

HTRF® Research Reagents

St-D2 Quality Control

Product number : 610STDLA Lot Number : 01RA

Manufacturing date : 29/07/2022 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	23A	0.4 nMf
St-D2 reference	R&D	2.5 à 40 nMf
Pept-02	01	5 à 80 nMf

	CURRENT BATCH LOT NUMBER	ASSAY CONCENTRATION
St-D2 current batch	01RA	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 :

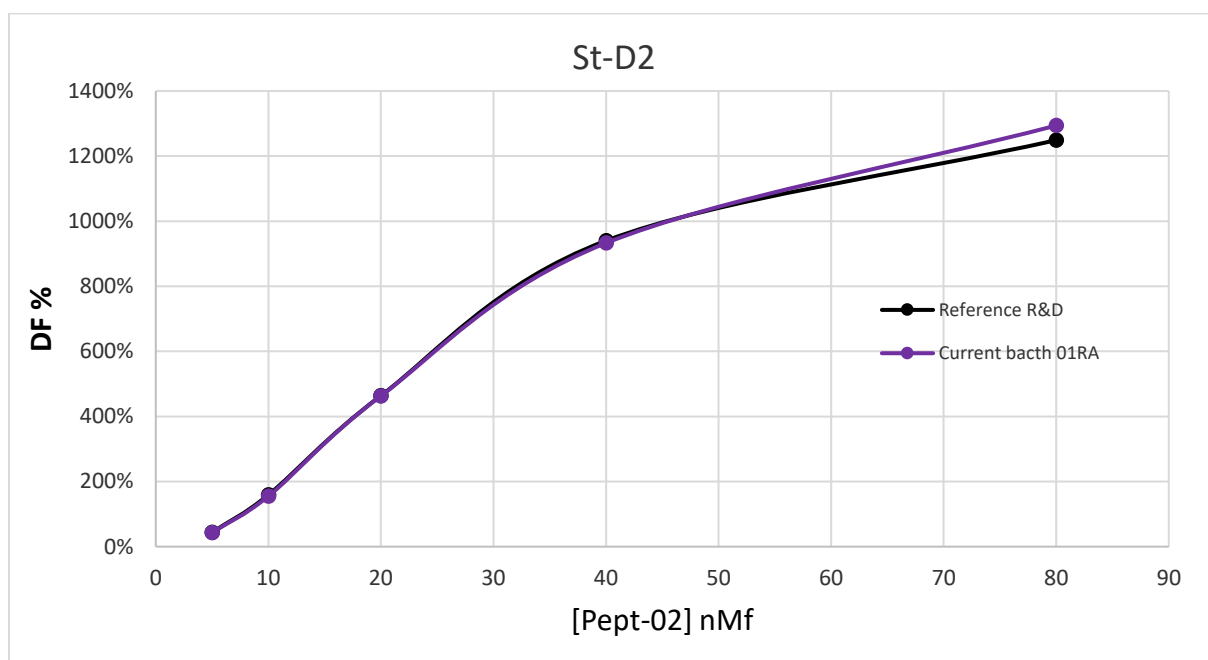
- 5 µL diluent
- 5 µL Pept-02 (5 µL diluent for negative control)
- 5 µL D2 conjugate
- 5 µL Tb conjugate

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	44 % 2.6 %	43 % 6.9 %	-2.3 %	
10	% Delta F % CV	159 % 1.9 %	155 % 8.1 %	-2.5 %	-0.4 %
20	% Delta F % CV	464 % 1.6 %	463 % 8.1 %	-0.2 %	
40	% Delta F % CV	940 % 1.6 %	933 % 4.0 %	-0.7 %	± 20 %
80	% Delta F % CV	1 249 % 2.0 %	1 294 % 1.0 %	3.6 %	

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



St-D2 batch # 01RA

Accepted



Rejected



Operator's initials: AL

Date: 30/05/2023

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