ATLANTA VA MEDICAL CENTER MICROBIOLOGY LABORATORY , Decatur, GA

AMPLIPREP WASH REAGENT **YEAR_____**

Record the date opened, lot number, expiration date, and initial each time reagent is changed.

DATE OPENED/CHANGED	LOT NUMBER	EXPIRATION DATE	INITIALS

Form 2/5/10 jw

ATLANTA VAMC MICROBIOLOGY LABORATORY ROCHE HIV-1 HIMCAP PCR KIT (Version2)

HIV PCR DAILY RUN QUALITY CONTROL LOT NUMBER T15622 Date kit received 10-22

-2015

Kit exp 01-31-2017 ***temporary ranges set at manufacturer mean +- .3 log.*** *Floating for at least 10 points; to be set.*

DATE of TESTING:	EACH RUN: EXTERNAL QC with KIT	Acceptable ranges +-3SD (LOG):	Actual result (LOG):	Accepted? Yes/No	Run Number (1, 2, 3...)	Tech Initials	Comments
	CTM (-) C	TND					
	HIV-1 L(+)C	2.34-2.94 LOG					
	HIV-1 H(+)C	5.20-5.80 LOG					
DATE of TESTING:	EACH RUN: EXTERNAL QC with KIT	Acceptable ranges +-3SD (LOG):	Actual result (LOG):	Accepted? Yes/No	Run Number (1, 2, 3...)	Tech Initials	Comments
	CTM (-) C	TND					
	HIV-1 L(+)C	2.34-2.94 LOG					
	HIV-1 H(+)C	5.20-5.80 LOG					
DATE of TESTING:	EACH RUN: EXTERNAL QC with KIT	Acceptable ranges +-3SD (LOG):	Actual result (LOG):	Accepted? Yes/No	Run Number (1, 2 ,3...)	Tech Initials	Comments
	CTM (-) C	TND					
	HIV-1 L(+)C	2.34-2.94 LOG					
	HIV-1 H(+)C	5.20-5.80 LOG					
DATE of TESTING:	EACH RUN: EXTERNAL QC with KIT	Acceptable ranges +-3SD (LOG):	Actual result (LOG):	Accepted? Yes/No	Run Number (1, 2 ,3...)	Tech Initials	Comments
	CTM (-) C	TND					
	HIV-1 L(+)C	2.34-2.94 LOG					
	HIV-1 H(+)C	5.20-5.80 LOG					

REVIEWED BY_____DATE_____ (NOTE any CORRECTIVE ACTIONS on REVERSE OF THIS FORM.)

ATLANTA VAMC MICROBIOLOGY **ROCHE HIV-1 HIMCAP PCR KIT (Version2) HIV PCR**

NEW LOT, or NEW SHIPMENT

CROSS-CHECK QUALITY CONTROL Kit LOT NUMBER_____ Date rec'd in lab_____Exp_____

CROSS-CHECK: 1. Is this a new shipment, same lot number? Is this a new shipment, NEW lot number? Is this run after computer or major system maintenance? Every 30 days?	Yes/No Yes/No Yes/No Yes/No	If YES to NEW LOT/shipment: perform external QC and all three patient/surrogate QC (along with known negative patient test from previous lot or shipment). If YES to computer maintenance, major system repairs/30 days: perform external QC and patient (surrogate Low/Mid/High) QC only.			If YES, continue with cross-check. If NO, no further action is required.
1) AcroMetrix Low QC from Freezer		Acceptable range (LOG): +-3SD	Actual result (LOG):	Accepted? Yes/No	Comments
2) AcroMetrix Mid QC from freezer		Acceptable range (LOG): +-3SD	Actual result (LOG):	Accepted? Yes/No	Comments
3) AcroMetrix HIGH QC from freezer		Acceptable range (LOG): +-3SD	Actual result (LOG):	Accepted? Yes/No	Comments
4) A known TND negative patient tested using previous lot		Expected result (LOG): <1.3 log (TND)	Actual result (LOG):	Accepted? Yes/No	Comments
CROSS-CHECK ACCEPTED?	Yes/No		Action: Place green stickers on kits that have passed Cross-check.		

