

HTRF® Research Reagents

Anti-6HIS-XL665 Quality Control

Product number : 61HISXLA Lot Number : 72AR

Manufacturing date : 14/09/2023 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	37A	90 ng/mLf
Anti-6HIS-XL665	71A	250 à 1 000 ng/mLf
Pept-6HIS-Biotin	CQ03	5 nMf

	CURRENT BATCH LOT NUMBER	ASSAY CONCENTRATION
Anti-6HIS-XL665 current batch	72AR	250 à 1 000 ng/mLf

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

If applicable, streptavidin / biotin ratio was set up at : 1/2

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

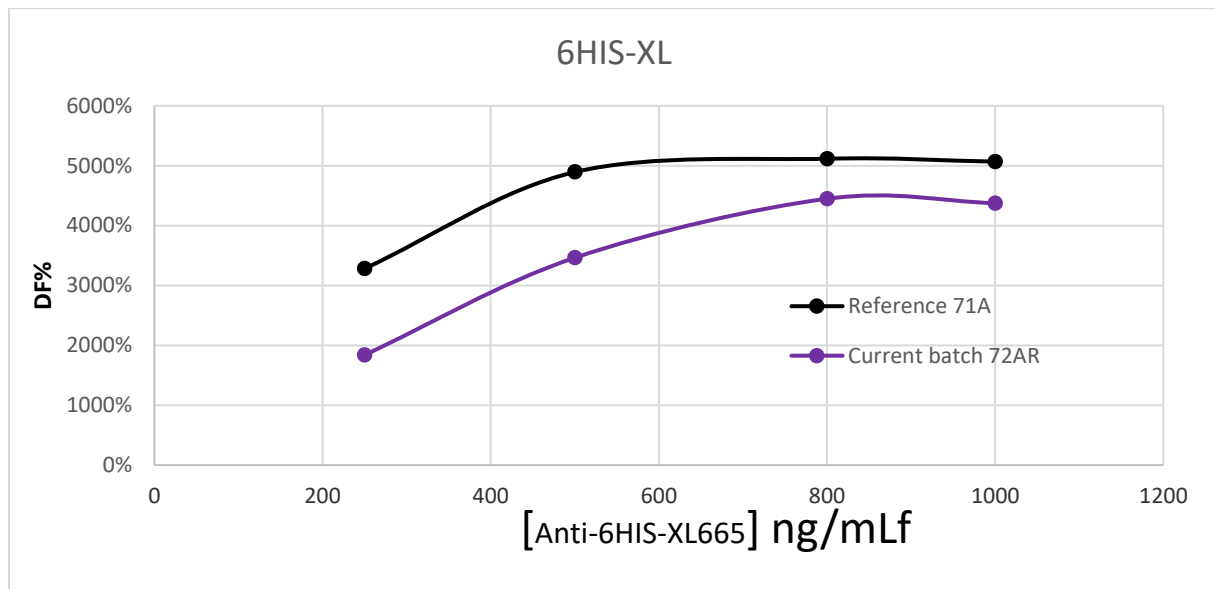
Incubation took place for 150 min at 2-8°C. The plate was read on Phera Star ® under standard conditions.

RESULTS

[Anti-6HIS-XL665] ng/mL _r		Anti-6HIS-XL665 REFERENCE	Anti-6HIS-XL665 CURRENT BATCH	VARIATION	ACCEPTABLE VARIATION
250	% Delta F % CV	3282 % 1.1 %	1839 % 0.9 %	-44.0 %	-25.0 %*
500	% Delta F % CV	4894 % 2.8 %	3462 % 0.7 %	-29.3 %	
800	% Delta F % CV	5116 % 2.7 %	4448 % 1.6 %	-13.1 %	± 20 %
1000	% Delta F % CV	5067 % 2.0 %	4374 % 3.0 %	-13.7 %	

*=> new batch of XL665

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



Anti-6HIS-XL665
batch # 72AR

Accepted

Rejected

Operator's initials: AL

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