

HTRF® Research Reagents

Mab anti MBP-Tb Quality Control

Product number : 61MPBTAB

Lot Number : 03RA

Manufacturing date : 31/03/2022

Document version : 1

EXPERIMENTAL CONDITION

The batch to be controlled was compared to the reference batch currently in use, at increasing MBP-Biotin concentrations.

Mab anti MBP-Tb is frozen in buffer PO4 100 mM pH7; 0.1% BSA.

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

ASSAY FORMAT

SA-XL + MBP-Biotin + anti MBP-Tb

REAGENTS

| | REFERENCE LOT NUMBER | ASSAY CONCENTRATION |
|-----------------------|----------------------|---------------------------|
| SA-XL | 161 | 0.37 – 1.1 – 3.3 – 10 nMf |
| Anti MBP-Tb reference | 02A | 0.5 nMf |
| MBP-Biotin | 02 | 0.37 – 1.1 – 3.3 - 10 nMf |

| | CURRENT BATCH LOT NUMBER | ASSAY CONCENTRATION |
|----------------------------------|--------------------------|---------------------|
| Anti MBP-Tb current batch | 03RA | 0.5 nMf |

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

EXPERIMENTAL PROCEDURE

Reagents were dispensed as follows :

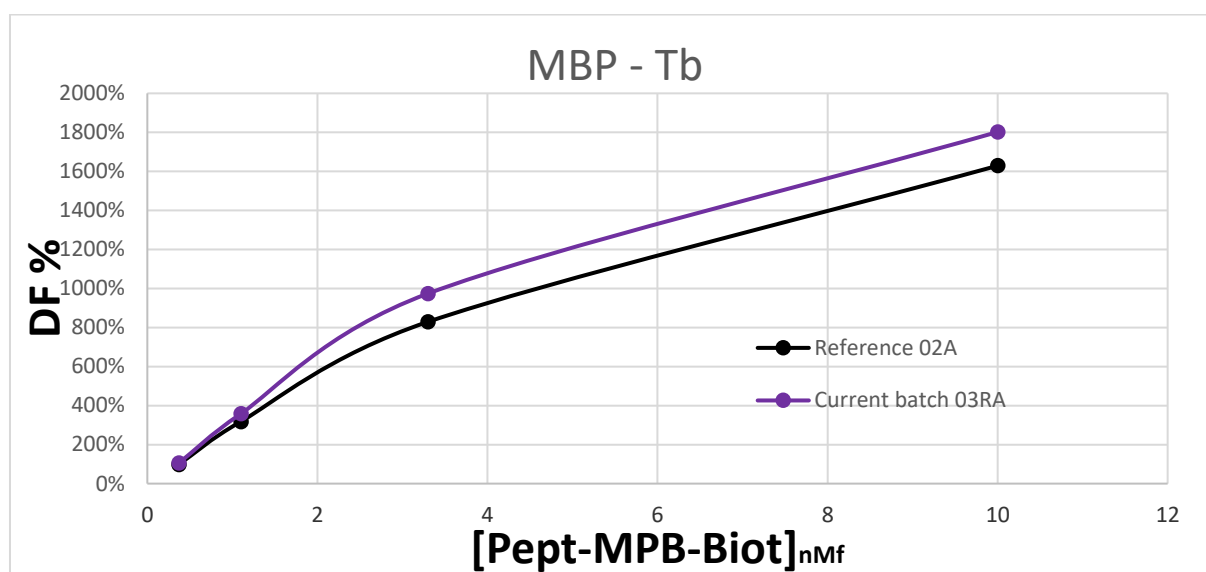
- 5 µL MBP-Biotin (5 µL diluent for negative)
- 10 µL XL conjugate
- 5 µL Tb Conjugate

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

RESULTS

| [MBP Biotin] nMf | | Anti MBP-Tb reference | Anti MBP-Tb Current Batch | Variation | Mean Acceptable variation |
|---------------------|-------------------|--------------------------|---------------------------------|-----------|---------------------------------|
| 0.37 | % Delta F % CV | 98 % 0.49 % | 105 % 0.33 % | 7.5 % | 11.4% |
| 1.1 | % Delta F % CV | 318 % 0.61 % | 358 % 0.86 % | 12.6 % | |
| 3.3 | % Delta F % CV | 829 % 0.86 % | 974 % 0.36 % | 17.5 % | |
| 10 | % Delta F % CV | 1 629 % 1.87 % | 1 802 % 0.01 % | 10.6 % | ± 20 % |

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



MBP-Tb batch # 03RA

Accepted



Rejected



Operator's initials: FTV

Date : 31/03/2022

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