Tech_____ Date of Testing_____ Daily RUN # (1, 2, 3,...) _____

Reviewed by_____ Date_____

CORRECTIVE ACTION:

_____

_____

ATL VAMC MICROBIOLOGY LABORATORY

HIV PCR VIRAL LOAD: ROCHE VERSION 2 HIV KITS

kit lot NUMBER	Date kit lot REC'D	Date kit lot PLACED IN USE

ATL VAMC HIV PCR VIRAL LOAD
ROCHE VERSION 2.0
QUALITY CONTROL

Average Standard Deviation using several batches of product lot numbers:

	LPC	HPC	Surrogate 1:100	Surrogate 1:100,000	
Lot#					
Lot#					
Lot#					
Lot#					
Lot#					
Lot#					
Lot#					
Lot#					
Lot#					

Date calculated: _____ Tech _____

Running Average SD					

Date calculated: _____ Tech _____

Running Average SD					

Date calculated: _____ Tech _____

Running Average SD					

Date calculated: _____ Tech _____

Running Average SD					

2013

HIV PCR VIRAL LOAD CALCULATION OF MONTHLY QC STATISTICS

NOTES

When a new lot/new shipment of HIV PCR manufacturer's QC material (or patient surrogate QC material) arrives, perform the following steps:

1. When less than 10 data points are available, historical target mean and target SD will be used to calculate, "Are values within +- 3SD of calculated laboratory mean?"

   This means that we can "fix" the SD for purposes of daily monitoring until 10 points have been accumulated. Note this on the **daily run QC sheet**.

   To "fix" the tightened range for purposes of accepting a daily run:
   a) First, calculate the manufacturer folded mean and accepted ranges for each QC material
   b) Second, calculate +-0.3 log around the manufacturer folded mean (CLSI) – **THIS IS GOING TO BE THE ACCEPTED / FIXED RANGE for now. (For new surrogate QC, calculate +-0.2 log around the expected mean, according to CLSI.)**
   c) Once enough points have been obtained (see "2" below), you can "fix" a temporary, tighter+-3SD range based on the historic running SDs. **Use this tighter range on the daily run QC sheet, but NOT on the end-of-month LJ chart calculations.**

2. Once enough data points are available, the mean and SD calculated by the Excel spreadsheet will be used to calculate, "Are values within +-3SD of calculated laboratory mean?"

   This means that we can then "float" the mean and SD for purposes of monthly monitoring after we have reached at least 10 data points. Be sure to note this on the **end-of-month QC (LJ chart)** and **monthly review** form. (Note which mean and SD you chose to calculate the monthly statistics.)

3. If it appears that many data points are available but ranges are too tight, reset based on the floating mean at the close of the month. Note on QC review form.

Always note when (the date) that any ranges were set, or re-set, and what values were used in calculating the ranges (whether on the daily QC sheet, or on the end-of-month QC (LJ chart) and monthly QC review forms.

Jw 2/3/2013

Roche Ampliprep Taqman HIV PCR viral load VERSION2
System software up-grade date: _____
Cross-Check QC

Accn Lot R00580 Lot_____

HIV ACCN	Date: actual result (log)	Date: actual result (log)	Comments
1:100 surrogate	5/16 5.20		
1:100000 surrogate	5/16 2.38		
CAP06	5/29 2.83		
CAP07	5/29 6.05		
CAP08	5/29 TND		
CAP09	5/29 4.14		
CAP10	5/29 5.05		
0509 16	6/4 <1.3 VD		
0529 68	6/4 3.48		
0530 26	6/4 TND		
0530 28	6/4 TND		
0531 49	6/4 5.05		
0531 48	6/4 4.66		
0530 36	6/4 1.70		
0530 46	6/4 3.92		
0530 20	6/4 <1.3 VD		
0530 21	6/4 <1.3 VD		
0530 1	6/4 1.55		
0522 93	5/29 5.85		
0521 57	5/29 2.65		
0521 53	0529 TND		

REVIEWED BY _____DATE _____

Monthly REVIEW of HIV PCR VIRAL LOAD QUANTITATIVE QC:

