

HTRF® Research Reagents

Streptavidin-d2 Quality Control

Product number : 610SADLF Lot Number : 28A

Manufacturing date : 25/09/2024 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 Ref	27A	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	28A	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) or with 3 mL H2O (if packaged under 60,000 tests) or thawed (if frozen) before use.

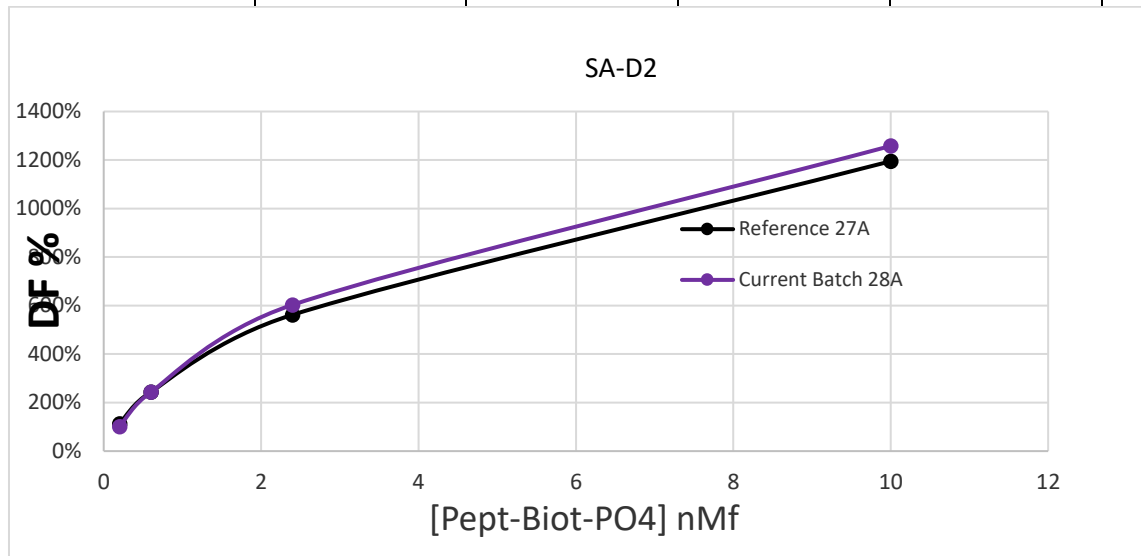
Reagents were dispensed as follows :

- 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 EnVision® under standard conditions.

RESULTS

[Pept-PO4-Biotin] nMf		SA-d2 Ref	SA-d2 CURRENT BATCH	VARIATION	MEAN ACCEPTABLE VARIATION
0.2	% Delta F % CV	113 % 0.7 %	101 % 0.2%	-11.2%	+0.21 %
0.6	% Delta F % CV	244 % 2.2 %	243 % 1.9 %	-0.6 %	
2.4	% Delta F % CV	562 % 1.2 %	603 % 0.9 %	+7.3 %	± 20 %
10	% Delta F % CV	1195 % 6.4 %	1258 % 1.4 %	+5.3 %	



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

SA-d2 batch # 28A

Accepted

Rejected

Operator's initials: ML

Date : 01/10/2024

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