

03 March 2014

VQA HIV GEN Proficiency Testing Program for HIV Integrase (INT)

The VQA has been collecting data for HIV GEN proficiency testing for the integrase (INT) gene from testing laboratories unofficially since GEN020 in November of 2010. To date, reports for these rounds of testing included alignments, homology tables and mutation calls (samples tested during this period contained polymorphisms but no actual integrase drug resistance mutations), but no scores. In an effort to start evaluating data sets officially, the VQA Statistical Group (SAG) at RTI compiled the data from the last three round of testing and applied scoring rules to the data sets. The same rules used for scoring reverse transcriptase (RT) and protease (PR) genes were used for scoring integrase. A watch region was selected to include amino acids associated with integrase-inhibitor drug resistance based on the report by the IAS-USA dated March 2013. Scores were determined for all submitted sequences from GEN022 through GEN025 and those scores were reported in a memo to the VQAAB from the VQA Statistical Group (SAG) at RTI dated 10 December 2013 (refer to the Integrase Consolidated Summary Report).

To summarize, 1-4 data sets were submitted by 24 laboratories over the four rounds of testing (Table 1). Five laboratories submitted data generated with a ViroSeq RUO (VS) assay; and 19 laboratories submitted data generated with an internally developed (IH) assay. Scores varied across the laboratories and panels. A total of 6 laboratories participated in and received scores of C for all 4 rounds of testing. As with the HIV GEN proficiency testing for RT and PR gene regions, the VQA will require that a laboratory pass 2 five-member panels as prequalification, then pass a minimum of two more panels, with a score of C to become fully approved. Based on these criteria, the six laboratories with scores of C on all four rounds of testing would be considered "Approved" for HIV GEN INT testing. The remaining laboratories will be listed as "Not Rated or Provisionally Approved" depending on the scores obtained during this unofficial period. Laboratories may be permitted to test historical panels in order to fast-track their approval rating (see VQA GEN Participation Document). If this proposal is approved by the network leadership, this proficiency testing program, and the resultant scores will become official with the scoring of the GEN026 panel, which should be completed in Feb 2014.

VQA HIV GEN participation and scoring documents have been updated to include testing for RT, PR and INT. Once these documents are finalized, they will be distributed to participating laboratories and posted on the HANC website. Laboratories that have achieved an "Approved" rating will receive Change in Status letters. Laboratories that have not achieved an "Approved" rating may contact the VQA laboratory in order to receive additional panels if they are interested in fast-tracking their approval. Ongoing proficiency will be monitored per the regular proficiency testing schedule.

VQA Proposal for VQAHIV GEN-INT Proficiency Testing

Table 1: Proposed Scoring and Approval Rating for HIV GEN-INT Data Sets/Laboratories Based on Results Submitted During Observation Period

HIV DRUG RESISTANCE GENOTYPING PROFICIENCY TESTING							New Score			
CUMULATIVE CERTIFICATION RESULTS FOR PANELS GEN022-INT (Nov 2011) thru GEN025-INT (May 2013)							Recent Score			
							On Hold (OH), WITHDRAWN (WD), OR SWITCHED PLATFORMS (SW)			
							Exception			
							Change in Status			
							Score overturned by VQAAB			
LAB	SERIES MONTH YEAR	KIT*	GEN022	GEN023	GEN024	GEN025	PS**	Previous Status	Current Status	Comment
			11	5	11	5				
			11	12	12	13				
1		IH	PC	C	C	PC ^C	6	NR	PA	
2		VS	PC	C	C	C ^C	5	NR	PA	
3		TG	PC	C	C	C ^C	5	NR	PA	
4		IH			P	C	5	NR	NR	
5		IH	C	C	C ^C	C	4	NR	A	NEW LETTER - NEWLY APPROVED
6		IH	C	C	C ^C	C	4	NR	A	NEW LETTER - NEWLY APPROVED
7		VS	C	C	C ^C	C	4	NR	A	NEW LETTER - NEWLY APPROVED
8		IH	C	PC	C	PC ^C	6	NR	PA	
9		VS	C	C	C ^C	C	4	NR	A	NEW LETTER - NEWLY APPROVED
10		VS	C		C	C ^C	3	NR	PA	
11		IH	PC	C	C	C ^C	5	NR	PA	
12		VS			P		4	NR	NR	
13		TG			C		1	NR	NR	
14		IH		C	C	C ^C	3	NR	PA	
15		IH	C		C		2	NR	PA	
16		IH			C		1	NR	NR	
17		IH	C	C	C ^C	C	4	NR	A	NEW LETTER - NEWLY APPROVED
18		IH			C		1	NR	NR	
19		IH	C				1	NR	NR	
20		IH	P		P		8	NR	NR	
21		IH	C				1	NR	NR	
22		IH	P				4	NR	NR	
23		IH			PC		2	NR	NR	
24		IH	C	C	C ^C	C	4	NR	A	NEW LETTER - NEWLY APPROVED

*KIT=Commercial kit used in latest round of proficiency testing;
 VS = ViroSeq, TG = TruGene, IH = In House Assay;
 **PS=Performance score over the last four certification rounds;
 (C=Certified, PC=Provisionally Certified, P=Probational,