ATL VAMC MICROBIOLOGY LAB MONTH YEAR

MANUFACTURER QC		
1. For NC: Is all QC within Target not Detected range?	Check obtained values with expected Target not Detected result.	OK? Yes/No
2. For QC (LPC and HPC): Is all QC within calculated manufacturer folded ranges?	Compare obtained values with calculated range	OK? Yes/No
3. For QC (LPC and HPC): Is the obtained mean (and all obtained values) within +-0.3 log of calculated manufacturer folded mean?	Compare obtained values with calculated range	OK? Yes/No
4. For QC (LPC and HPC): Are all values within +-3SD?	Look at LJ Chart	OK? Yes/No
5. For QC (LPC and HPC): Are all values within 10x rule?	Look at LJ Chart – no more than 10 consecutive values on either side of the lab mean?	OK? Yes/No
SURROGATE QC (AcroMetrix or Patient QC)		
1. For Surrogate QC (Low/Mid/High): Is the obtained mean (and all obtained values) within +-0.2 log of calculated (expected) mean?	Compare obtained value with expected mean	OK? Yes/No
2. For Surrogate QC (Low/Mid/High): Are all values within +-3SD?	Look at LJ Chart	OK? Yes/No
3. For Surrogate QC (Low/Mid/High): Are all values within 10x rule?	Look at LJ Chart – no more than 10 consecutive values on either side of the lab mean?	OK? Yes/No
PM/Corrective Actions		
1. Review monthly pm sheet(s) and Ampliprep logs	Pull Ampliprep/Taqman service/pm logs from Amplilink computer. Review.	OK? Yes/No
2. Review any corrective actions/occurences for the month	Review any separate corrective actions/comments	OK? Yes/No

