

HTRF® Research Reagents

Anti-6His-D2 Quality Control

Product number : 61HISDLF Lot Number : 40A

Manufacturing date : 05/12/2024 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	39A	125, 250, 500, 800 ng/ml _f
Pept-6HIS-Biotin	CQ03	5 nM _f

	CURRENT BATCH LOT NUMBER	ASSAY CONCENTRATION
Anti-6HIS-d2	40A	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 :

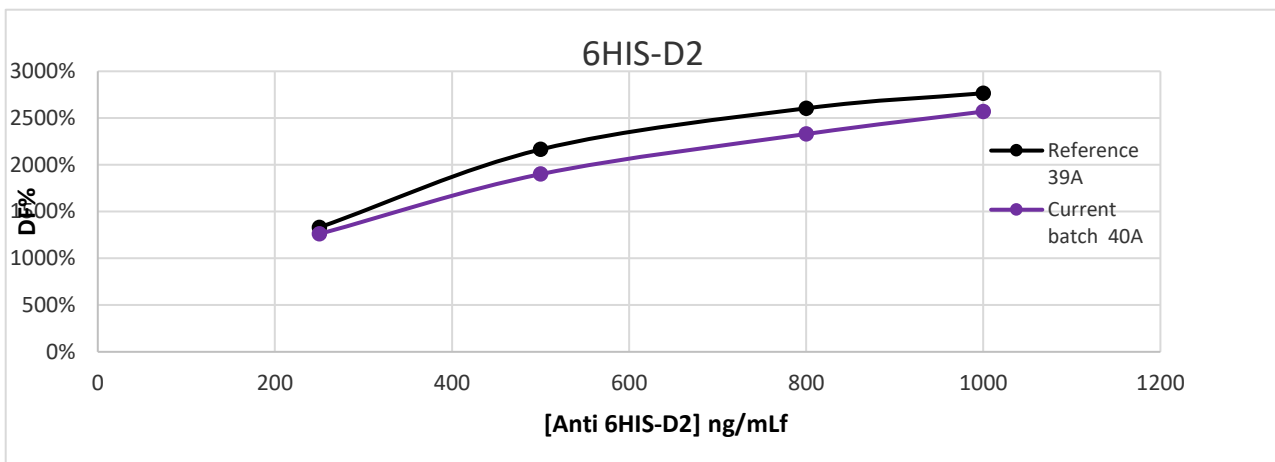
- 5 µL Pept-6HIS-Biotin (5 µL diluent for negative control)
- 10 µL d2 conjugate
- 5 µL K conjugate

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	1330 % 4.0%	1260 % 4.1%	-11.8%	-13.9 %
250	% Delta F % CV	2167% 4.7%	1900 % 0.2 %	-16.4%	
500	% Delta F % CV	2604 % 3.8 %	2329% 1.4 %	-14.0%	Acceptable variation
800	% Delta F % CV	2765 % 3.2 %	2569 % 2.7 %	-13.4%	+/- 20 %

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



6 HIS -d2 batch # 40A

Accepted

Rejected

Operator's initials:

ML

06/12/2024

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