

HTRF® Research Reagents

FLAGM2-XL Quality Control

Product number : 61FG2XLB Lot Number : 34RA

Manufacturing date : 30/11/2022 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	32A	6.67 nMf
Pept-6HIS-Flag	CQ11	0.012 - 9 nMf

	CURRENT BATCH LOT NUMBER	ASSAY CONCENTRATION
FLAGM2-XL current batch	34RA	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

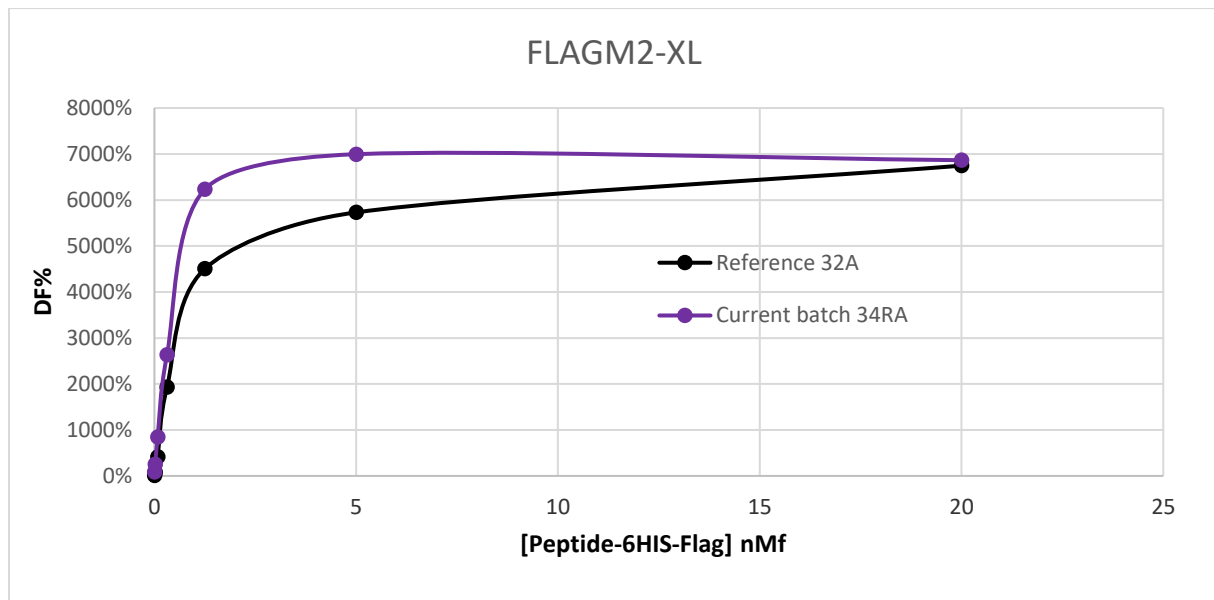
Incubation took place for 120 min at room temperature. The plate was read on Phera Star ® under standard conditions.

RESULTS

[Pept-6HIS-Flag] nMf		FLAGM2-XL Reference	FLAGM2-XL CURRENT BATCH	VARIATION	MEAN ACCEPTABLE VARIATION
0.012	% Delta F % CV	13 % 6.0 %	84 % 3.1 %	546.5%	137.6 %*
0.037	% Delta F % CV	82 % 4.6 %	256 % 1.2 %	213.1%	
0.111	% Delta F % CV	412 % 0.1 %	844 % 2.4%	104.9%	
0.333	% Delta F % CV	1932 % 1.2 %	2637 % 2.4%	36.5%	
1	% Delta F % CV	4504 % 2.7%	6234 % 0.7%	38.4%	
3	% Delta F % CV	5730 % 4.3 %	6996 % 0.4 %	22.1%	± 20 %
9	% Delta F % CV	6746% 2.6%	6865% 1.9%	1.8%	

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

* → new batch XL665



FLAGM2-XL batch # 34RA

Accepted

Rejected

Operator's initials: MT

Date : 06/12/2022

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