Reviewed by _____

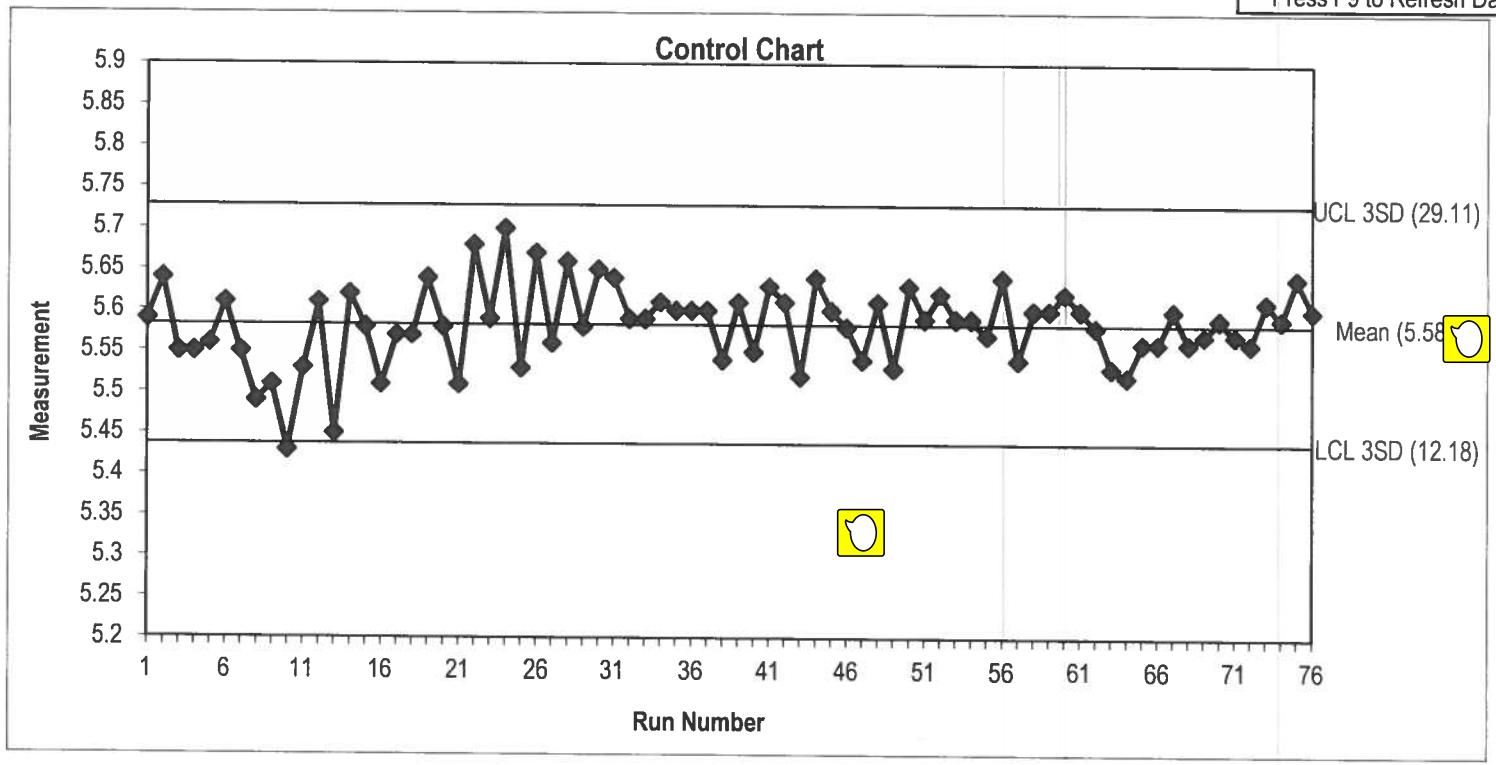
Comments _____

_____

ROCHE HIV PCR viral load PCR
LOT S18246 HPC FEB 2015

Control Chart		UCL +3SD	Mean + 2 SD	Mean + 1 SD	Mean	Mean - 1 SD	Mean - 2 SD	LCL + 3SD	StDev
Run Number	Measurement	5.728139801	5.67968092	5.631222039	5.582763158	5.534304277	5.485845396	5.437386515	0.048458881
1	5.59								
2	5.64								
3	5.55								
4	5.55								
5	5.56								
6	5.61								
7	5.55								
8	5.49								
9	5.51								
10	5.43								
11	5.53								
12	5.61								
13	5.45								
14	5.62								
15	5.58								
16	5.51								
17	5.57								
18	5.57								
19	5.64								
20	5.58								
21	5.51								
22	5.68								
23	5.59								
24	5.7								
25	5.53								
26	5.67								
27	5.56								
28	5.66								
29	5.58								
30	5.65								
31	5.64								
32	5.59								
33	5.59								
34	5.61								
35	5.6								
36	5.6								
37	5.6								

5.52 Target Mean
0.084 Target SD
Press F9 to Refresh Data



1. Are all values within manufacturer (calculated) folded ranges?
Range in log: Acceptable: Yes / No
2. Are values within ±0.3 log of calculated manufacturer folded mean?
Range in log: Acceptable: Yes / No
3. Are values within ±3SD of calculated laboratory mean? (Using derived floating Excel mean of _____log and floating SDs)
Range in log: Acceptable: Yes / No
4. Do all values adhere to 10x rule? Acceptable: Yes / No

