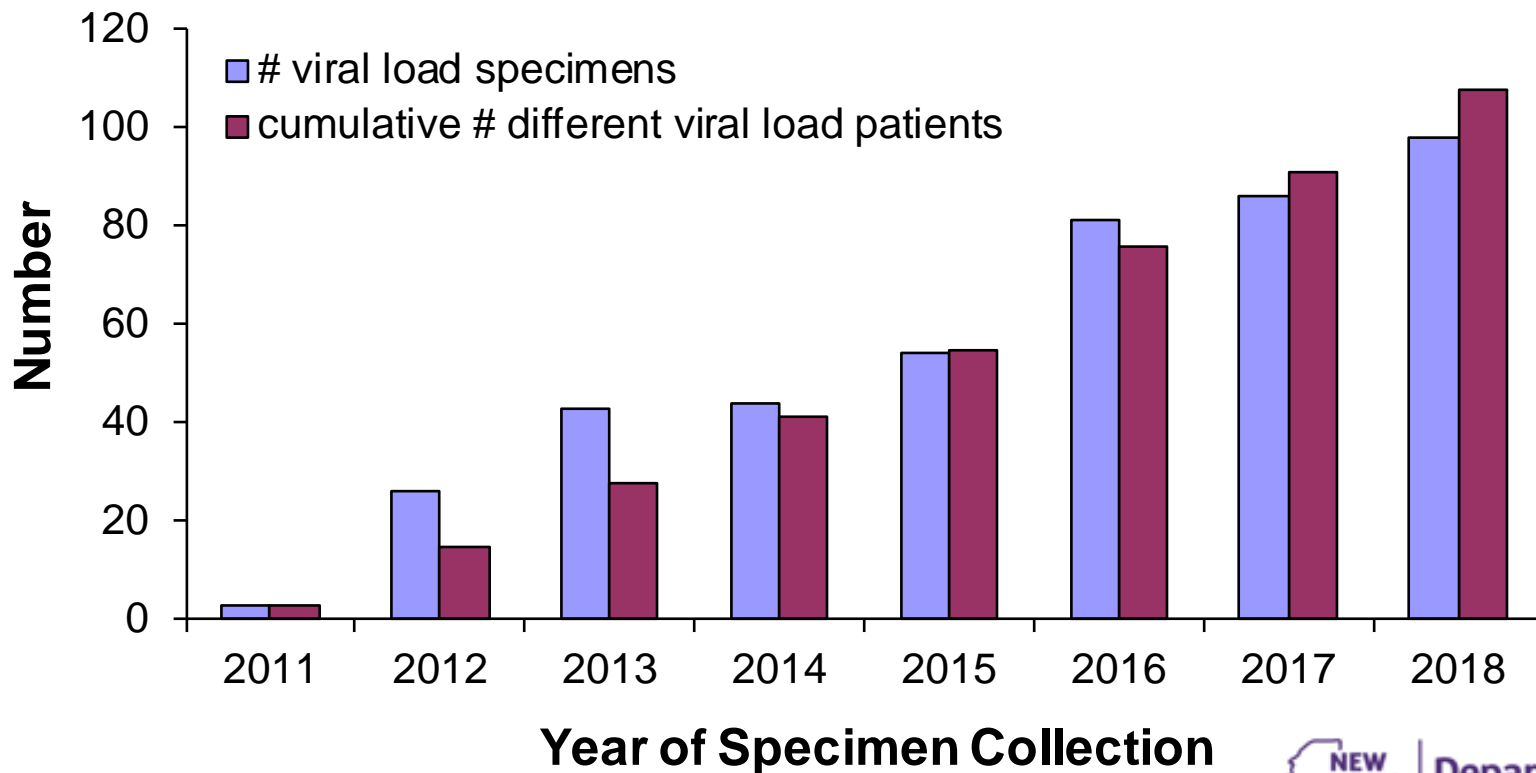
Random Hexamer

4. DUPLEX REAL TIME PCR



LOD: 7 IU/ml (0.9 mL), 32 IU/ml (0.2 mL)
LLOQ: 41 IU/ml (0.9mL), 185 IU/ml (0.2mL)

