

HTRF® Research Reagents

SA-XL^{ent!} Quality Control

Product number : 611SAXLA Lot Number : 26RA

Manufacturing date : 06/05/2020 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-XL^{ent!} 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-XL^{ent!} + PT66-K

REAGENTS

	REFERENCE LOT NUMBER	ASSAY CONCENTRATION
PT66-K	59A	50 ng/mLf
SA-XL ^{ent!} Reference	25A	0.1 - 0.3 - 1.2 - 5 nMf
Pept-PO4-Biotin	CQ06	0.2 - 0.6 - 2.4 - 10 nMf

	CURRENT BATCH LOT NUMBER	ASSAY CONCENTRATION
SA-XL ^{ent!} current batch	26RA	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-XL^{ent!} 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 :

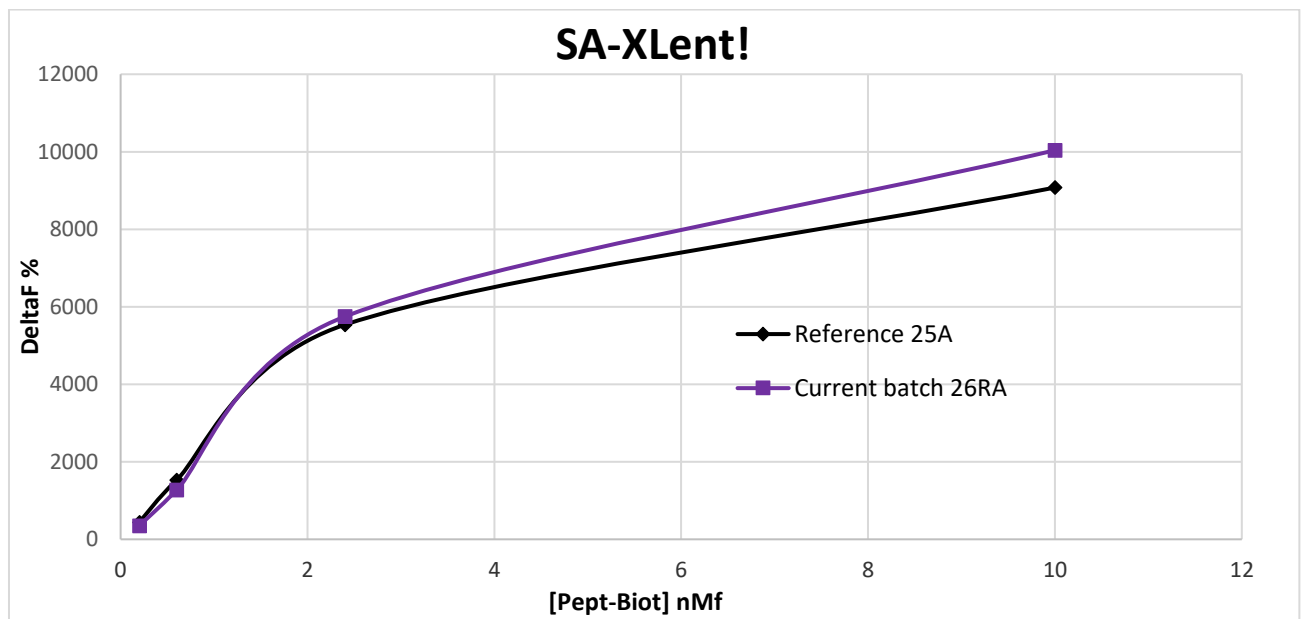
- 5 µL Pept-PO4-Biotin (5 µL diluent for negative control)
- 10 µL XL conjugate
- 5 µL K conjugate

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-XL ^{ent!} Reference	SA-XL ^{ent!} CURRENT BATCH	VARIATION	MEAN ACCEPTABLE VARIATION
0.2	% Delta F % CV	441 % 3.6 %	352 % 4.0 %	-20.1 %	-5.6 %
0.6	% Delta F % CV	1 529 % 1.9 %	1 272 % 0.7 %	-16.8 %	
2.4	% Delta F % CV	5 537 % 1.9%	5 747 % 0.9 %	3.8 %	± 20 %
10	% Delta F % CV	9 076 % 0.2 %	10 038 % 2.0 %	10.6 %	

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



SA-XL^{ent!} batch # 26RA

Accepted



Rejected



Operator's initials: LN

Date : 06/05/2020

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