

HTRF[®] Research Reagents

ANTI hFc-d2 Quality Control

Product number : 61HFCDAA		Lot Number : 10A	
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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	A 110 ng/mLf	
Anti hFc-d2 Ref	09A	1000 nMf	
Ac Human-Biotin	CQ01	0.187 - 1.5 nM f	

	CURRENT BATCH LOT NUMBER	ASSAY CONCENTRATION				
Anti hFc-d2 current batch	10A	1000 nMf				

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

EXPERIMENTAL PROCEDURE

Reagents were dispensed as follows :

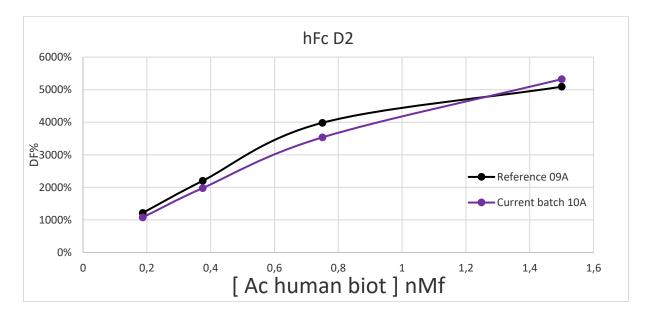
- 5 µL Ac Human-Biotin
- 10 µL d2 conjugate
- 5 µL K conjugate

Incubation took place for 180 min at room temperature. The plate was read on Phera Star $\ensuremath{\mathbb{B}}$ 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	1216 % 0.8 %	1078 % 1.2 %	-11.4 %	%
0.375	% Delta F % CV	2201 % 2.1 %	1978 % 1.1 %	-10.1 %	
0.75	% Delta F % CV	3683 % 0.8 %	3535 % 1.4 %	-11.3 %	± 20 %
1.5	% Delta F % CV	5081 % 0.7 %	5323 % 0.5 %	4.8 %	

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



Anti hFc-d2 batch # 10A Accepted Rejected

Operator's initials: MP

Date: 03/06/2024

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