

HTRF® Research Reagents

Anti-6HIS-D2 Quality Control

Product number : 61HISDLF 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 :

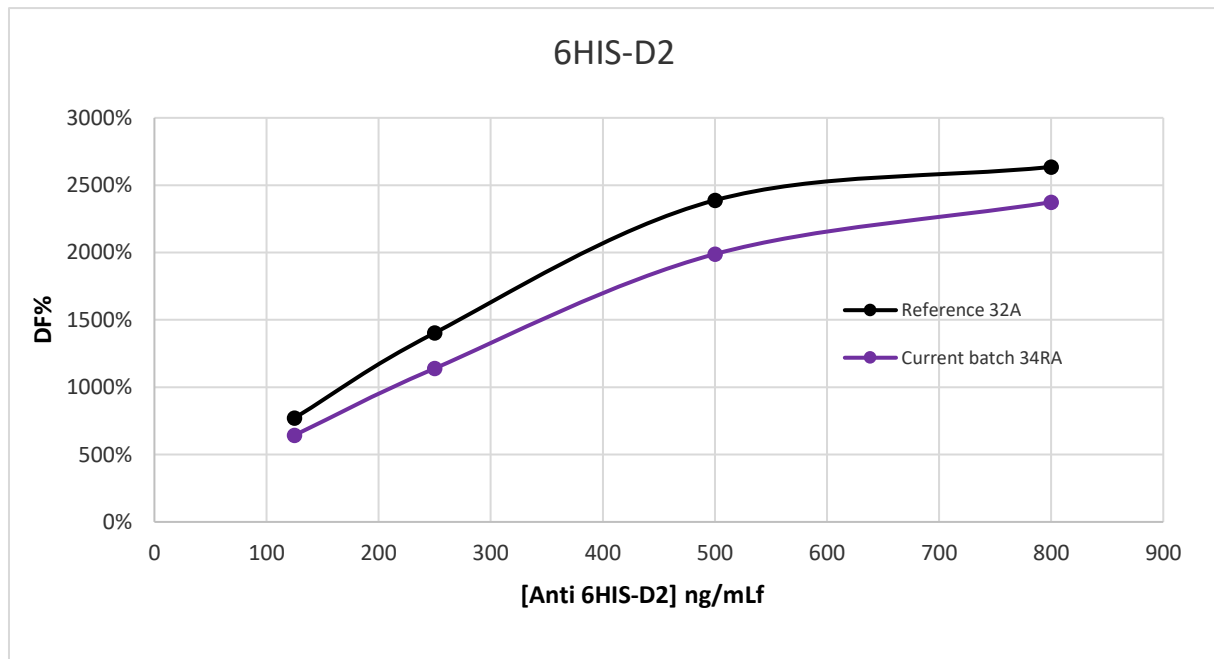
- 5 µL Pept-6HIS-Biotin (5 µL diluent for negative control)
- 10 µL D2 conjugate
- 5 µL K conjugate

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 % | 644 % 0.9 % | -16.6 % | -15.5 % |
| 250 | % Delta F % CV | 1 403 % 0 % | 1 140 % 0.9 % | -18.8 % | |
| 500 | % Delta F % CV | 2 388 % 2.5 % | 1 989 % 0.6 % | -16.7 % | ± 20 % |
| 800 | % Delta F % CV | 2 636 % 0 % | 2 374 % 3.4 % | -9.9 % | |

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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