

HTRF® Research Reagents

Anti-6HIS-XL665 Quality Control

Product number : 61HISXLA Lot Number : 71RA

Manufacturing date : 01/12/2022 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	29A	90 ng/mLf
Anti-6HIS-XL665 reference	70A	250 à 1 000 ng/mLf
Pept-6HIS-Biotin	CQ03	5 nMf

	CURRENT BATCH LOT NUMBER	ASSAY CONCENTRATION
Anti-6HIS-XL665 current batch	71RA	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 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-6HIS-Biotin (5 µL diluent for negative control)
- 10 µL XL conjugate
- 5 µL K conjugate

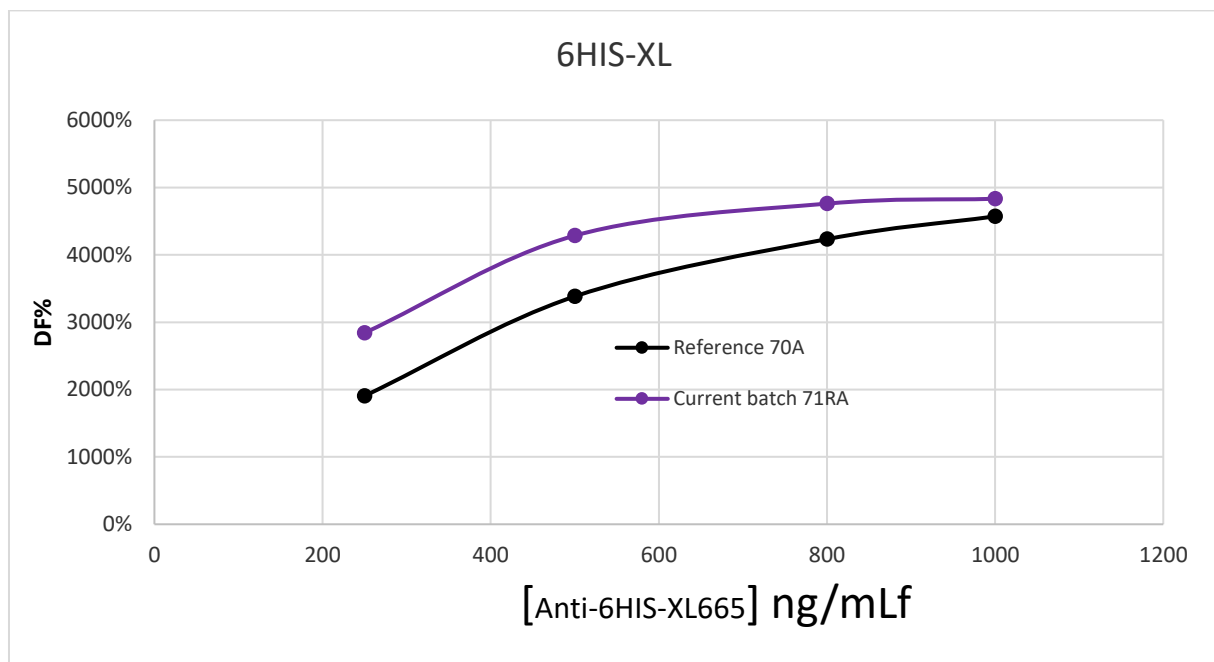
Incubation took place for 150 min at 2-8°C. The plate was read on Phera Star ® under standard conditions.

RESULTS

[Anti-6HIS-XL665] ng/mLf		Anti-6HIS- XL665 Reference	Anti-6HIS- XL665 CURRENT BATCH	VARIATION	MEAN ACCEPTABLE VARIATION
250	% Delta F % CV	1906 % 6.7 %	2842 % 2.3 %	49.1 %	23.5 %*
500	% Delta F % CV	3383 % 4.4 %	4286 % 3.8 %	26.7 %	
800	% Delta F % CV	4234 % 7.6 %	4761 % 9.4 %	12.4 %	± 20 %
1000	% Delta F % CV	4571 % 6.4 %	4833 % 7.6 %	5.7 %	

* → new batch XL665

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



Anti-6HIS-XL665 batch # 71RA

Accepted



Rejected



Operator's initials: MB

Date: 14/12/2022

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