

HTRF® Research Reagents

Anti hFc-d2 Quality Control

Product number: 61HFCDAA Lot Number: 07RC

Manufacturing date: 02/02/2023 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	34A	110 ng/mLf	
Anti hFc-d2 reference	07A	1000 ng/mLf	
Ab Human-Biotin	CQ01	0.187 nMf - 1.5 nMf	

	CURRENT BATCH LOT NUMBER	ASSAY CONCENTRATION
Anti hFc-d2 current batch	07RC	1000 ng/mLf

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

EXPERIMENTAL PROCEDURE

Reagents were dispensed as follows:

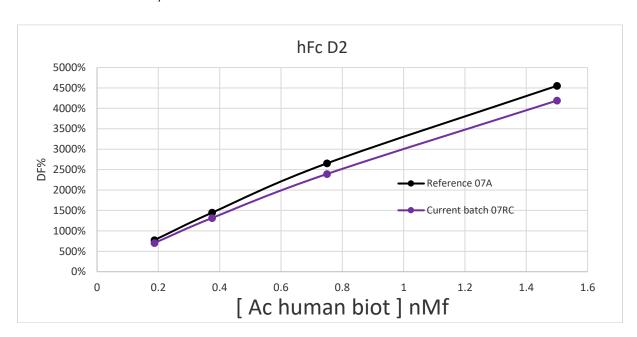
- 5 μL Ab Human-Biotin (5 μL diluent for negative control)
- 10 μL D2 conjugate
- 5 μL K conjugate

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	774% 0.8%	702 % 3.1%	-9.2%	-9.0%
0.375	% Delta F % CV	1445% 2.3%	1315% 0.5%	-9.0%	
0.75	% Delta F % CV	2654% 2.1%	2393% 3.9%	-9.8%	± 20 %
1.5	% Delta F % CV	4551% 2.1%	4189% 2.1%	-7.9%	

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





Operator's initials: MB Date: 02/02/2023

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