

HTRF® Research Reagents

Protein A-XL665 Quality Control

Product number : 61PRAXLA 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 :

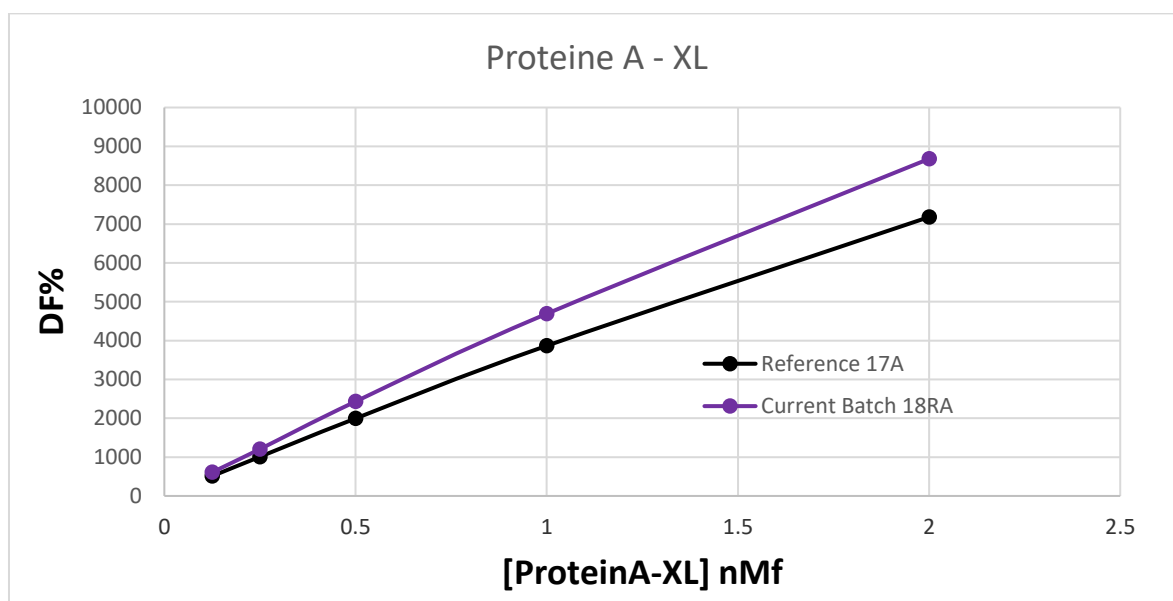
- 10 µL XL conjugate
- 10 µL K conjugate

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 % | 609% 1.1 % | 19.5 % | 20.6 % |
| 0.25 | % Delta F % CV | 1009 % 2.1 % | 1206 % 1.0 % | 19.5 % | |
| 0.5 | % Delta F % CV | 1994 % 5.3 % | 2430% 0.4 % | 21.8 % | |
| 1 | % Delta F % CV | 3866 % 1.6 % | 4690 % 0.2 % | 21.3 % | ± 20 % |
| 2 | % Delta F % CV | 7180 % 1.1 % | 8678 % 0.4 % | 20.9 % | |

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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