

MAb Anti GST-Tb cryptate
Quality Control

Product reference : 61GSTTLB

Batch : 14A

1- Experimental conditions

The batch to be controlled was compared to the reference batch currently in use, at increasing antigen concentrations (GST-Biotin).

MAb Anti GST-Tb cryptate is lyophilized in PO4 buffer 100 mM pH7 + 0.5 % BSA + stabilizers. In the assay all the reagents are diluted PPI - Terbium detection buffer, #61DB10RDF

2- Assay format

Streptavidin-XL + GST-Biotin + MAb Anti GST-Tb cryptate

3- Reagents

	Reference lot number	Assay Concentration
Streptavidin-XL	169A	0.2-2.4 nMf
Mab Anti GST-Tb cryptate _{Ref}	10A	0.83 nMf
GST-Biotin	09	0.2 – 2.4 nM _f

	Current batch lot number	Assay Concentration
Mab anti GST-Tb cryptate _{CQ}	14A	0.83 nMf

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

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

4- Experimental procedure

Reconstitute MAb anti GST-Tb cryptate vial with 250µl H2O (if packaged under 5,000 tests) or 1 ml H2O (if packaged under 20,000 tests).

Reagents were dispensed as follows :

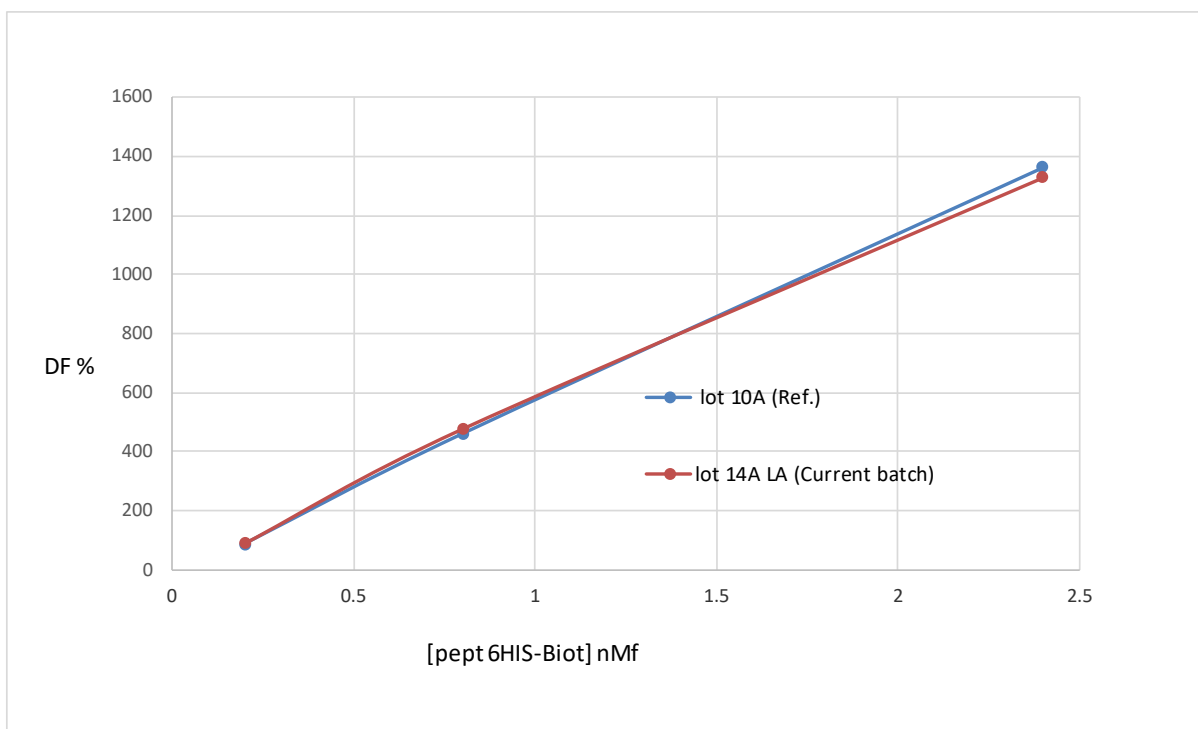
- 5 µl GST-Biotin
- 10 µl XL conjugate
- 5 µl Tb conjugate

Incubation took place for 120 min at room temperature. The plate was read on Pherastar Plus under standard conditions.

5- Results

[GST-Biotin] nM _f		Mab Anti GST-Tb cryptate Ref	Mab Anti GST-Tb cryptate Current batch	Variation	Acceptable variation
0.2	% Delta F % CV	86 % 2.4 %	79 % 0.3 %	-8.4 %	-7.0% ± 20 %
0.8	% Delta F % CV	460 % 1.4%	442 % 1.4 %	-4 %	
2.4	% Delta F % CV	1 365 % 0.1 %	1 250 % 2.8%	-8.4 %	

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



Anti GST-Tb batch # 14A

Accepted

Rejected

Operator's initials : NL

Supervisor's initials and date : 2021-08-11 LN