

HTRF® Research Reagents

Anti hFc-d2 Quality Control

Product number : 61HFCDAF Lot Number : 06RA

Manufacturing date : 21/12/2017 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-d2 is frozen in PO4 buffer 100mM pH7, 0.1% BSA.

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

ASSAY FORMAT

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

REAGENTS

	REFERENCE LOT NUMBER	ASSAY CONCENTRATION
SA-K	29A	90 ng/mLf
Anti hFc-d2 reference	05B	1000 ng/mLf
Ab Human-Biotin	CQ01	0.187 nMf - 1.5 nMf

	CURRENT BATCH LOT NUMBER	ASSAY CONCENTRATION
Anti hFc-d2 current batch	06RA	1000 ng/mLf

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

EXPERIMENTAL PROCEDURE

Reagents were dispensed as follows :

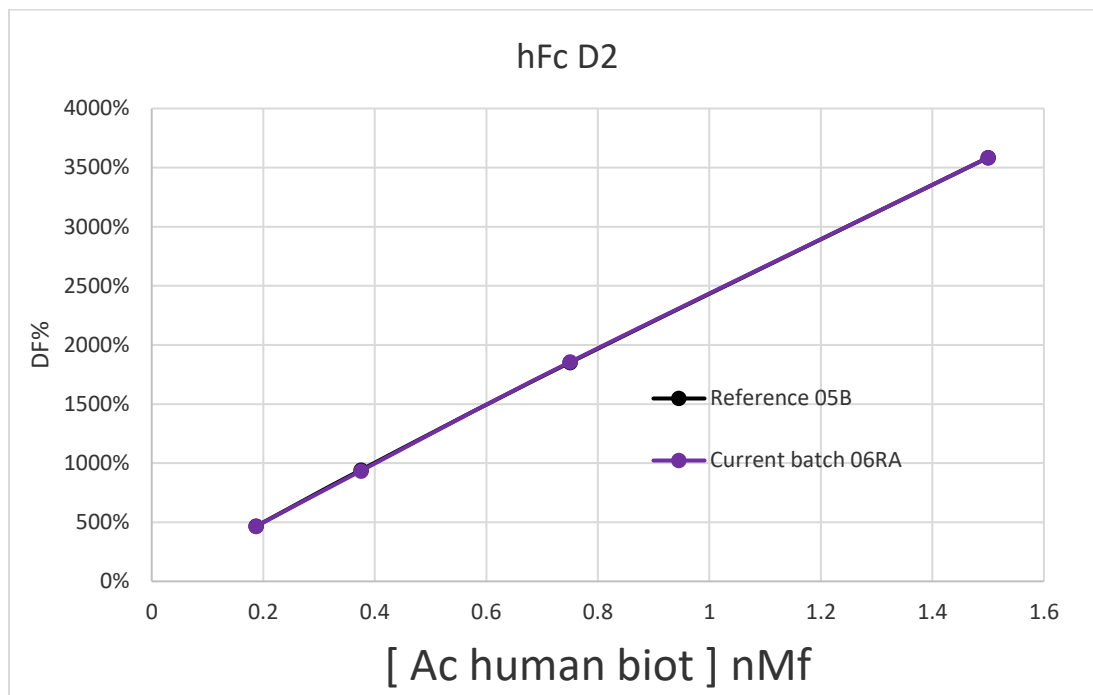
- 5 µL Ab Human-Biotin (5 µL diluent for negative control)
- 10 µL D2 conjugate
- 5 µL K conjugate

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

RESULTS

[Ab Human-Biotin] nMf		Anti hFc-d2 Reference	Anti hFc-d2 CURRENT BATCH	VARIATION	MEAN ACCEPTABLE VARIATION
0.187	% Delta F % CV	466% 2.5 %	465 % 0.1 %	-0.2 %	-0.3%
0.375	% Delta F % CV	942 % 1.7 %	934 % 0.6 %	-0.8 %	
0.75	% Delta F % CV	1 851 % 0.1 %	1 855 % 0.2 %	-0.2 %	± 20 %
1.5	% Delta F % CV	3 585 % 0.4 %	3 584 % 0.5 %	0.0 %	

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



Anti hFc-d2 batch # 06RA

Accepted



Rejected



Operator's initials: FTV

Date : 21/12/2017

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