

HTRF® Research Reagents

Anti-6HIS-XL665 Quality Control

Product number: 61HISXLF Lot Number: 70RD

Manufacturing date: 29/09/2021 Document version: 1

EXPERIMENTAL CONDITION

The batch to be controlled was compared to the reference batch currently in use, at increasing Anti-6HIS-XL665 concentrations.

Anti-6HIS-XL665 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-6HIS-Biotin + Streptavidin-Cryptate + Anti-6HIS-XL665

REAGENTS

	REFERENCE LOT NUMBER	ASSAY CONCENTRATION
Streptavidin-Cryptate	34A	1.8 nMf
Anti-6HIS-XL665 reference	66B	250 à 1 000 ng/mLf
Pept-6HIS-Biotin	CQ02	5 nMf

	CURRENT BATCH LOT NUMBER	ASSAY CONCENTRATION
Anti-6HIS-XL665 current batch	70RD	250 à 1 000 ng/mLf

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

EXPERIMENTAL PROCEDURE

Reconstitute Anti-6HIS-XL665 vial with 250 μ L 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:

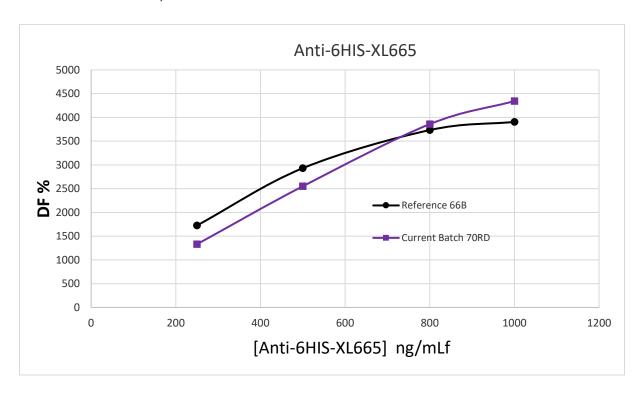
- 5 μL Pept-6HIS-Biotin (5 μL diluent for negative control)
- 10 μL XL conjugate
- 5 μL K conjugate

Incubation took place for 150 min at 2-8°C. The plate was read on Phera Star ® under standard conditions.

RESULTS

[Anti-6HIS-XL665] ng/mLf		Anti-6HIS- XL665 Reference	Anti-6HIS- XL665 CURRENT BATCH	VARIATION	MEAN ACCEPTABLE VARIATION
250	% Delta F % CV	1725 % 1.7 %	1330% 0.7 %	-22.9 %	-5.3 %
500	% Delta F % CV	2931 % 1.7 %	2550 % 1.0 %	-13.0 %	
800	% Delta F % CV	3733 % 1.8 %	3858 % 1.3 %	3.3 %	± 20 %
1000	% Delta F % CV	3905 % 1.8 %	4343 % 3.9 %	11.2 %	

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



Anti-6HIS-XL665 batch # 70RD	Accepted	Rejected	
71111 01110 712000 801011 11 7 0118	Accepted	Rejected	

Operator's initials: AL Date: 29/09/2021

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