

HTRF® Research Reagents

Anti Mouse-XL Quality Control

Product number : 61PAMXLB Lot Number : 12RW

Manufacturing date : 28/08/2003 Document version : 1

EXPERIMENTAL CONDITION

The batch to be controlled was compared to the reference batch currently in use, at increasing Anti Mouse-XL concentrations.

Anti Mouse-XL is lyophilized in PO4 buffer 100 mM pH7 ; 0.1% BSA ; Stabilizers.

All the reagents involved were diluted in PPI-Europium detection buffer (#61DB9RDF).

ASSAY FORMAT

Chèvre-XL / Anti Mouse-XL + IgG1-K

REAGENTS

	REFERENCE LOT NUMBER	ASSAY CONCENTRATION
IgG1-K	CQ01	0.42 nMf
Anti Mouse-XL reference	09GA	0.42 - 3.36 nMf
Ab Chèvre-XL	CQ01	0.42 - 3.36 nMf

	CURRENT BATCH LOT NUMBER	ASSAY CONCENTRATION
Anti Mouse-XL current batch	12RW	0.42 - 3.36 nMf

Other reagents were the same as those used for the reference test.

EXPERIMENTAL PROCEDURE

Reconstitute Anti Mouse-XL vial with 250 µL H2O (if packaged under 5,000 tests or 1,000 tests) or 1 mL H2O (if packaged under 20,000 tests).

Reagents were dispensed as follows :

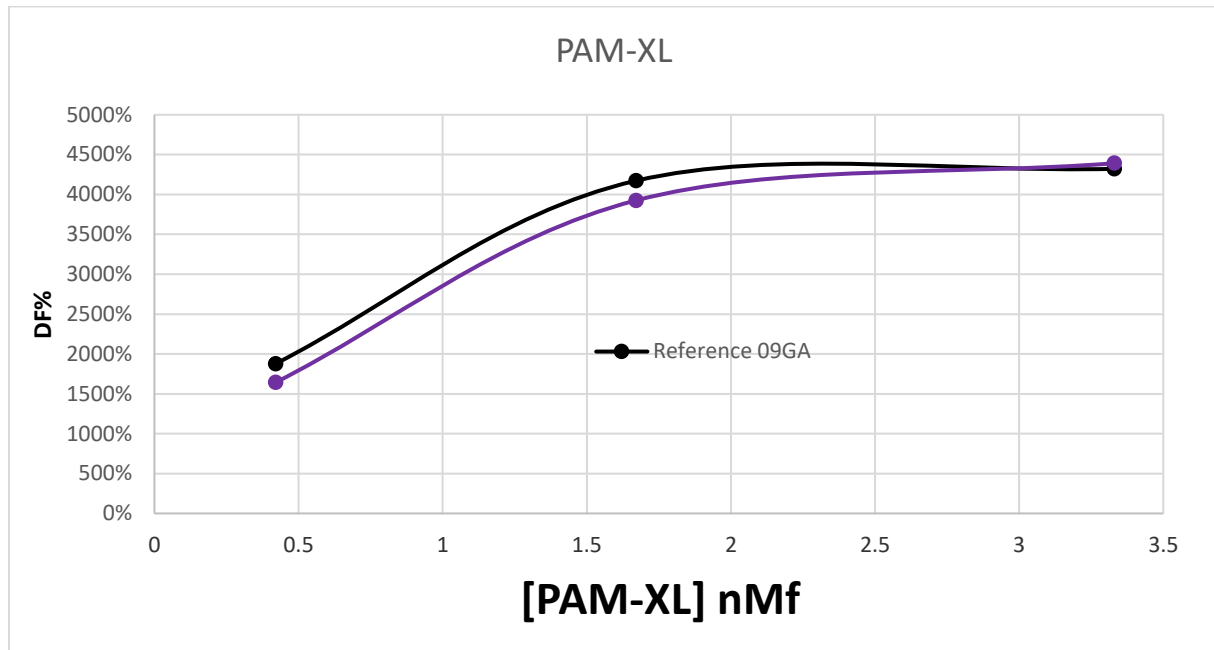
- 5 µL XL conjugate
- 10 µL PPI-Europium detection buffer (#61DB9RDF)
- 5 µL K conjugate

Incubation took place for 120 min at room temperature. The plate was read on Ruby Star ® under standard conditions.

RESULTS

[Anti-Mouse-XL] nMf		Anti Mouse-XL Reference	Anti Mouse-XL CURRENT BATCH	VARIATION	MEAN ACCEPTABLE VARIATION
0.42	% Delta F % CV	1877 % 0.5 %	1642 % 1.0 %	-12.5 %	-5.6 %
1.68	% Delta F % CV	4172 % 0.4 %	3925 % 0.9 %	-5.9 %	
3.36	% Delta F % CV	4322 % 0.9 %	4392 % 2.6 %	1.6 %	± 20 %

For the batch release, variation in delta F must be less than 20 %.



Anti Mouse-XL batch # 12RW

Accepted

Rejected

Operator's initials: LP

Date : 15/09/2003

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