

HTRF® Research Reagents

Streptavidin-D2 Quality Control

Product number : 610SADLF Lot Number : 26RB

Manufacturing date : 08/02/2023 Document version : 1

EXPERIMENTAL CONDITION

The batch to be controlled was compared to the reference batch currently in use, at increasing Pept-PO4-biotin concentrations.

SA-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-PO4-Biotin + SA-D2 + PT66-K

REAGENTS

| | REFERENCE LOT NUMBER | ASSAY CONCENTRATION |
|-----------------|----------------------|--------------------------|
| PT66-K | 61A | 50 ng/mLf |
| SA-D2 Reference | 24A | 0.1 - 0.3 - 1.2 - 5 nMf |
| Pept-PO4-Biotin | CQ07 | 0.2 - 0.6 - 2.4 - 10 nMf |

| | CURRENT BATCH LOT NUMBER | ASSAY CONCENTRATION |
|---------------------|--------------------------|-------------------------|
| SA-D2 current batch | 26RB | 0.1 - 0.3 - 1.2 - 5 nMf |

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

If applicable, streptavidin / biotin ratio was set up at : 1/2

EXPERIMENTAL PROCEDURE

Reconstitute SA-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 :

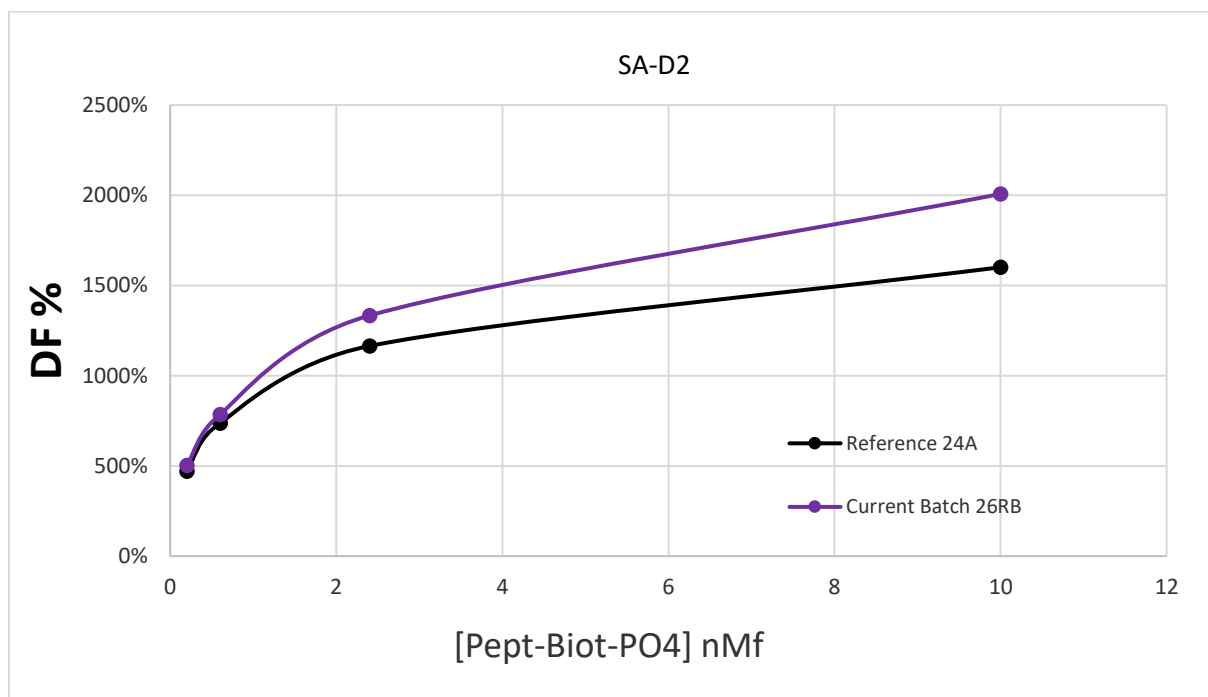
- 5 µL Pept-PO4-Biotin (5 µL diluent for negative control)
- 10 µL D2 conjugate
- 5 µL K conjugate

Incubation took place for 120 min at room temperature. The plate was read on Phera Star ® under standard conditions.

RESULTS

| [Pept-PO4-Biotin] nMf | | SA-D2 Ref | SA-D2 CURRENT BATCH | VARIATION | MEAN ACCEPTABLE VARIATION |
|-----------------------|-------------------|-----------------|---------------------|-----------|---------------------------|
| 0.2 | % Delta F % CV | 471 % 2.0 % | 504 % 1.2 % | 6.9 % | 13.3 % |
| 0.6 | % Delta F % CV | 737 % 0.5 % | 785 % 0.2 % | 6.5 % | |
| 2.4 | % Delta F % CV | 1165 % 1.3 % | 1333 % 3.1 % | 14.5 % | ± 20 % |
| 10 | % Delta F % CV | 1601 % 3.0 % | 2007 % 2.4 % | 25.4 % | |

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



SA-D2 batch # 26RB

Accepted



Rejected



Operator's initials: MT

Date : 14/02/2023

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