

HTRF® Research Reagents

St-K Quality Control

Product number : 610STKLA Lot Number : 01RA

Manufacturing date : 01/09/2022 Document version : 1

EXPERIMENTAL CONDITION

The batch to be controlled was compared to the reference batch currently in use, at increasing pept-05 concentrations.

St-K 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

St-K + Flag-XL + Pept-05

REAGENTS

	REFERENCE LOT NUMBER	ASSAY CONCENTRATION
Flag-XL	30A	6.67 nMf
St-K reference	R&D	1.5 nMf
Pept-05	01	5 - 160 nMf

	CURRENT BATCH LOT NUMBER	ASSAY CONCENTRATION
St-K current batch	01RA	1.5 nMf

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

EXPERIMENTAL PROCEDURE

Reconstitute St-K 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 :

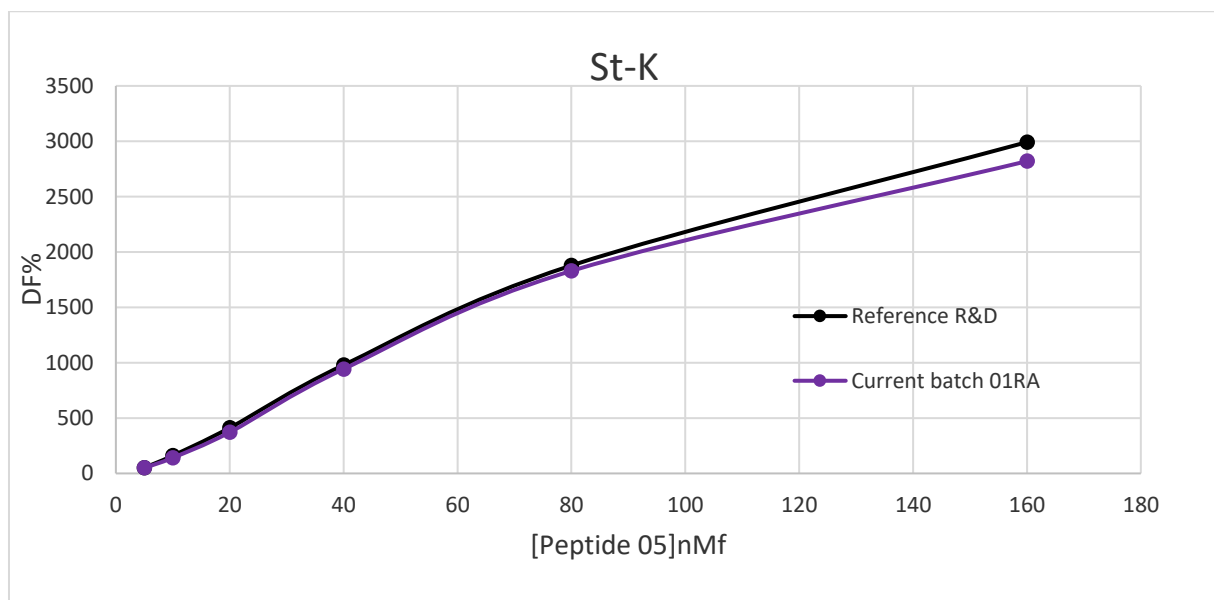
- 10 µL Pept-05 (10 µL diluent for negative control)
- 5 µL XL conjugate
- 5 µL K conjugate

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

RESULTS

[Pept-05] nMf		St-K Reference	St-K CURRENT BATCH	VARIATION	MEAN ACCEPTABLE VARIATION
5	% Delta F % CV	51 % 4.0 %	50 % 4.0 %	-2.0 %	
10	% Delta F % CV	161 % 2.0 %	142 % 1.0 %	-11.8 %	-5.9 %
20	% Delta F % CV	412 % 3.0 %	372 % 1.0 %	-9.7 %	
40	% Delta F % CV	979 % 6.0 %	943 % 1.0 %	-3.7 %	
80	% Delta F % CV	1 878 % 1.0 %	1 829 % 1.0 %	-2.6 %	± 20 %
160	% Delta F % CV	2 992 % 1.0 %	2 820 % 2.0 %	-5.7 %	

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



St-K batch # 01RA

Accepted



Rejected



Operator's initials: AL

Date: 30/05/2023

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