

Human Fc-Tb Quality Control

Product reference : 61HFCTAA

Batch # : 04A

1- Experimental conditions

The batch to be controlled was compared to the reference batch currently in use, at increasing protein concentrations (Ac-Human-Biot).

hFc-Tb is frozen in PO4 buffer 100mM PH7 ; 0.1% BSA .

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

2- Assay format

hFc-Tb + Ac-Human-biot + SA-XL

3- Reagents

	Reference lot number	Assay Concentration
SA- XL	163A	0.1 - 8 nM _f
hFc-Tb	03A	0.666 nM _f
Ac-Human-Biot	CQ01	0.025 - 2 nM _f

	Current batch lot number	Assay Concentration
hFc-Tb	04A	0.666 nM _f

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

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

4- Experimental procedure

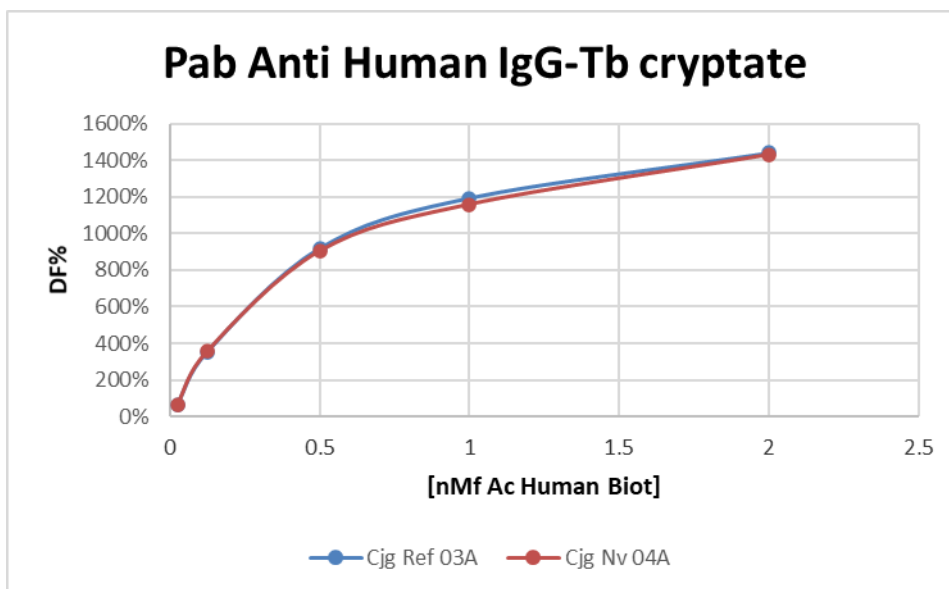
Reagents were dispensed as follows :

- 5 µl Tb conjugate
- 10 µl XL conjugate
- 5 µl Ac-Human-Biot

Incubation took place for 150 min at room temperature. The plate was read on Pherastar Plus under standard conditions.

5- Results

[Ac-Human-Biot] nM _r		hFc-Tb Ref	hFc-Tb Current Batch	Variati on / ref	Variation Moy acceptable
0.025	% Delta F % CV	66% 2.0%	65% 1.5%	-1%	-1.2% +/- 20% / ref
0.125	% Delta F % CV	353% 2.6%	356% 2.1%	1%	
0.5	% Delta F % CV	918% 0.7%	904% 3.1%	-2%	
1	% Delta F % CV	1193% 1.9%	1159% 1.9%	-3%	
2	% Delta F % CV	1439% 2.0%	1431% 1.4%	-1%	



hFc-Tb batch #04A

Accepted

Rejected

Date & Operator's initials : 06/11/2020 ML

Supervisor's initials and date