Since 2011, tested 434 specimens from 108 HIV-2 infected patients



Confirm HIV-2 infection with antibody & RNA testing

Test	Result	# Patients	Additional Results
HIV-2 RNA	HIV-2 RNA Detected	23	No sample left for Ab testing
Multispot n=47	HIV-2 Positive	46	
	HIV Undifferentiated	1	HIV-1 RNA D, HIV-2 RNA D
Geenius n=38	HIV-2 Positive w/ HIV-1 CR	17	
	HIV-2 Positive	16	
	HIV Positive, Untypable	1	HIV-2 VL: 3000 IU/ml
	HIV-2 Indeterminate (gp36 only)	1	HIV-2 DNA detected
	HIV Indeterminate (gp36, gp41)	1	HIV-2 Pos, 10 months later
	Negative	1	HIV-2 RNA Detected
	HIV-1 Positive (gp36, gp160, gp41)	1	HIV-2 VL: 1000 IU/ml

Total 108



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Case 1: HIV-2 viral load specimen, Geenius negative

Date	HIV-2 VL	Geenius	HIV Ag/Ab
March 2017	Not Detected	Negative	Reactive, 13.3
August 2017	HIV-2 RNA Detected	Negative	Reactive, 18.3
October 2017	Not Detected	Negative	Reactive, 11.5
October 2018	200 IU/ml	Negative	Reactive, 10.3

Patient from Cape Verde. HIV-2 WB positive in 2011 (CDC).
On ARV treatment. No immune system abnormalities.

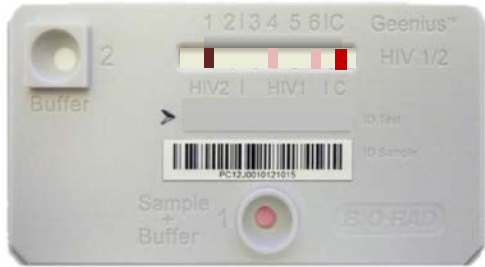


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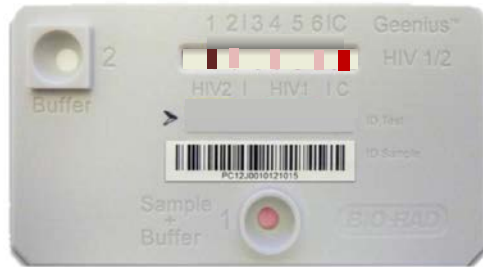
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Case 2: HIV-2 viral load specimen, Geenius HIV-1 Pos

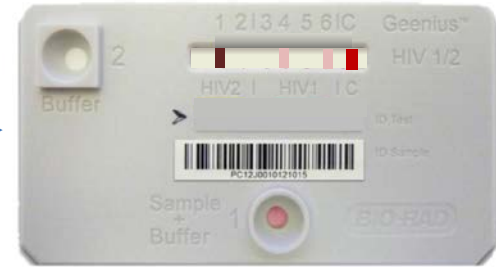
Date	HIV-2 VL	Geenius	HIV Ag/Ab	HIV-1 RNA
Oct 2018	1200 IU/ml	HIV-1 Positive	Reactive, 95	Not Detected



“HIV-1 Positive”



“HIV-2 Positive w/ HIV-1 CR”



“HIV-1 Positive”

Patient from Ivory Coast. Tested with HIV-1 viral load since 2004 (undetectable). March 2018 HIV Ag/Ab and Geenius HIV-2 Positive. Patient on ARV treatment.



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Demographics of 108 HIV-2 Viral Load Patients

Age	#	%
0-19	3	3%
20-29	0	0%
30-39	7	6%
40-49	14	13%
50-59	47	44%
60-69	29	27%
70-79	6	6%
>79	2	2%

Mean Age = 55 years

Sex	#	%
Male	50	46%
Female	58	54%

Residence	#	%
New York City	67	62%
Rest of New York State	5	5%
Out-of-State (26 from contracted facility in MA)	36	33%

Race/Ethnicity	#	%
Black	87	81%
Unknown	14	13%
White/Hispanic	3	3%
White/Unknown	2	2%
Native American	1	1%
Pacific Islander	1	1%

