

HTRF® Research Reagents

Anti hFc-XL Quality Control

Product number : 61HFCXLF Lot Number : 14B

Manufacturing date : 01/02/2024 Document version : 1

EXPERIMENTAL CONDITION

The batch to be controlled was compared to the reference batch currently in use, at increasing Ab Human-Biotin concentrations.

Anti hFc-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

Ab Human-Biotin + Anti hFc-XL + SA-K

REAGENTS

	REFERENCE LOT NUMBER	ASSAY CONCENTRATION
SA-K	34A	110 ng/mLf
Anti hFc-XL reference	13A	1000 ng/mLf
Ab Human-Biotin	CQ01	0.187 nMf - 1.5 nMf

	CURRENT BATCH LOT NUMBER	ASSAY CONCENTRATION
Anti hFc-XL current batch	14B	1000 ng/mLf

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

EXPERIMENTAL PROCEDURE

Reconstitute Anti hFc-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 :

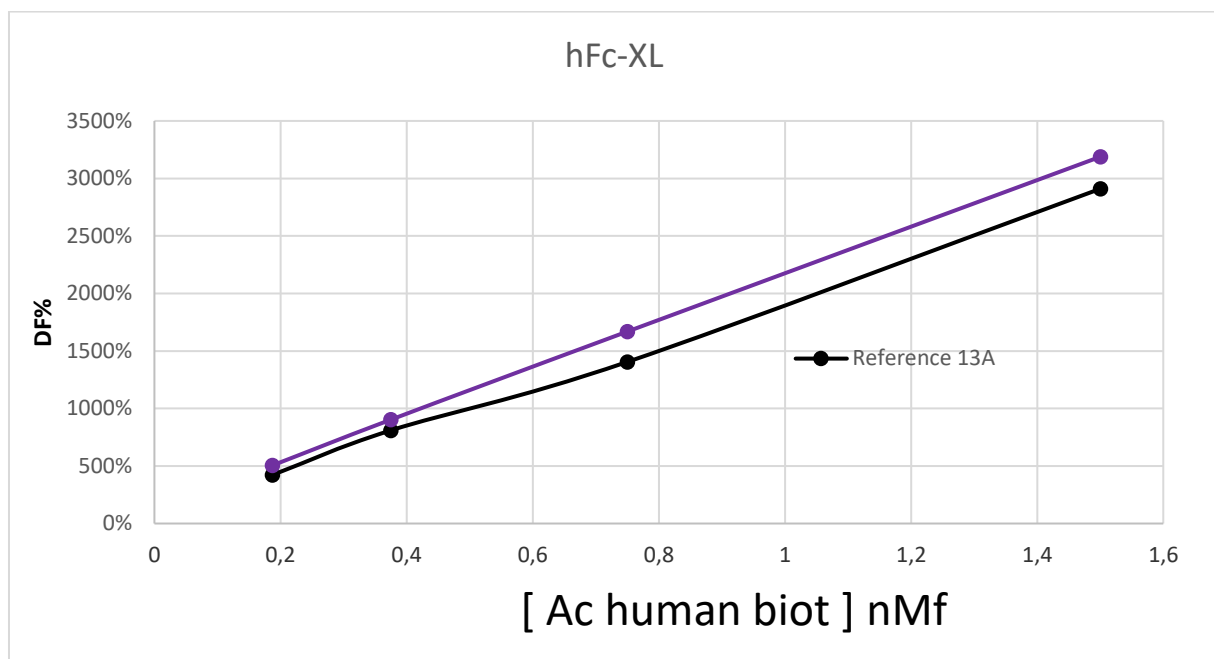
- 5 µL Ab Human-Biotin (5 µL diluent for negative control)
- 10 µL XL conjugate
- 5 µL K conjugate

Incubation took place for 180 min at room temperature. The plate was read on Envision® under standard conditions.

RESULTS

[Ab Human-Biotin] nMf		Anti hFc-XL Reference	Anti hFc-XL CURRENT BATCH	VARIATION	MEAN ACCEPTABLE VARIATION
0.187	% Delta F % CV	422 % 4.7 %	505 % 2.5 %	19.8 %	14.9 %
0.375	% Delta F % CV	810 % 1.9 %	903 % 0.6 %	11.5 %	
0.75	% Delta F % CV	1 405 % 3.7 %	1 669 % 2.2 %	18.8 %	± 20 %
1.5	% Delta F % CV	2 910 % 3.3 %	3 188 % 4.6 %	9.5 %	

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



Anti hFc-XL batch # 14B

Accepted



Rejected



Operator's initials: FTV

Date : 01/02/2024

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