

HTRF® Research Reagents

Protein A-XL665 Quality Control

Product number : 61PRAXLB Lot Number : 18RA

Manufacturing date : 22/12/2021 Document version : 1

EXPERIMENTAL CONDITION

The batch to be controlled was compared to the reference batch currently in use, at increasing Protein A-XL concentrations.

Protein A-XL 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

Protein A-XL + anti GST-Cryptate or Streptavidin-Cryptate

REAGENTS

	REFERENCE LOT NUMBER	ASSAY CONCENTRATION
Streptavidin-Cryptate	29A	1.5 nMf
Protein A-XL reference	17A	0.125 nMf - 2 nMf
Anti GST-Cryptate	101A	0.83 nMf

	CURRENT BATCH LOT NUMBER	ASSAY CONCENTRATION
Protein A-XL current batch	18RA	0.125 nMf - 2 nMf

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

EXPERIMENTAL PROCEDURE

Reconstitute Protein A-XL 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 :

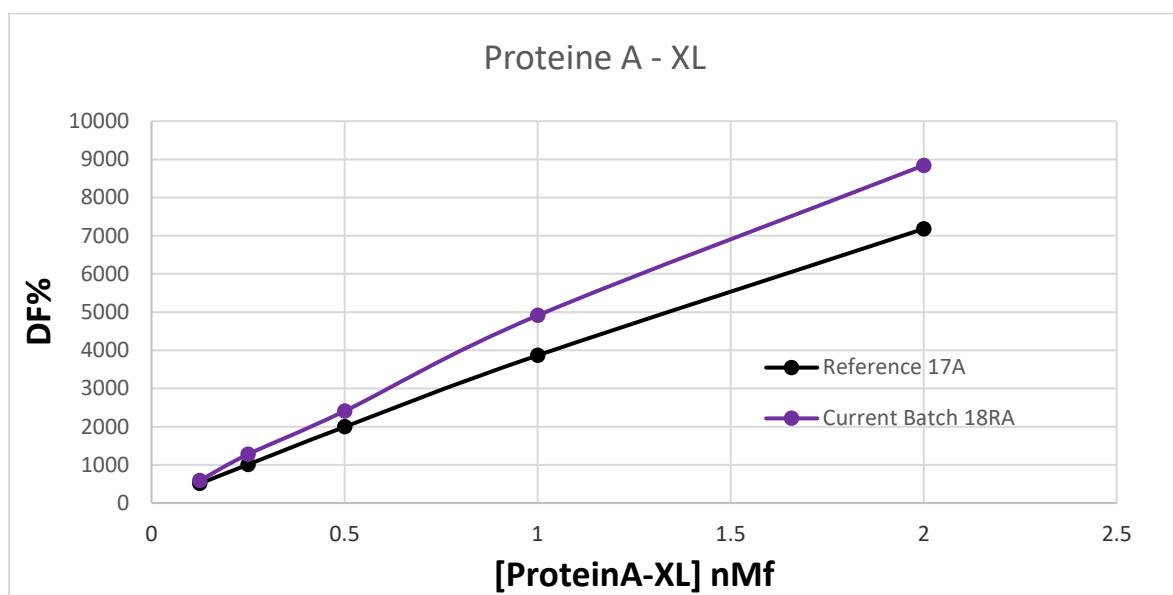
- 10 µL XL conjugate
- 10 µL K conjugate

Incubation took place for 60 min at room temperature. The plate was read on Phera Star ® under standard conditions.

RESULTS

[Protéine A-XL] nMf		Protein A-XL Reference	Protein A-XL CURRENT BATCH	VARIATION	MEAN ACCEPTABLE VARIATION
0.125	% Delta F % CV	510 % 2.9 %	592% 1.3 %	16.9 %	22.7 %
0.25	% Delta F % CV	1009 % 2.1 %	1277 % 0.4 %	26.5 %	
0.5	% Delta F % CV	1994 % 5.3 %	2409% 1.9 %	20.8 %	
1	% Delta F % CV	3866 % 1.6 %	4912% 2.3 %	27.1 %	± 20 %
2	% Delta F % CV	7180 % 1.1 %	8841 % 2.7 %	23.1 %	

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



Protein A-XL batch # 18RA

Accepted



Rejected



Operator's initials: MB

Date : 28/12/2021

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