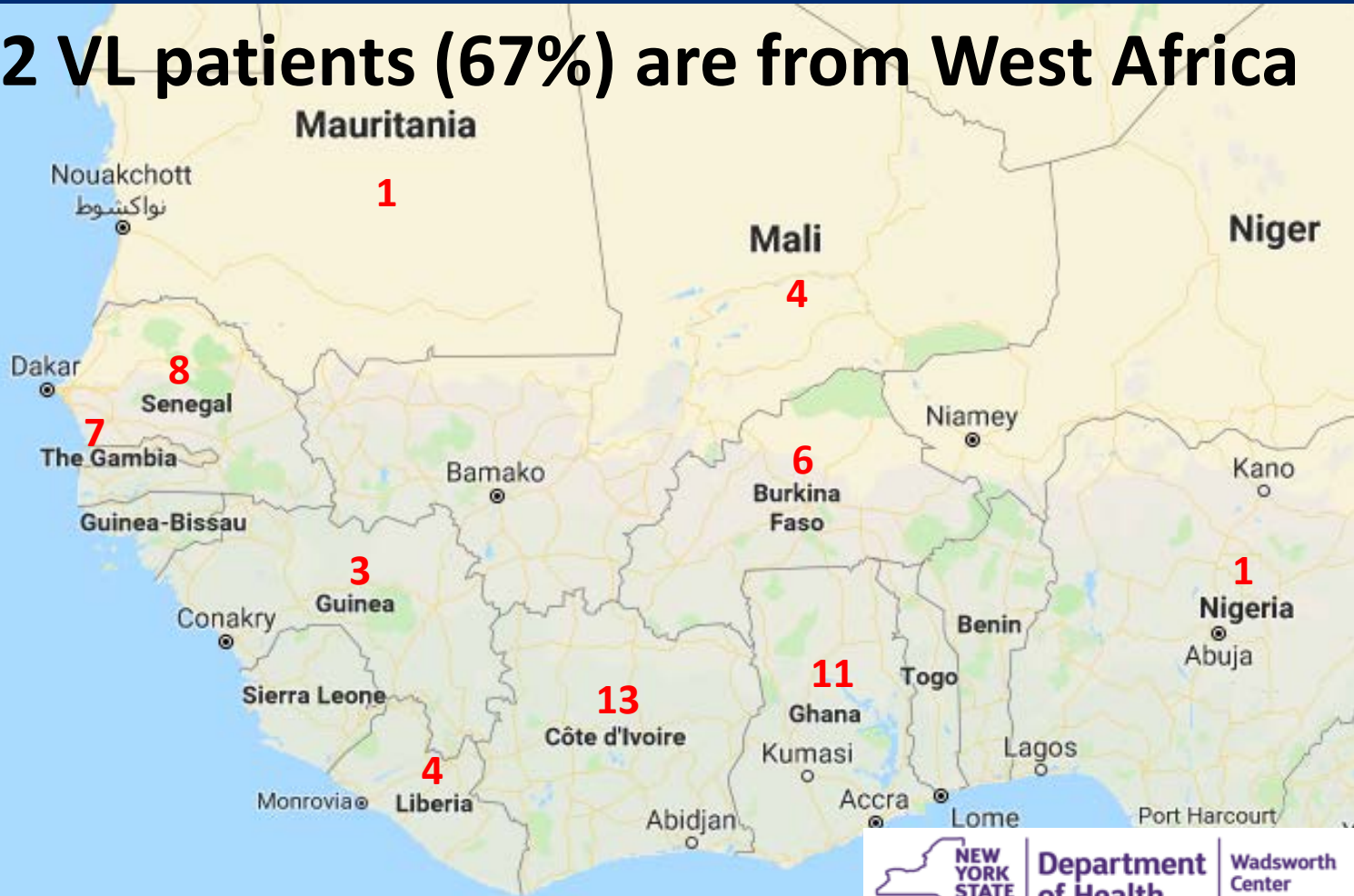


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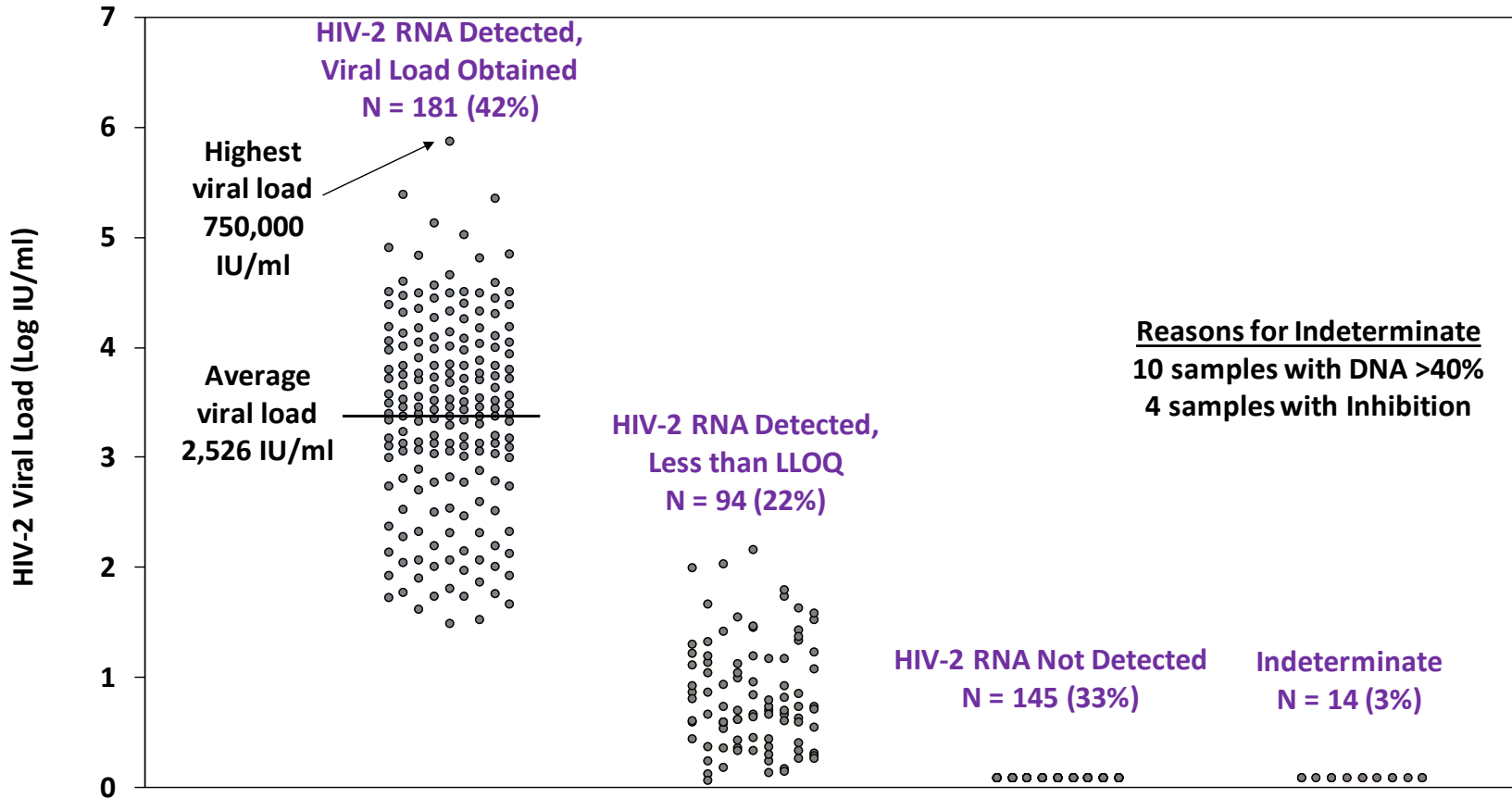
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Most HIV-2 VL patients (67%) are from West Africa

Cape Verde	14
Central Africa	2
East Africa	2
Mexico	2
India	1
Pakistan	1
Unknown	28



