

HTRF® Research Reagents

Anti-6HIS-D2 Quality Control

Product number : 61HISDLB Lot Number : 34RA

Manufacturing date : 25/08/2022 Document version : 1

EXPERIMENTAL CONDITION

The batch to be controlled was compared to the reference batch currently in use, at increasing Anti-6HIS-D2 concentrations.

Anti-6HIS-D2 is lyophilized in PO4 buffer 100 mM pH7 ; 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	34A	110 ng/mLf
Anti-6HIS-D2 reference	32A	125 - 250 - 500 - 800 ng/mLf
Pept-6HIS-Biotin	CQ03	5 nMf

	CURRENT BATCH LOT NUMBER	ASSAY CONCENTRATION
Anti-6HIS-D2 current batch	34RA	125 - 250 - 500 - 800 ng/mLf

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 :

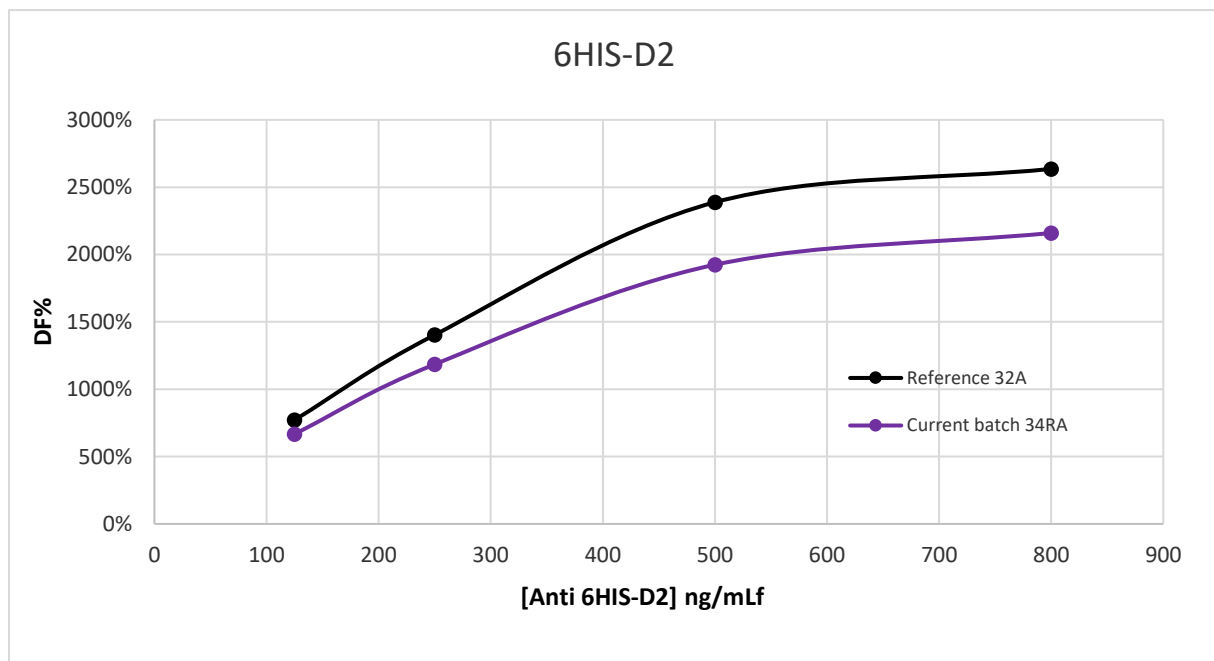
- 5 µL Pept-6HIS-Biotin (5 µL diluent for negative control)
- 10 µL D2 conjugate
- 5 µL K conjugate

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

RESULTS

[Anti-6HIS-D2] ng/mLf		Anti-6HIS-D2 Reference	Anti-6HIS-D2 CURRENT BATCH	VARIATION	MEAN ACCEPTABLE VARIATION
125	% Delta F % CV	772 % 3.9 %	668 % 1.2 %	-13.5 %	-16.6%
250	% Delta F % CV	1 403 % 0 %	1 185 % 0.2 %	-15.6 %	
500	% Delta F % CV	2 388 % 2.5 %	1 924 % 1.3 %	-19.4 %	± 20 %
800	% Delta F % CV	2 636 % 0 %	2 160 % 4.8 %	-18.1 %	

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



Anti-6HIS-D2 batch # 34RA

Accepted



Rejected



Operator's initials: FTV

Date: 29/08/2022

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