

HTRF® Research Reagents

FLAGM2-D2 Quality Control

Product number : 61FG2DLF

Lot Number : 22RA

Manufacturing date : 15/02/2023

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-D2 is lyophilized in PO4 buffer 100 mM pH7 ; 0.1% BSA ; Stabilizers.

All the reagents involved were diluted in PPI-Terbium detection buffer (#61DB10RDF).

ASSAY FORMAT

6HIS-Gold-Tb + Pept-6HIS-Flag + FLAGM2-D2

REAGENTS

	REFERENCE LOT NUMBER	ASSAY CONCENTRATION
6HIS-Gold- Tb	22A	0.35 nMf
FLAGM2-D2 reference	20A	6.66 nMf
Pept-6HIS-Flag	CQ11	0.078 - 20 nMf

	CURRENT BATCH LOT NUMBER	ASSAY CONCENTRATION
FLAGM2-D2 current batch	22RA	6.66 nMf

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

EXPERIMENTAL PROCEDURE

Reconstitute FLAGM2-D2 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 :

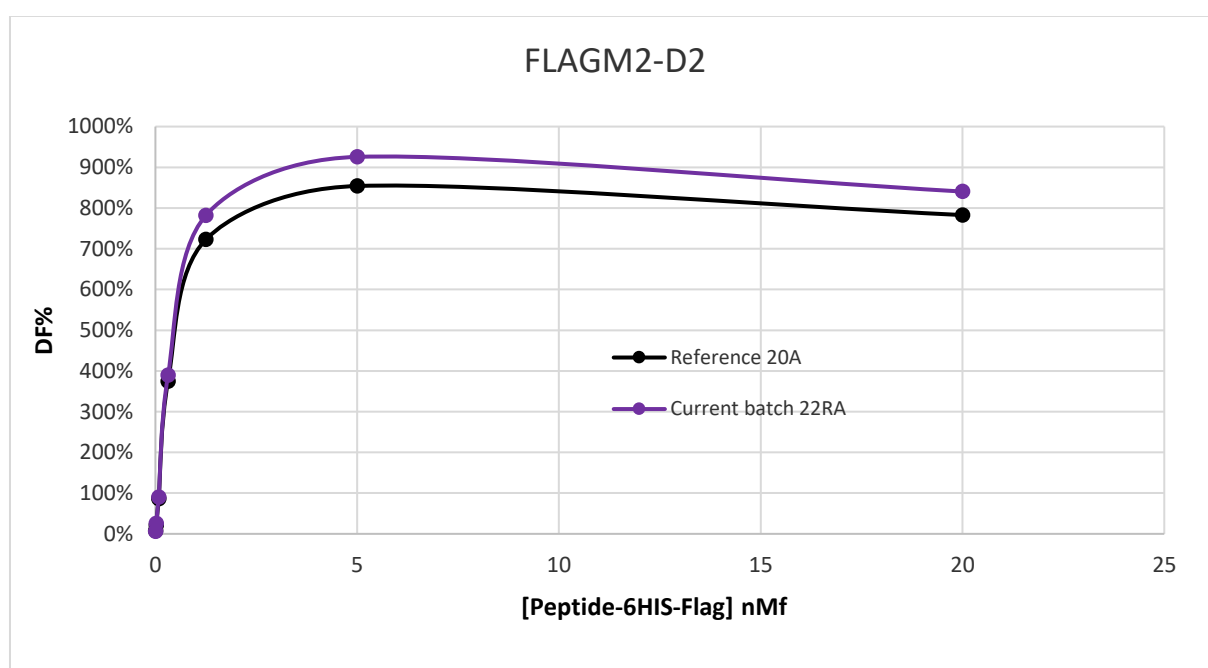
- 10 µL Pept-6HIS-Flag (10 µL diluent for negative control)
- 5 µL D2 conjugate
- 5 µL K conjugate

Incubation took place for 180 min at room temperature. The plate was read on Phera Star ® under standard conditions.

RESULTS

[Pept-6HIS-Flag] nMf		FLAGM2-D2 Reference	FLAGM2-D2 CURRENT BATCH	VARIATION	MEAN ACCEPTABLE VARIATION
0.078	% Delta F % CV	86 % 1.1 %	90 % 1.1 %	4.4 %	6.5 %
0.3125	% Delta F % CV	375 % 0.9 %	390 % 2.1 %	4.0 %	
1.25	% Delta F % CV	723 % 0.4 %	782 % 0.4 %	8.2 %	
5	% Delta F % CV	854 % 0.4 %	926 % 1.3 %	8.4 %	± 20 %
20	% Delta F % CV	783 % 2.2 %	840 % 0.9 %	7.4 %	

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



FLAGM2-D2 batch # 22RA

Accepted



Rejected



Operator's initials: MB

Date : 27/02/2023

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