

HTRF® Research Reagents

Anti hFc-XL Quality Control

Product number : 61HFCXLF Lot Number : 13RC

Manufacturing date : 13/03/2018 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	CQ02	200 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	13RC	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 :

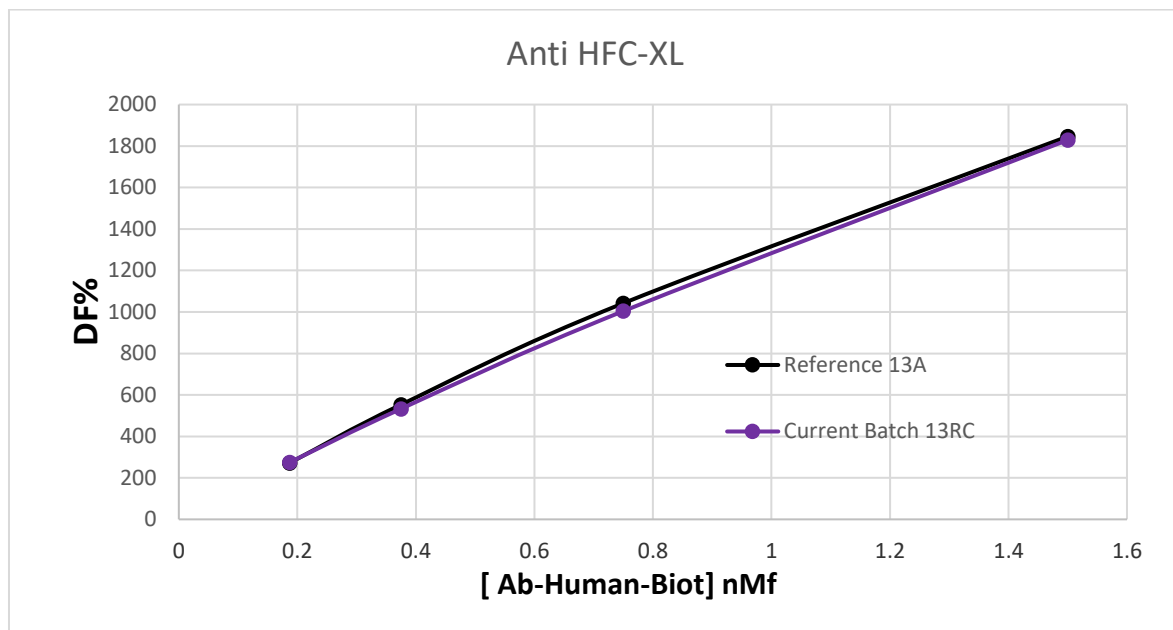
- 5 µL Ab Human-Biotin (5 µL diluent for negative control)
- 10 µL XL conjugate
- 5 µL K conjugate

Incubation took place for 180 min at room temperature. The plate was read on Phera Star ® 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	272 % 7.1 %	275 % 0.2 %	0.9 %	-1.8 %
0.375	% Delta F % CV	553 % 0.0 %	533 % 1.0 %	-3.6 %	
0.75	% Delta F % CV	1042 % 1.1 %	1004 % 0.5 %	-3.6 %	± 20 %
1.5	% Delta F % CV	1846 % 2.0 %	1829 % 1.0 %	-0.9 %	

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



Anti hFc-XL batch # 13RC

Accepted



Rejected



Operator's initials: MB

Date : 04/09/2018

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