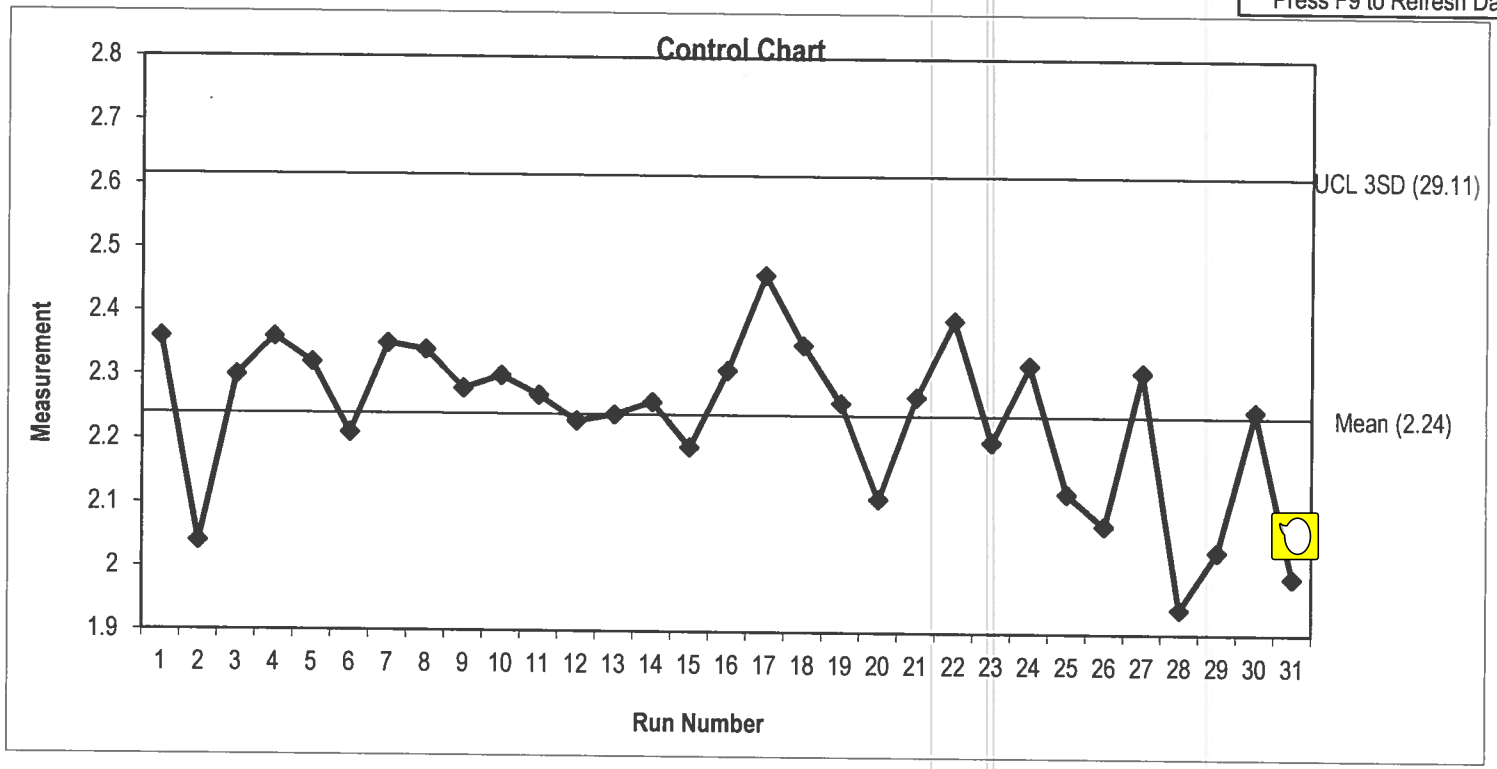
Reviewed by: Technologist _____Date_____; Supervisor _____Date_____

38	5.54
39	5.61
40	5.55
41	5.63
42	5.61
43	5.52
44	5.64
45	5.6
46	5.58
47	5.54
48	5.61
49	5.53
50	5.63
51	5.59
52	5.62
53	5.59
54	5.59
55	5.57
56	5.64
57	5.54
58	5.6
59	5.6
60	5.62
61	5.6
62	5.58
63	5.53
64	5.52
65	5.56
66	5.56
67	5.6
68	5.56
69	5.57
70	5.59
71	5.57
72	5.56
73	5.61

74	5.59
75	5.64
76	5.6

ROCHE HIV PCR viral load PCR
ACROMETRIX LOW as of DECEMBER 2015

Control Chart			UCL +3SD	Mean + 2 SD	Mean + 1 SD	Mean	Mean - 1 SD	Mean - 2 SD	LCL + 3SD	StDev	2.3	Target Mean
Run Numb	Measurement	Month Ran	2.615135849	2.489983039	2.364830229	2.239677419	2.11452461	1.9893718	1.86421899	0.12515281	0.089	Target SD
											Press F9 to Refresh Data	
1	2.36											
2	2.04											
3	2.3											
4	2.36											
5	2.32											
6	2.21											
7	2.35											
8	2.34											
9	2.28											
10	2.3											
11	2.27											
12	2.23											
13	2.24											
14	2.26											
15	2.19											
16	2.31											
17	2.46											
18	2.35											
19	2.26											
20	2.11											
21	2.27											
22	2.39											
23	2.2											
24	2.32											
25	2.12											
26	2.07											
27	2.31											
28	1.94	Nov-15										
29	2.03	Nov-15										
30	2.25	Nov-15										
31	1.99	Dec-15										



1. Are all values within manufacturer (calculated) folded ranges?
Range in log: N/A for AcroMetrix Acceptable: Yes / No
2. Are values within ±0.2 log (CLSI) of calculated manufacturer folded mean?
Range in log: 2.10-2.50 LOG Acceptable: Yes / No
3. Are values within ±3SD of calculated laboratory mean? (Using derived/floating Excel mean of _____log and floating SDs)
Range in log: 1.86-2.62 LOG Acceptable: Yes / No
4. Do all values adhere to 10x rule? Acceptable: Yes / No

Reviewed by: Technologist _____Date_____; Supervisor _____Date_____

2.1 2.5