HTRF® Research Reagents

Mab Anti Flag M2-K		Quality Control		
Product number :	61FG2KLB	Lot Number :	25A	
Manufacturing date :	16/10/2024	Document version :	1	\mathbf{V}

EXPERIMENTAL CONDITION

The batch to be controlled was compared to the reference batch currently in use, at increasing Prot-6HIS-Flag concentrations.

Mab Anti FlagM2-K is lyophilized in PO4 buffer 100 mM pH7; 0.5% BSA + Stabilizers.

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

ASSAY FORMAT

Prot-6HIS-flag + 6HIS-XL + Mab Anti FlagM2-K

REAGENTS

	REFERENCE LOT NUMBER	ASSAY CONCENTRATION		
6HIS-XL	73A	1000 ng/mLf		
FlagM2-K	29AR	75 ng/mlf		
prot -6HIS- Flag	CQ11	0.156-0.62 - 2.5 -10 nMf		

	CURRENT BATCH LOT NUMBER	ASSAY CONCENTRATION
FlagM2-K current batch	25C	70 ng/mlf

Other reagents were the same as those used for the reference test. If applicable, streptavidin / biotin ratio was set up at : 1/2

EXPERIMENTAL PROCEDURE

Reconstitute Mab Anti FlagM2-Tb 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 :

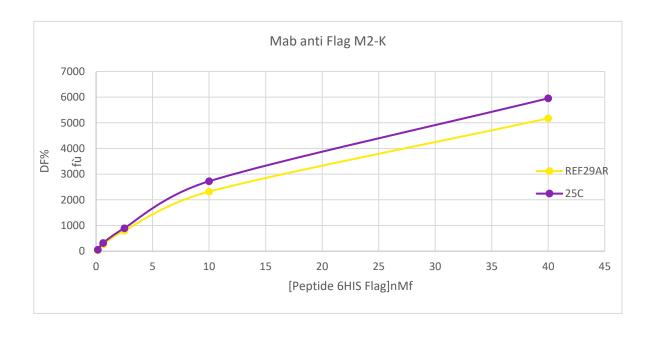
- 10 µL Prot-6HIS-Flag (10µL diluent for negative control)
- 5 µL XL conjugate
- 5 µL K conjugate

Incubation took place for Over Night at 4°C. The plate was read on ${\tt Envision} \ensuremath{\mathbb{R}}$ under standard conditions.

RESULTS

[Prot-6HIS -Flag] nMf		FlagM2-K Ref	FlagM2-K CURRENT BATCH	VARIATION	MEAN ACCEPTABLE VARIATION
0.156	% Delta F % CV	35 % 5.9%	54% 6.1 %		15.9 %
0.625	% Delta F % CV	262 % 0.8%	321 % 3.5%	22.5 %	
2.5	% Delta F % CV	798% 4.5%	895 % 2.9 %	12.2 %	± 20 %
10	% Delta F % CV	2321% 0.2%	2633% 4.7%	13.4%	
40	% Delta F % CV	5175% 1.2%	5962% 0.3%	15.2%	

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





Operator's initials: ML

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