

#### HTRF® Research Reagents

# FLAGM2-D2 Quality Control

Product number: 61FG2DLB 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 CONCENTRATIO	
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  $\mu$ L 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:

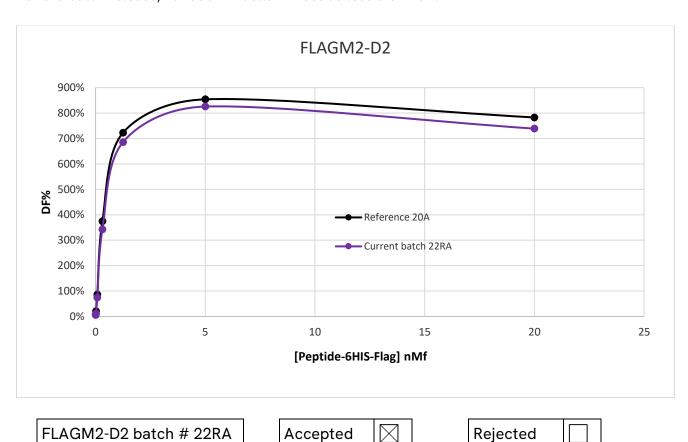
- 10 μL Pept-6HIS-Flag (10 μL diluent for negative control)
- 5 μL D2 conjugate
- 5 µL K conjugate

Incubation took place for 180 min at room temperature. The plate was read on Phera Star  ${}^{\circledR}$  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 %	74 % 0.8 %	-13.8 %	-7.3 %
0.3125	% Delta F % CV	375 % 0.9 %	342 % 1.3 %	-8.6 %	
1.25	% Delta F % CV	723 % 0.4 %	686 % 1.7 %	-5.1 %	
5	% Delta F % CV	854 % 0.4 %	826 % 0.5 %	-3.3 %	± 20 %
20	% Delta F % CV	783 % 2.2 %	739 % 2.2 %	-5.6 %	

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



Operator's initials: MB

Date: 27/02/2023

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