

HTRF® Research Reagents

ANTI hFc-d2 Quality Control

Product number : 61HFCDAB Lot Number : 09A

Manufacturing date : 31/01/2024 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	07B	1000 nMf
Ac Human-Biotin	CQ01	0.187 - 1.5 nMf

	CURRENT BATCH LOT NUMBER	ASSAY CONCENTRATION
Anti hFc-d2 current batch	09A	1000 nMf

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

EXPERIMENTAL PROCEDURE

Reagents were dispensed as follows :

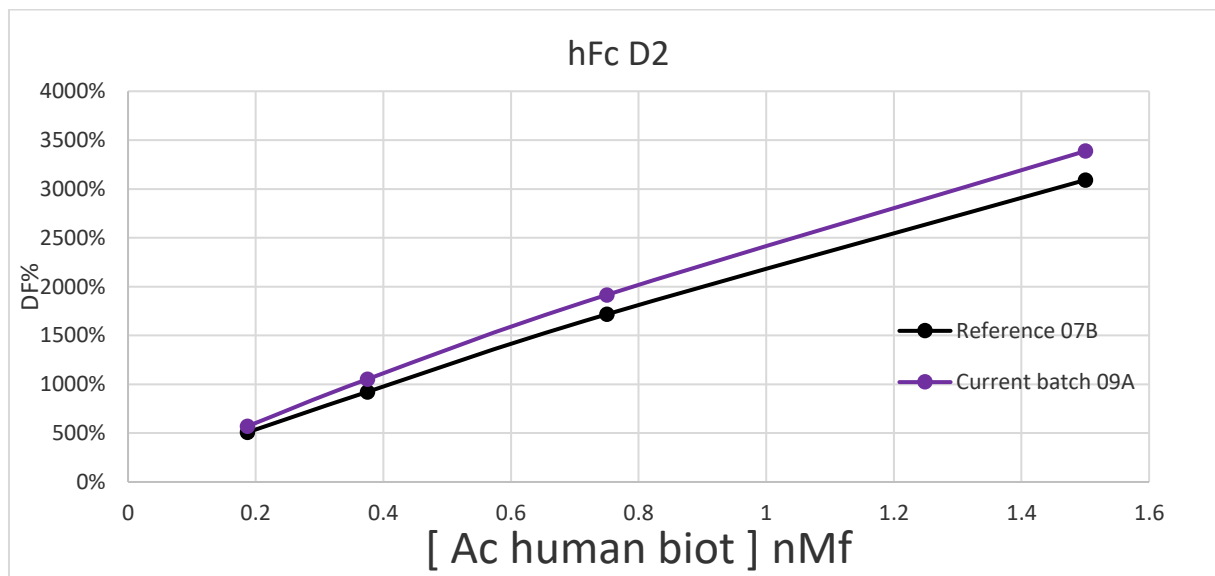
- 5 µL Ac Human-Biotin
- 10 µL d2 conjugate
- 5 µL K conjugate

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	508 % 2.3 %	570 % 1.8 %	12.3%	11.9 %
0.375	% Delta F % CV	922 % 2.7 %	1052 % 2.1 %	14.1 %	
0.75	% Delta F % CV	1716 % 3.0 %	1915 % 1.1 %	11.6 %	± 20 %
1.5	% Delta F % CV	3091% 2.3 %	3387% 2.3 %	9.6 %	

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



Anti hFc-d2 batch # 09A

Accepted

Rejected

Operator's initials: ML

Date : 19/02/2024

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