

HTRF® Research Reagents

Anti-Mouse-K Quality Control

Product number : 61PAMKLA Lot Number : 27RB

Manufacturing date : 11/08/2022 Document version : 1

EXPERIMENTAL CONDITION

The batch to be controlled was compared to the reference batch currently in use, at increasing conjugate XL concentrations (IgG1-XL).

Anti-Mouse-K 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

Anti-Mouse-K or Anti-Rabbit-K + IgG1-XL

REAGENTS

	REFERENCE LOT NUMBER	ASSAY CONCENTRATION
IgG1- XL	CQ01	0.21 - 3.33 nMf
Anti-Mouse-K	27A	62.5 ng/mLf
Anti-Rabbit-K	18A	180 ng/mLf

	CURRENT BATCH LOT NUMBER	ASSAY CONCENTRATION
Anti-Mouse-K current batch	27RB	62.5 ng/mLf

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

EXPERIMENTAL PROCEDURE

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

Reagents were dispensed as follows :

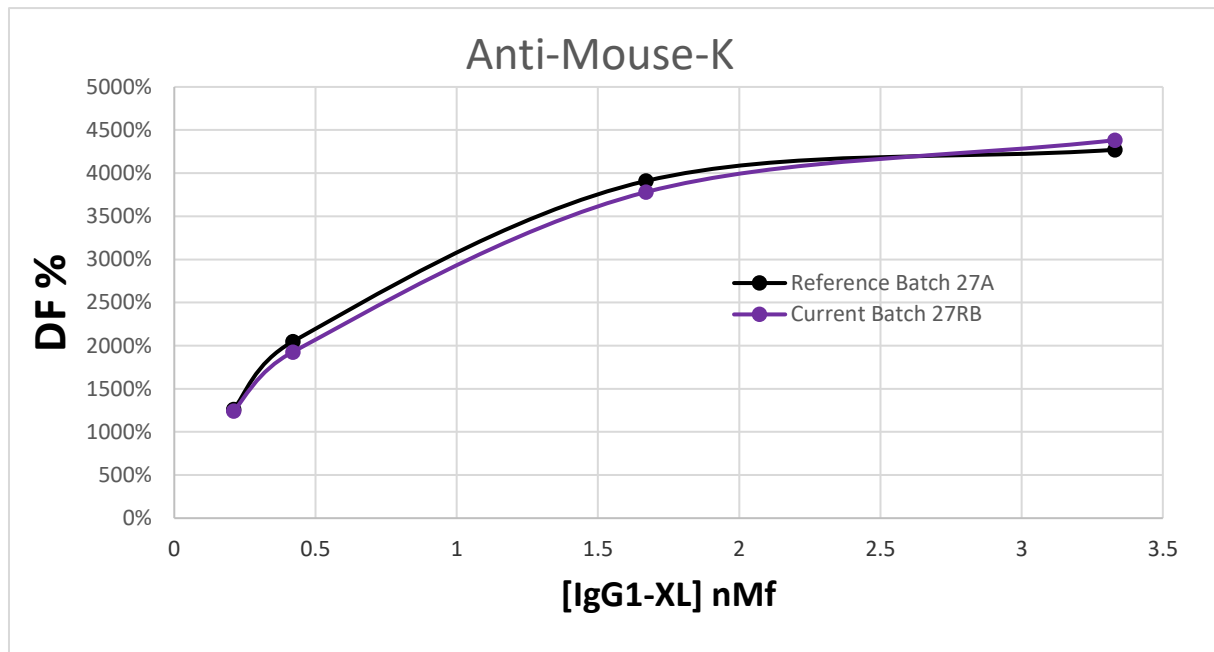
- 10 µL PPI - Europium detection buffer
- 5 µL IgG1-XL
- 5 µL K conjugate

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

RESULTS

[IgG1-XL] nM _f		Anti-Mouse-K Reference	Anti-Mouse-K CURRENT BATCH	VARIATION	MEAN ACCEPTABLE VARIATION
0.21	% Delta F % CV	1262% 1.7%	1243% 1.6%	-1.5 %	-2.0%
0.42	% Delta F % CV	2048% 1.6%	1928% 2.1%	-5.9 %	
1.67	% Delta F % CV	3910% 1.1%	3781% 4.2%	-3.3 %	± 20 %
3.33	% Delta F % CV	4271% 2.7%	4382% 0.4%	2.6 %	

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



Anti-Mouse-K batch # 27RB

Accepted

Rejected

Operator's initials: MT

Date:16/08/2022

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