

HTRF® Research Reagents

FLAGM2-XL Quality Control

Product number : 61FG2XLB

Lot Number : 36A

Manufacturing date : 31/05/2024

Document version : 1

EXPERIMENTAL CONDITION

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

FLAGM2-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

6HIS-Gold-K + Pept-6HIS-Flag + FLAGM2-XL

REAGENTS

	REFERENCE LOT NUMBER	ASSAY CONCENTRATION
6HIS-Gold- K	18A	0.5 nMf
FLAGM2-XL reference	35A	6.67 nMf
Pept-6HIS-Flag	CQ11	0.012 - 9 nMf

	CURRENT BATCH LOT NUMBER	ASSAY CONCENTRATION
FLAGM2-XL current batch	36A	6.67 nMf

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

EXPERIMENTAL PROCEDURE

Reconstitute FLAGM2-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 :

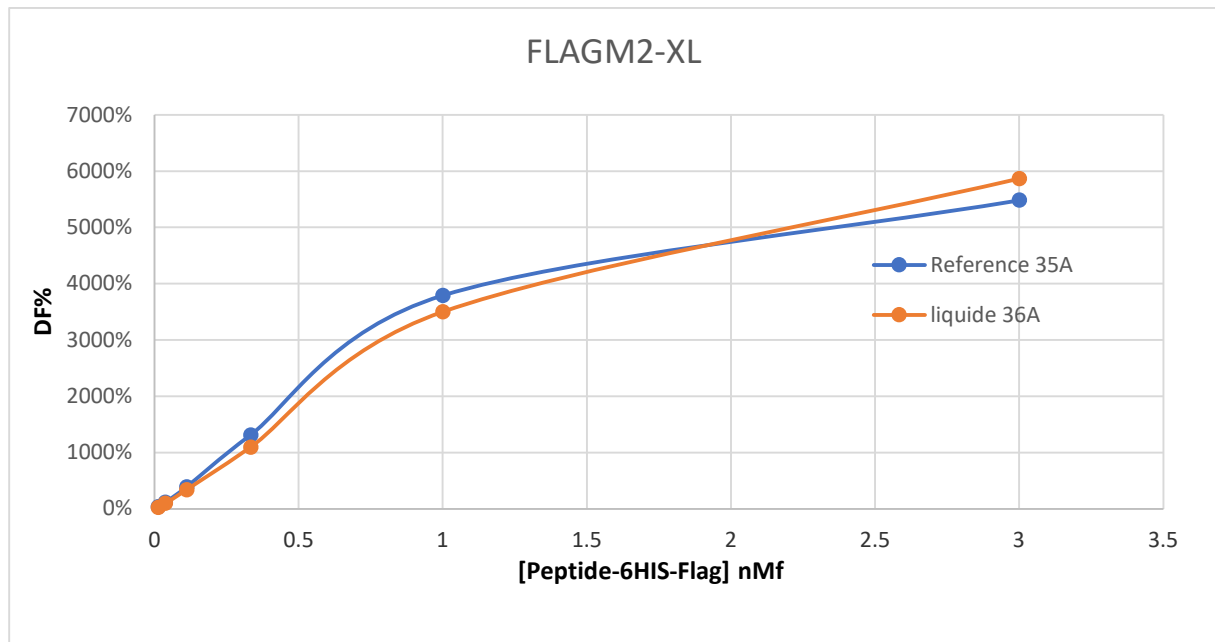
- 5 µL Pept-6HIS-Flag (5 µL diluent for negative control)
- 10 µL XL conjugate
- 5 µL K conjugate

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

RESULTS

[Pept-6HIS-Flag] nMf		FLAGM2-XL Reference	FLAGM2-XL CURRENT BATCH	VARIATION	MEAN ACCEPTABLE VARIATION
0.012	% Delta F % CV	34 % 1.6 %	26% 0.8 %	-25 %	
0.037	% Delta F % CV	114 % 2.8 %	97 % 0.8 %	-15%	-12.42 %
0.111	% Delta F % CV	389 % 2.4 %	340 % 0.8 %	-12.5%	
0.333	% Delta F % CV	1313 % 4.4 %	1096 % 6.8 %	-16.6%	
1	% Delta F % CV	3791 % 2.6 %	3501 % 11.1%	-7.6 %	
3	% Delta F % CV	5484 % 0.6 %	5003 % 2.5 %	-8.8 %	± 20 %
9	% Delta F % CV	5937% 0.2%	5868% 1.7%	-1.2%	

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



FLAGM2-XL batch # 36A

Accepted



Rejected



Operator's initials: AC

Date : 04/06/2024

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