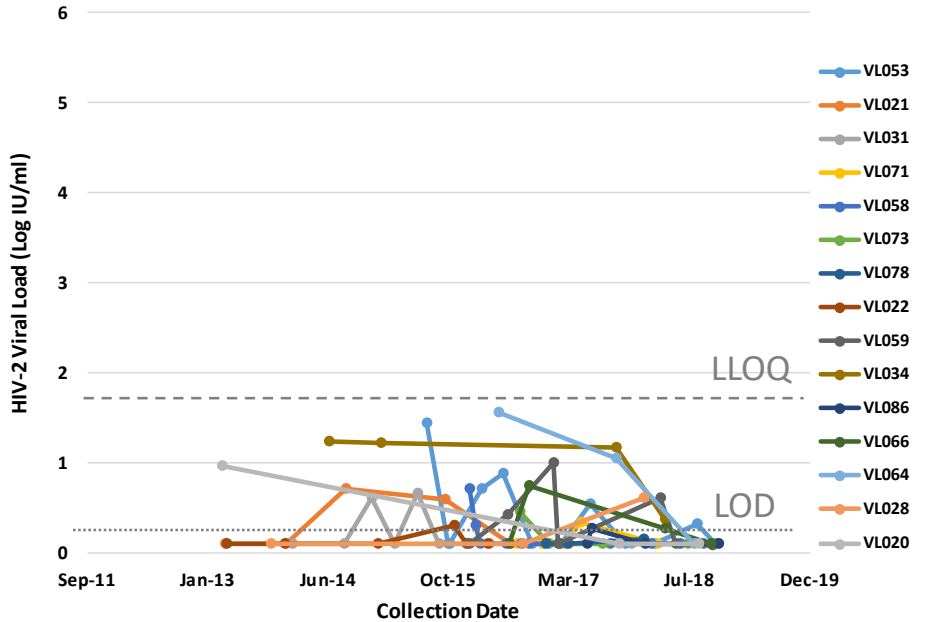
Summary of HIV-2 Viral Load Results by Specimen



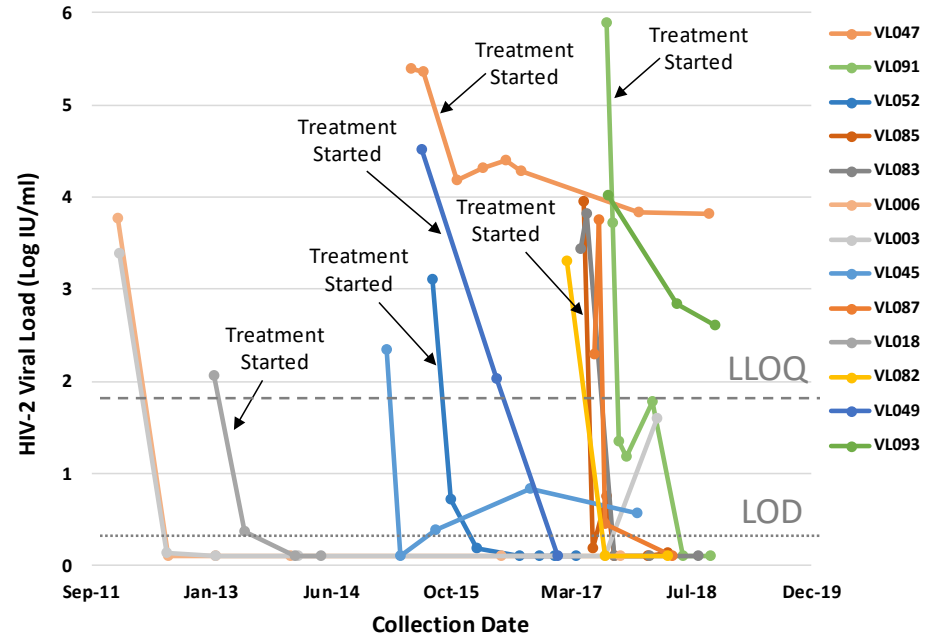
HIV-2 Viral Load Patterns in 53 Patients with ≥ 3 specimens

RNA Detected $<LLOQ$

15 (28%)



Successful Treatment (>1.5 log drop) 13 (25%)

