

HTRF® Research Reagents

## St-D2 Quality Control

Product number : 610STDLA Lot Number : 01B

Manufacturing date : 28/10/2027 Document version : 1

### EXPERIMENTAL CONDITION

The batch to be controlled was compared to the reference batch currently in use, at increasing pept-02 concentrations.

St-D2 is lyophilized in PO4 buffer 100 mM pH7 ; 0.1% BSA ; Stabilizers.

All the reagents involved were diluted in PPI-Terbium detection buffer (#61DB10RDF).

### ASSAY FORMAT

St-D2 + Flag-Tb + Pept-02

### REAGENTS

	REFERENCE LOT NUMBER	ASSAY CONCENTRATION
Flag-Tb	29RA	0.4 nMf
St-D2 reference	01RA	2.5 à 40 nMf
Pept-02	01	5 à 80 nMf

	CURRENT BATCH LOT NUMBER	ASSAY CONCENTRATION
St-D2 current batch	01B	2.5 à 40 nMf

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

### EXPERIMENTAL PROCEDURE

Reconstitute St-XL 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 :

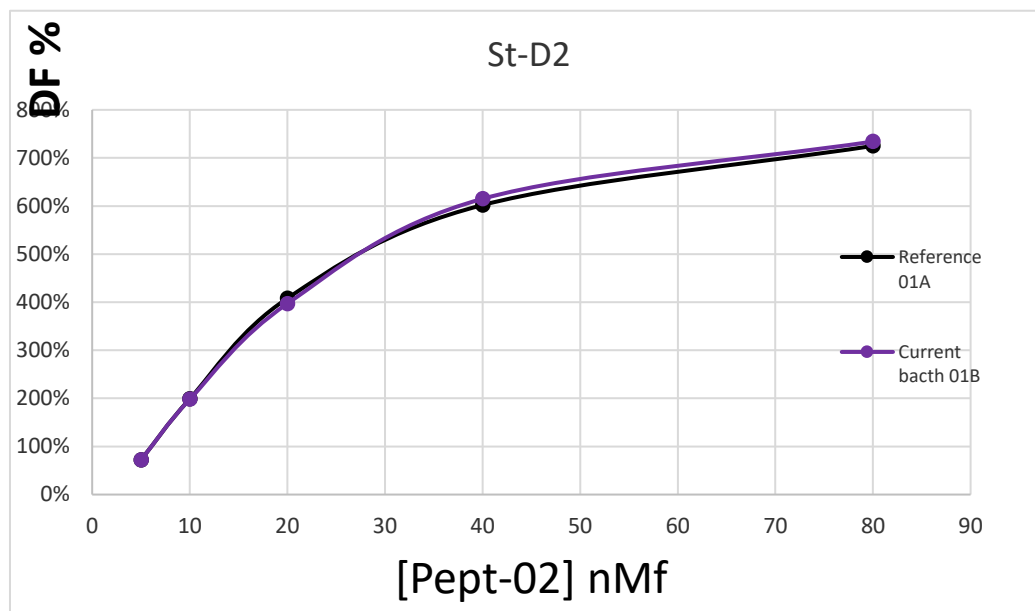
- 5 µL diluent
- 5 µL Pept-02 (5 µL diluent for negative control)
- 5 µL D2 conjugate
- 5 µL Tb conjugate

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

## RESULTS

[Pept-02] nMf		St-D2 Reference	St-D2 CURRENT BATCH	VARIATION	MEAN ACCEPTABLE VARIATION
5	% Delta F % CV	72 % 1.7 %	72% 1.1 %	0.6%	
10	% Delta F % CV	199 % 1.1 %	198 % 1.0 %	-0.6 %	0.2 %
20	% Delta F % CV	408% 1.8 %	397 % 0.6 %	-2.6 %	
40	% Delta F % CV	602 % 1.3 %	615 % 0.7 %	2.1%	± 20 %
80	% Delta F % CV	725% 0.9%	734 % 1.3 %	1.2 %	

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



St-D2 batch # 01B

Accepted



Rejected



Operator's initials: ML

Date: 28/10/2024

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