

HTRF® Research Reagents

ANTI hFc-d2 Quality Control

Product number : 61HFCDA A Lot Number : 11A

Manufacturing date : 08/11/2024 Document version : 1

EXPERIMENTAL CONDITION

The batch to be controlled was compared to the reference batch currently in use, at increasing anti body concentrations (Ac Human-Biotin).

Anti hFc-d2 is frozen in PO4 buffer 100 mM pH7; 0.1% BSA.

All the reagents involved were diluted in PPI-Europium detection buffer (#61DB9RDF).

ASSAY FORMAT

Ac Human Biotin + Anti hFc -d2 + SA-K

REAGENTS

	REFERENCE LOT NUMBER	ASSAY CONCENTRATION
SA-K	37 A	110 ng/mLf
Anti hFc-d2 Ref	10A	1000 nMf
Ac Human-Biotin	CQ01	0.187 - 1.5 nMf

	CURRENT BATCH LOT NUMBER	ASSAY CONCENTRATION
Anti hFc-d2 current batch	11A	1000 nMf

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

EXPERIMENTAL PROCEDURE

Reagents were dispensed as follows :

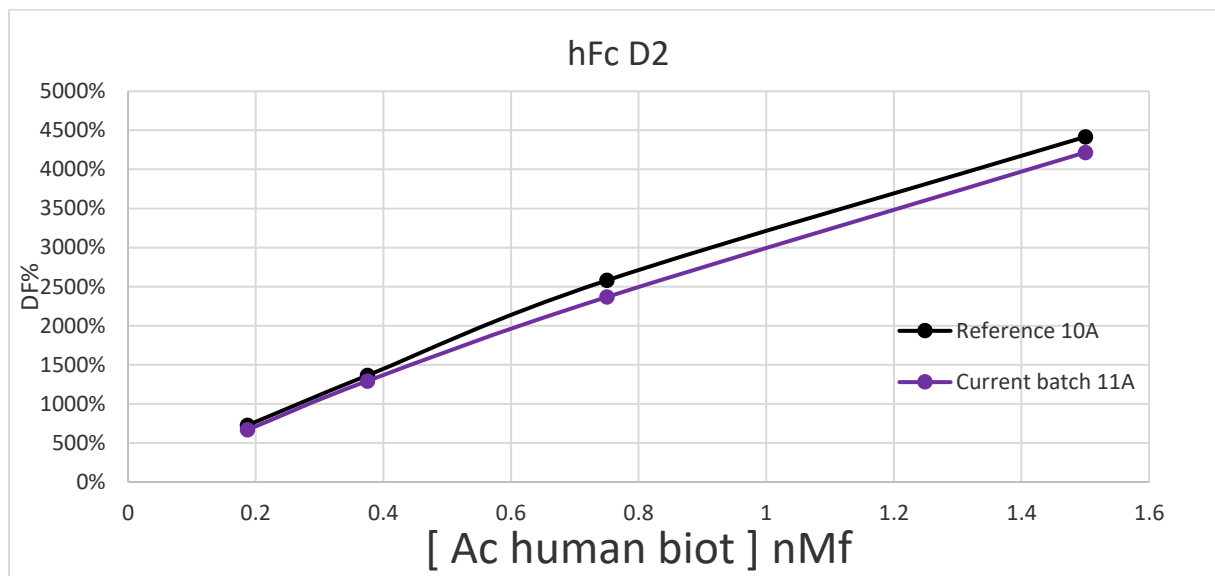
- 5 µL Ac Human-Biotin
- 10 µL d2 conjugate
- 5 µL K conjugate

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

RESULTS

[Ac Human-Biotin] nMf		Anti hFc-d2 Ref	Anti hFc-d2 CURRENT BATCH	VARIATION	ACCEPTABLE VARIATION
0.187	% Delta F % CV	725 % 3.6 %	667% 4.4 %	-8.1 %	-6.5%
0.375	% Delta F % CV	1363 % 1.0 %	1292% 1.3 %	-5.2%	
0.75	% Delta F % CV	2579 % 3.8 %	2366 % 3.1 %	-8.3 %	± 20 %
1.5	% Delta F % CV	4416 % 2.9 %	4217 % 2.7 %	-4.5 %	

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



Anti hFc-d2 batch # 11A

Accepted



Rejected



Operator's initials: ML

Date : 12/11/2024

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