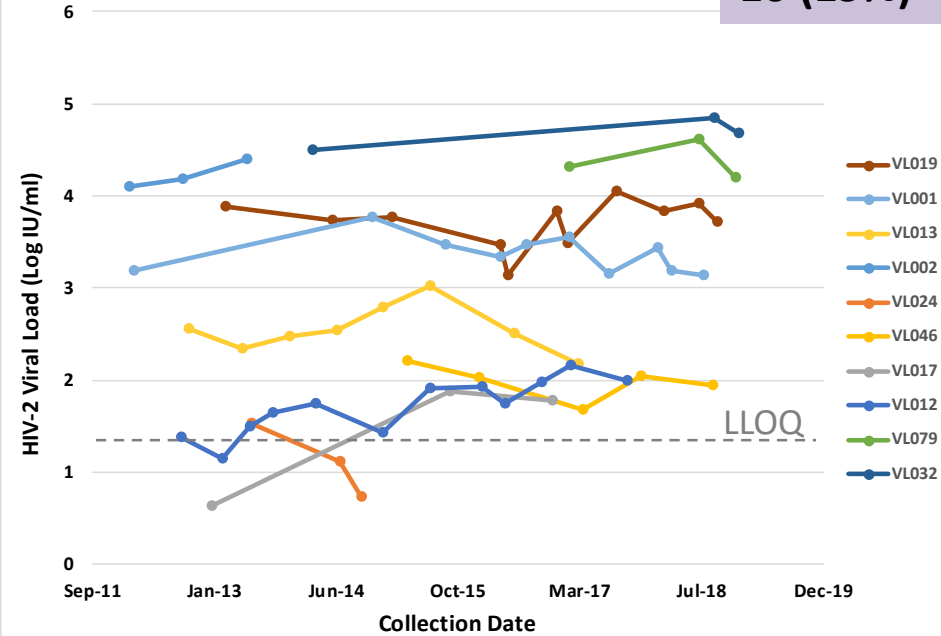


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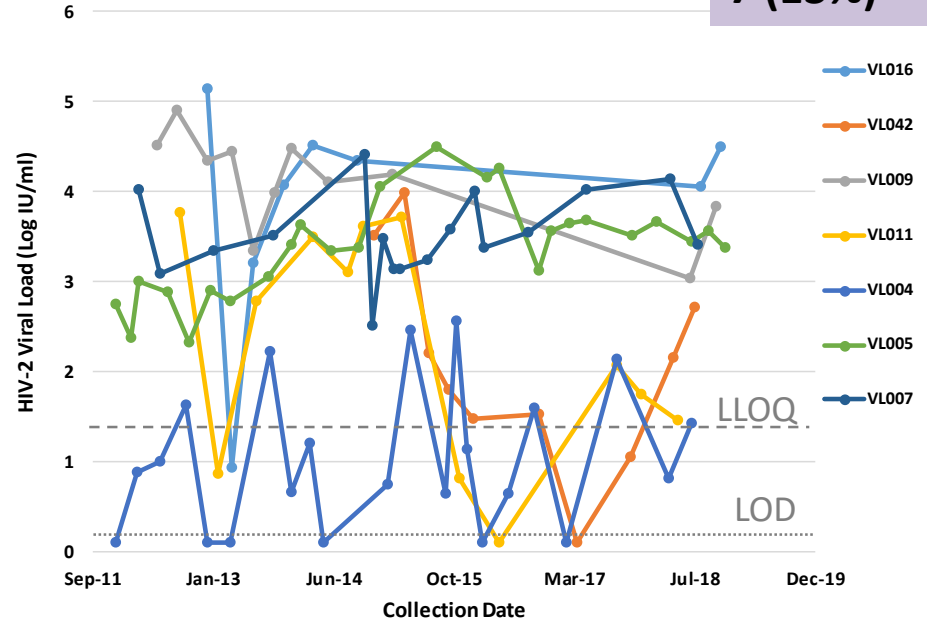
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HIV-2 Viral Load Patterns in 53 Patients with ≥ 3 specimens

Consistent Viral Load Values 10 (19%)

