

HTRF® Research Reagents

## FLAGM2-XL Quality Control

Product number : 61FG2XLB Lot Number : 35RA

Manufacturing date : 22/06/2023 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	15B	0.5 nMf
FLAGM2-XL reference	34A	6.67 nMf
Pept-6HIS-Flag	CQ11	0.012 - 9 nMf

	CURRENT BATCH LOT NUMBER	ASSAY CONCENTRATION
FLAGM2-XL current batch	35RA	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 :

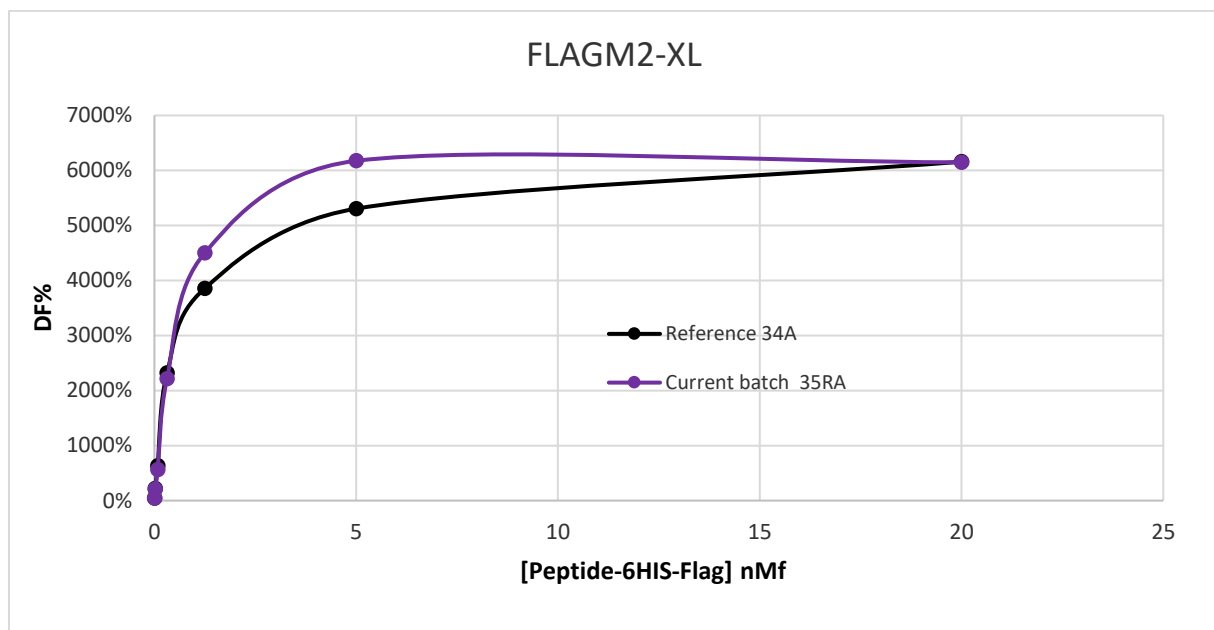
- 5 µL Pept-6HIS-Flag (5 µL diluent for negative control)
- 10 µL XL conjugate
- 5 µL K conjugate

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	45 % 5.0 %	45 % 2.9 %	0%	
0.037	% Delta F % CV	217 % 4.7 %	208 % 4.8 %	-4.3%	1.87 %
0.111	% Delta F % CV	629 % 2.4 %	560 % 4.4%	-11.1%	
0.333	% Delta F % CV	2318 % 4.7 %	2216 % 2.8%	-4.4%	
1	% Delta F % CV	3857 % 3.8%	4501 % 0.3%	16.7%	
3	% Delta F % CV	5306 % 4.6 %	6176 % 3.8 %	16.4%	± 20 %
9	% Delta F % CV	6159% 0.1%	6148% 4.9%	-0.2%	

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



FLAGM2-XL batch # 35RA

Accepted



Rejected



Operator's initials: FTV

Date : 23/06/2023

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