

Reinventing blood safety

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Utility of External Run Control for NAT Screening

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Background:

Procleix HIV-1/HCV Assay have been routinely implemented and samples tested are subdivided on average into 3 analytical sessions, range between 300 and 1000 units. The samples tested on each day are almost validated by the end of the day.

Materials and Methods:

A run control is included in each analytical run. In compliance with the European Guidelines, this control must have a concentration of 3 times the Detection Limit and lower than 100 IU/ml. Such a run control was initially prepared with the ISS HCV RNA 0498 Standard produced by the Italian Superior Institute of Health (ISS) diluted to a final concentration of 30 IU/ml. We studied the inter-series and intra-series analytical variation for this control. Furthermore, we assessed the variation of the method by using a negative plasma sample (NP) and a weakly reactive plasma sample (10 IU/ml).

		INTER-series	INTRA-series
30 IU/ml STD	n	36	20
	Ratio	7.47	7.38
	SD	1.33	1.12
	CV	17.80	15.18
10 IU/ml STD	n	36	20
	Ratio	6.33	6.48
	SD	1.64	1.47
	CV	25.9	22.68
NEGATIVE PLASMA	n	36	20
	Ratio	0.15	0.18
	SD	0.02	0.04
	CV	13.33	22.22

The ISS prepared a new standard, ISS0102, which is presently under study and will be tested in all analytical sessions, once defined its concentration. A new statistical analysis will be performed and relevant data presented.

Conclusion:

Even if the Ministerial Circular does not mention it and the Guidelines of ISS states that no reference preparations or panels are required when using routinely kits approved by the Ministry of Health with positive, negative and internal controls, we believe that a run control with a low viral load is able to detect even minimal deviations in the assay performance, which kit controls are not able to detect. In addition, this also allows keeping under statistical control the whole technology overtime.