
GREY ZONE UTILITY FOR MOLECULAR BIOLOGY TECHNIQUES EXPERIENCE IN ROUTINE WORK (P-286)

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INTRODUCTION

Since June 2003, in our Blood bank all blood donations have been screened for the three viruses (HIV, HCV, HBV) using a genome detection technique (NAT: PROCLEIX® ULTRIO® Assay). The manufacturer doesn't consider intermediates zones for results interpretation.

OBJECTIVE

To evaluate the utility of a security zone "Grey Zone" (GZ) in donations screening using NAT tests, facilitating the detection of false positive results.

MATERIAL AND METHODS

Results interpretation is performed automatically by the Assay software. For a sample with Analyte value signal less than the Analyte Cutoff (i.e., Analyte S/CO < 1), the sample is reported as Nonreactive. For a sample with the Analyte signal greater than or equal to the Analyte Cutoff (i.e., Analyte S/CO ≥ 1) the sample is reported as Reactive. Samples with S/CO values between 0.80 and 0.99 have been considered as GZ.

Reactive Samples or samples in GZ, are tested in duplicate, and when one of the repetitions is reactive, the dHIV, dHCV and/or dHBV tests are performed.

RESULTS

Since the 28th of June 2003 until December 2006, 82.022 samples have been tested. 66 samples of those 82.022 (0.08%) were considered as a GZ.

The repetition of those 66 samples in duplicate was negative.

Moreover, the dHXV assays were performed for 31 of those 66 samples, and all of them were negative.

Table 1. S/CO Values of GZ Samples

	1st lecture	2nd lecture
Average	0,86	0,14
Statistical mode	0,82	0,09
Range	0,80-0,99	0,01-0,71

CONCLUSIONS

This technique is cualitative, so the results can be considered as absolute. A Grey Zone establishment doesn't increase the security of the assay, but increases the cost and laboratory work.