

HTRF® Research Reagents

Anti hFc-Tb Quality Control

Product number: 61HFCTAF Lot Number: 04RA

Manufacturing date: 09/02/2023 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-Tb is frozen in PO4 buffer 100mM pH7, 0.1% BSA.

All the reagents involved were diluted in PPI-Terbium detection buffer (#61DB10RDF).

ASSAY FORMAT

Ab Human-Biotin + Anti hFc-Tb + SA-XL

REAGENTS

	REFERENCE LOT NUMBER ASSAY CONCENTRATION		
SA-XL	174A	0.1 - 8 nM _f	
Anti hFc-Tb reference	02A	0.666 nMf	
Ab Human-Biotin	CQ01	0.025 - 2 nMf	

	CURRENT BATCH LOT NUMBER	ASSAY CONCENTRATION
Anti hFc-Tb current batch	04RA	0.666 nMf

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

If applicable, streptavidin / biotin ratio was set up at: 4 / 1

EXPERIMENTAL PROCEDURE

Reagents were dispensed as follows:

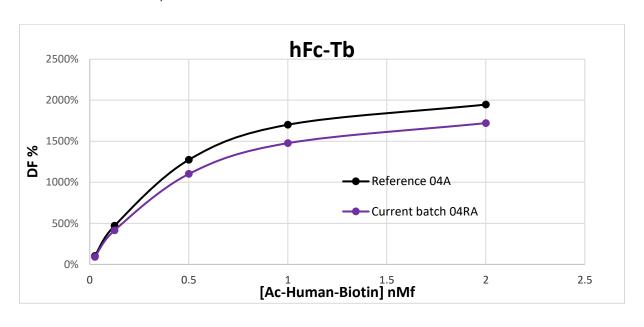
- 5 μL Ab Human-Biotin (5 μL diluent for negative control)
- 10 μL XL conjugate
- 5 μL Tb conjugate

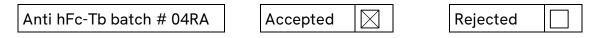
Incubation took place for 150 min at room temperature. The plate was read on Phera Star ® under standard conditions.

RESULTS

[Ab Human-Biotin] nMf		Anti hFc-Tb Reference	Anti hFc-Tb CURRENT BATCH	VARIATION	MEAN ACCEPTABLE VARIATION
0.025	% Delta F % CV	102 % 2.6 %	90 % 1.6 %	-11.3 %	-12.3 %
0.125	% Delta F % CV	470 % 1.4 %	414 % 1.7 %	-11.9 %	
0.5	% Delta F % CV	1274 % 0.8 %	1101 % 1.5 %	-13.6 %	± 20 %
1	% Delta F % CV	1701 % 1.2 %	1477 % 1.0 %	-13.2 %	
2	% Delta F % CV	1947 % 1.7 %	1721 % 0.7 %	-11.6 %	

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





Operator's initials: MB Date: 09/02/2023

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