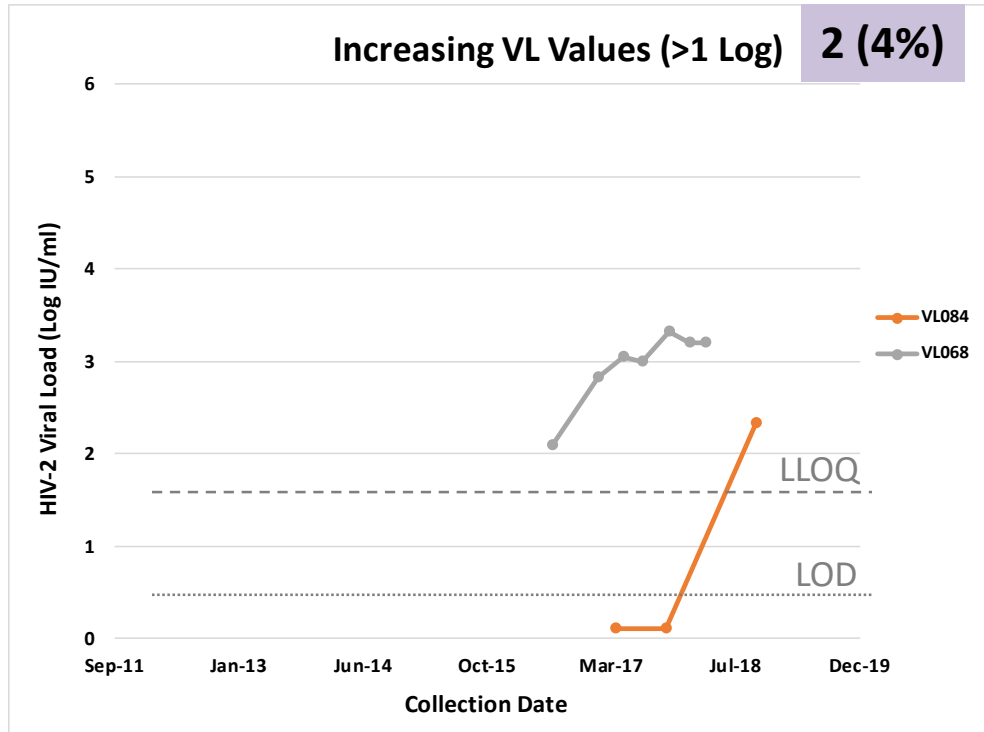


Fluctuating VL Values 7 (13%)



HIV-2 Viral Load Patterns in 53 Patients with ≥ 3 specimens

6 (11%)
RNA not
detected



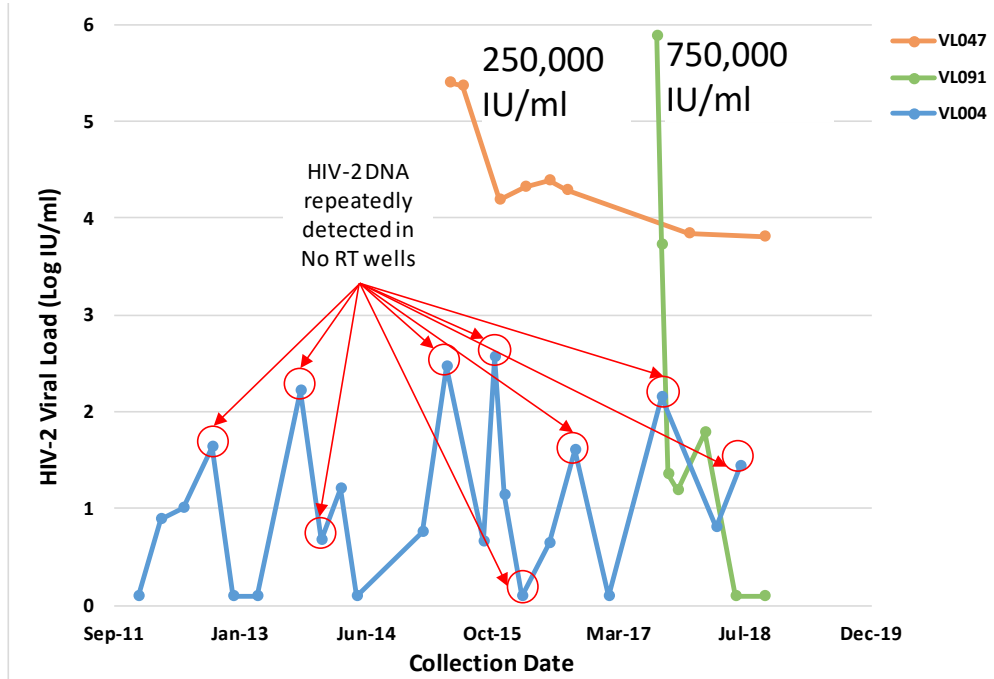
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Unusual HIV-2 Viral Load Cases

HIV-2 DNA in plasma

Black male,
50-60 years
On hemo-
dialysis,
kidney
transplant
in 2015



High HIV-2 Viral Load ($\geq 250,000$ IU/ml)

1. Black male, 15-19 years, poor response to treatment
2. Black female, 30-35 years, neurological symptoms, CSF VL = 7142 IU/ml, excellent treatment response



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Conclusions

- HIV-2 viral load testing is vital part of clinical care of HIV-2 infected patients
- Although HIV-2 viral loads are generally low, values above 10,000 IU/ml are not uncommon
- We have tested more than 100 different HIV-2 infected patients



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