

HTRF® Research Reagents

FLAGM2-XL Quality Control

Product number : 61FG2XLF Lot Number : 30RA

Manufacturing date : 04/02/2021 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	11A	0.5 nMf
FLAGM2-XL reference	28A	6.67 nMf
Pept-6HIS-Flag	04	0.012 - 3 nMf

	CURRENT BATCH LOT NUMBER	ASSAY CONCENTRATION
FLAGM2-XL current batch	30RA	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 :

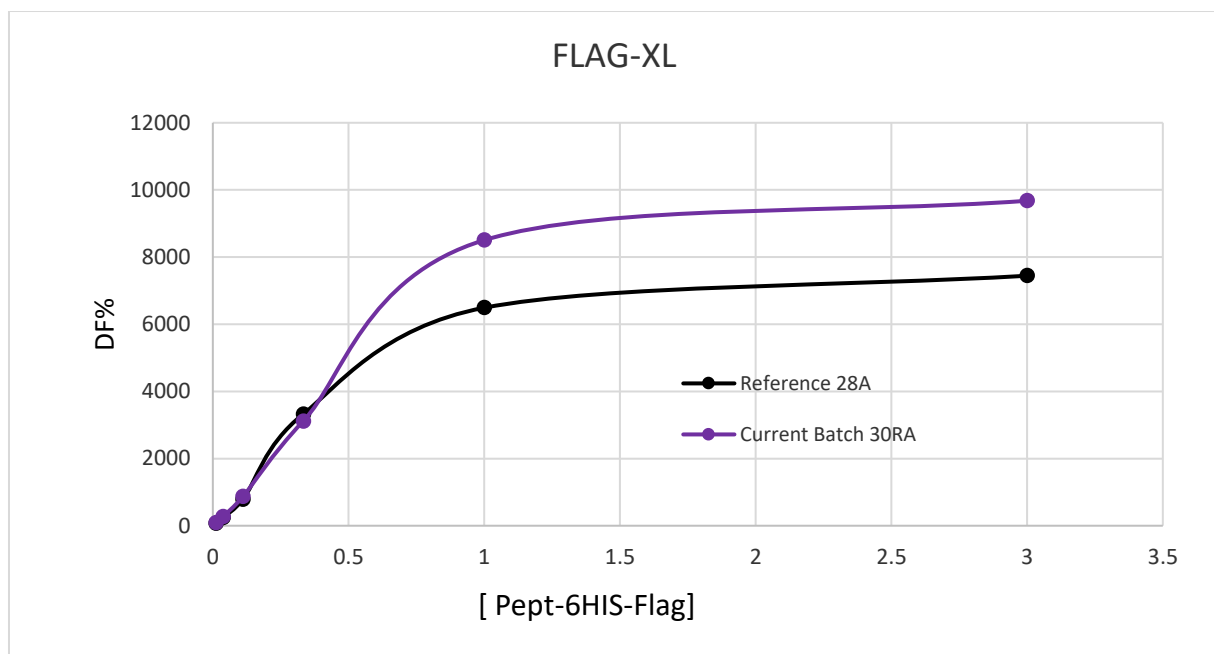
- 5 µL Pept-6HIS-Flag (5 µL diluent for negative control)
- 10 µL XL conjugate
- 5 µL K conjugate

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	66 % 6.1 %	89 % 2.8 %	34.3 %	
0.037	% Delta F % CV	240 % 6.1 %	270 % 1.2 %	12.5 %	18.7 %
0.111	% Delta F % CV	783 % 3.4 %	868 % 5.1 %	10.9 %	
0.333	% Delta F % CV	3 324 % 0 %	3 114 % 4.8 %	-6.3 %	
1	% Delta F % CV	6 491 % 5.8 %	8 505 % 0.2 %	31.0 %	± 20 %
3	% Delta F % CV	7 445 % 3.3 %	9 677 % 2.2 %	30. %	

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



FLAGM2-XL batch # 30RA

Accepted



Rejected



Operator's initials: FTV

Date : 10/02/2021

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