

HTRF® Research Reagents

FLAGM2-Tb Quality Control

Product number : 61FG2TLF Lot Number : 26RB

Manufacturing date : 31/01/2023 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-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 | 70C | 6.67 nMf |
| FLAGM2-Tb reference | 23A | 0.43 nMf |
| Pept-6HIS-Flag | CQ11 | 0.078 - 20 nMf |

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

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

EXPERIMENTAL PROCEDURE

Reconstitute FLAGM2-Tb 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 :

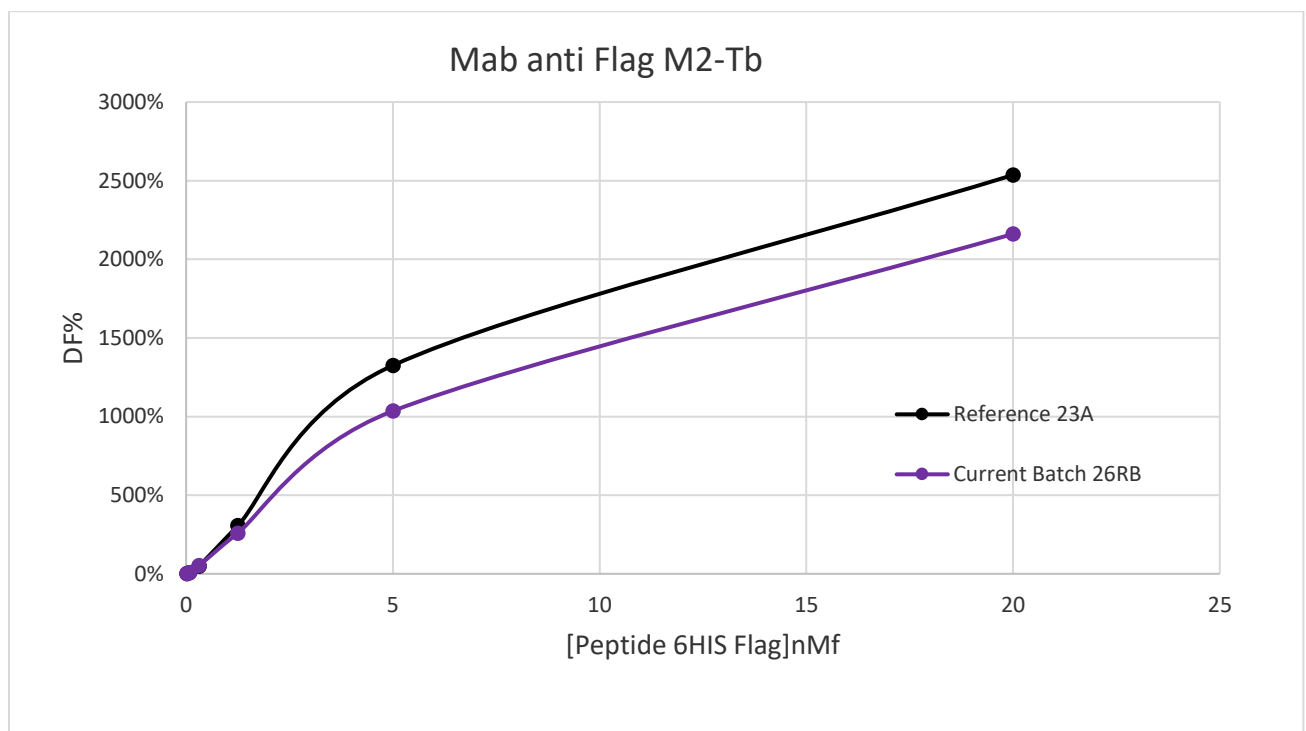
- 10 µL Pept-6HIS-Flag (10 µL diluent for negative control)
- 5 µL XL conjugate
- 5 µL Tb conjugate

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 |
|-------------------------|-------------------|------------------------|-------------------------------|-----------|---------------------------------|
| 0.078 | % Delta F % CV | 7% 0.9% | 8% 1.5% | 14% | -5.3% |
| 0.312 | % Delta F % CV | 49% 1.1% | 52% 1.9% | 5% | |
| 1.25 | % Delta F % CV | 306% 1.8% | 259% 1.8% | -15% | |
| 5 | % Delta F % CV | 1325% 3.3% | 1035% 1% | -22% | ± 20 % |
| 20 | % Delta F % CV | 2536% 1.6% | 2161% 1.2% | -15% | |

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



FLAGM2-Tb batch # 26RB

Accepted



Rejected



Operator's initials: MT

Date : 06/02/2023

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