

HTRF® Research Reagents

Anti-6His-D2 Quality Control

Product number : 61HISDLF Lot Number : 39

Manufacturing date : 08/05/2023 Document version : 1

EXPERIMENTAL CONDITION

The batch to be controlled was compared to the reference batch currently used, at increasing mab concentrations (Anti-6HIS-d2).

Anti-6HIS-d2 is lyophilized in PO4 buffer 100 mM pH 7 ; 0.1% BSA, Stabilizers

All the reagents involved were diluted in PPI-Europium detection buffer, #61DB9RDF

ASSAY FORMAT

Pept-6HIS-Biotin + Streptavidin-Cryptate + Anti-6HIS-d2

REAGENTS

	REFERENCE LOT NUMBER	ASSAY CONCENTRATION
Streptavidin-Cryptate	37A	110 ng/ml _f
Anti-6HIS-d2	34A	125, 250, 500, 800 ng/ml _f
Pept-6HIS-Biotin	CQ03	5 nM _f

	CURRENT BATCH LOT NUMBER	ASSAY CONCENTRATION
Anti-6HIS-d2	39	125, 250, 500, 800 ng/ml _f

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

EXPERIMENTAL PROCEDURE

Reconstitute Anti-6HIS-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 :

- 5 µL Pept-6HIS-Biotin (5 µL diluent for negative control)
- 10 µL d2 conjugate
- 5 µL K conjugate

Incubation took place for 150 min at 2-8°C. The plate was read on Phera Star ® under standard conditions.

RESULTS

[Pept-PO4-Biotin] nMf		SA-d2 Ref	SA-d2 CURRENT BATCH	VARIATION	ACCEPTABLE VARIATION
125	% Delta F % CV	850 % 0.8%	1 016 % 0.9 %	19.6 %	-14.4 %
250	% Delta F % CV	1351 % 1.7 %	1565 % 1.0 %	15.9 %	
500	% Delta F % CV	1688 % 4.5 %	1922 % 1.4 %	13.8 %	Acceptable variation
800	% Delta F % CV	1766 % 6.7 %	1913 % 6.2 %	8.3 %	+/- 20 %

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

SA-d2 batch # 26A

Accepted

Rejected

Operator's initials:

FMV

20/08/2024

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