

HTRF® Research Reagents

FLAGM2-Tb Quality Control

Product number: 61FG2TLB Lot Number: 26RA

Manufacturing date: 17/11/2022 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-Tb is lyophilized in PO4 buffer 100 mM pH7; 0.5% BSA; Stabilizers.

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

ASSAY FORMAT

FLAGM2-Tb + Pept-6HIS-Flag + 6HIS-XL

REAGENTS

	REFERENCE LOT NUMBER ASSAY CONCENTRATION		
6HIS-XL	70B	6.67 nMf	
FLAGM2-Tb reference	23A	0.43 nMf	
Pept-6HIS-Flag	CQ11	0.02 - 20 nMf	

	CURRENT BATCH LOT NUMBER	ASSAY CONCENTRATION	
FLAGM2-Tb current batch	26RA	0.43 nMf	

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

EXPERIMENTAL PROCEDURE

Reconstitute FLAGM2-Tb vial with 250 μ 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:

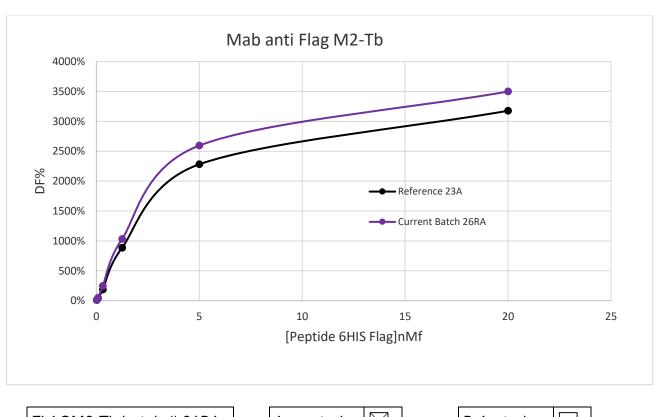
- 10 μL Pept-6HIS-Flag (10 μL diluent for negative control)
- 5 µL XL conjugate
- 5 μL Tb conjugate

Incubation took place for 120 min at 2-8°C. The plate was read on Phera Star ® under standard conditions.

RESULTS

[Pept-6HIS-Flag] nMf		FLAGM2-Tb Reference	FLAGM2-Tb CURRENT BATCH	VARIATION	MEAN ACCEPTABLE VARIATION
0.02	% Delta F % CV	9% 0.9%	11% 2.0%	19%	19 %
0.078	% Delta F % CV	38% 2.7%	46% 2.7%	22%	
0.312	% Delta F % CV	186% 2.9%	246% 2.3%	32%	
1.25	% Delta F % CV	884% 1.1%	1032% 3.4%	17%	
5	% Delta F % CV	2281% 1.3%	2595% 1.2%	14%	± 20 %
20	% Delta F % CV	3177% 1.1%	3499% 1.3%	10%	

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



FLAGM2-Tb batch # 26RA Accepted Rejected

Operator's initials: MT Date: 18/11/2022

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