

Anti-6HIS-XL665 Quality Control

Product reference : 61HISXLF

Batch # : 70B

1- Experimental conditions

The batch to be controlled was compared to the reference batch currently used, at increasing mab concentrations (Anti-6HIS-XL665).

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

2- Assay format

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

3- Reagents

	Reference lot number	Assay Concentration
Streptavidin-Cryptate	34A	1.5 nM _f
Anti-6HIS-XL665	70A	250 à 1 000 ng/ml _f
Pept-6HIS-Biotin	CQ02	5 nM _f

	Current batch lot number	Assay Concentration
Anti-6HIS-XL665	70B	250 à 1 000 ng/ml _f

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

4- Experimental procedure

Anti-6HIS-XL665 vial was reconstituted with 250 µl H₂O

Reagents were dispensed as follows :

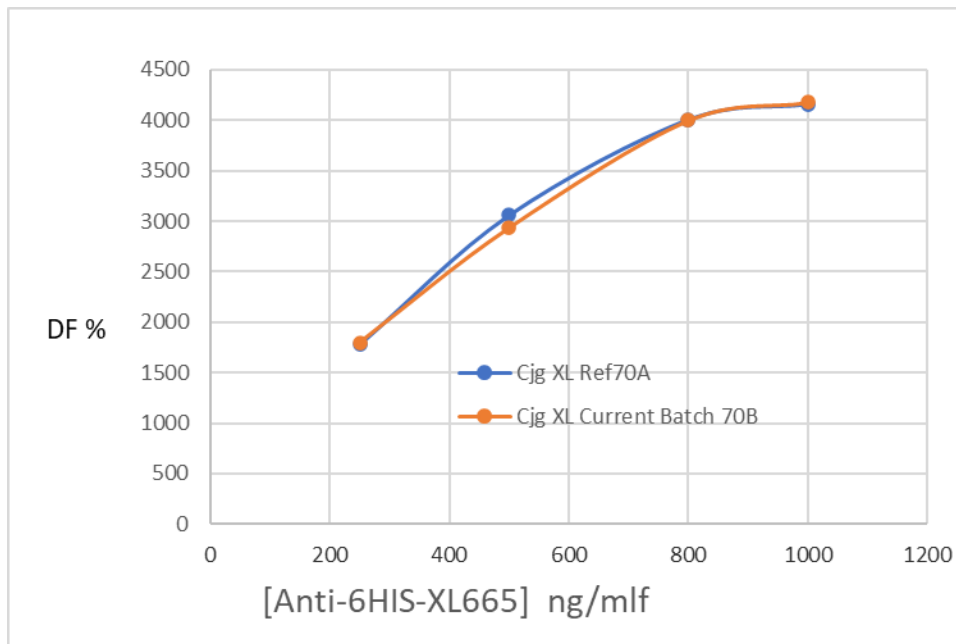
- 5 µl Pept-6HIS-Biotin
- 10 µl XL conjugate
- 5 µl Cryptate conjugate

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

5- Results

[Anti-6HIS-XL665] ng/ml _f		Anti-6HIS-XL665 Ref	Anti-6HIS-XL665 5.000 tests Current batch	Variation / Ref	Mean Acceptable variation
250	% Delta F % CV	1 781 % 5.9 %	1 795 % 4.1%	+0.8%	-0.82% ± 20 %
500	% Delta F % CV	3 062 % 2.9 %	2 933 % 2.0 %	-4.21%	
800	% Delta F % CV	4 008 % 4.1 %	3 998 % 2.7%	-0.25 %	
1 000	% Delta F % CV	4 162 % 5.2%	4 178 % 0.9 %	+0.38%	

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



Anti-6HIS-XL665 batch # 70B

Accepted

Rejected

Operator's initials
ML

Supervisor's initials and date