

HTRF® Research Reagents

SA-XL<sup>ent!</sup> Quality Control

Product number : 611SAXLA Lot Number : 27RA

Manufacturing date : 09/08/2022 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<sup>ent!</sup> 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<sup>ent!</sup> + PT66-K

## REAGENTS

	REFERENCE LOT NUMBER	ASSAY CONCENTRATION
PT66-K	61A	50 ng/mLf
SA-XL <sup>ent!</sup> Reference	26A	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-XL <sup>ent!</sup> current batch	27RA	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<sup>ent!</sup> 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

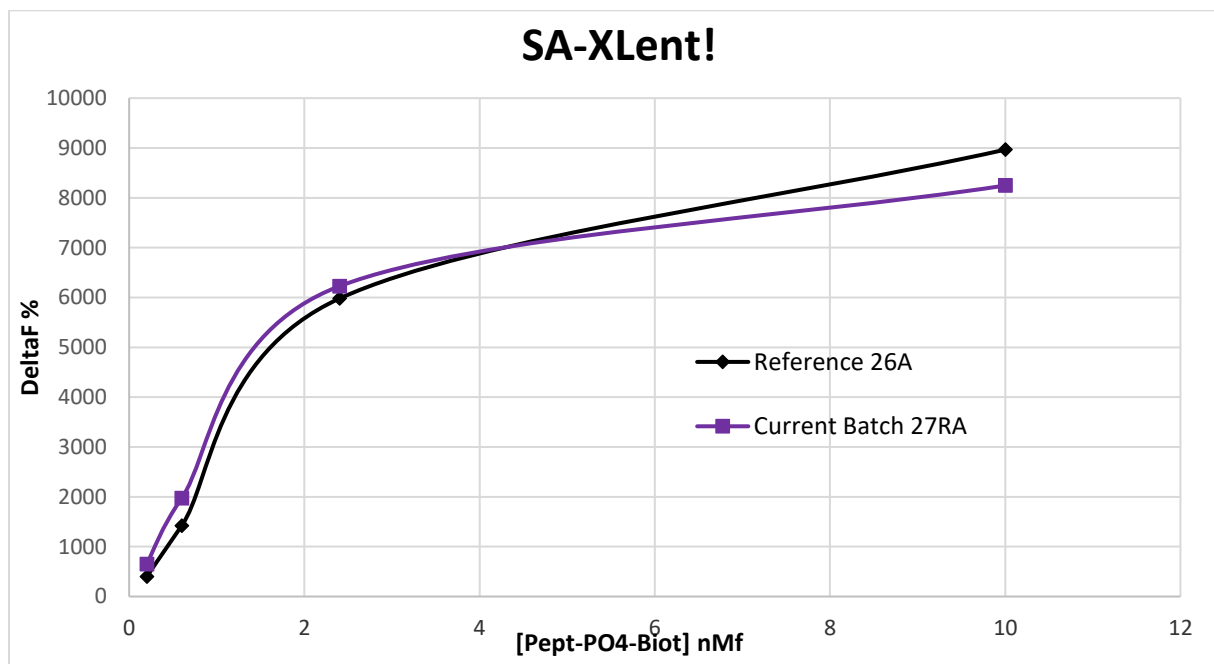
Incubation took place for 120 min at room temperature. The plate was read on Phera Star ® under standard conditions.

# RESULTS

[Pept-PO4-Biotin] nMf		SA-XL <sup>ent!</sup> Reference	SA-XL <sup>ent!</sup> CURRENT BATCH	VARIATION	MEAN ACCEPTABLE VARIATION
0.2	% Delta F % CV	397% 1.9 %	652 % 2.3 %	64.0%	24.7 %*
0.6	% Delta F % CV	1421 % 2.3 %	1972 % 3 %	38.7 %	
2.4	% Delta F % CV	5978 % 2.9%	6226 % 2.5 %	4.1 %	± 20 %
10	% Delta F % CV	8966 % 0.8%	8246 % 1.9 %	-8.0 %	

\* New batch XL665

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



SA-XL<sup>ent!</sup> batch # 27RA

Accepted



Rejected



Operator's initials: MB

Date : 16/08/2022

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