

SA-Tb Quality Control

Product reference : 610SATAH Batch # : 10A

1- Experimental conditions

The batch to be controlled was compared to the reference batch currently in use, at increasing Anti GST-d2 concentrations.

SA-Tb is lyophilized in PO4 0.1M Ph7 + BSA 0.5% + stabilizers or frozen in PO4 0.1M Ph7 + BSA 0.1% + Tween 0.1%

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

2- Assay format

SA-Tb + Pept-GST-biot. + Mab anti GST-d2

3- Reagents

	Reference lot number	Assay Concentration
Mab anti GST-d2	11A LA	0.1 – 0.375 – 0.75 – 1.5 nM _f
SA-Tb	08A	500 pM _f
Pept-GST-Biot	CQ08	2.5 nM _f

	Current batch lot number	Assay Concentration
SA-Tb	10A	500 pM _f

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

4- Experimental procedure

Reagents were dispensed as follows :

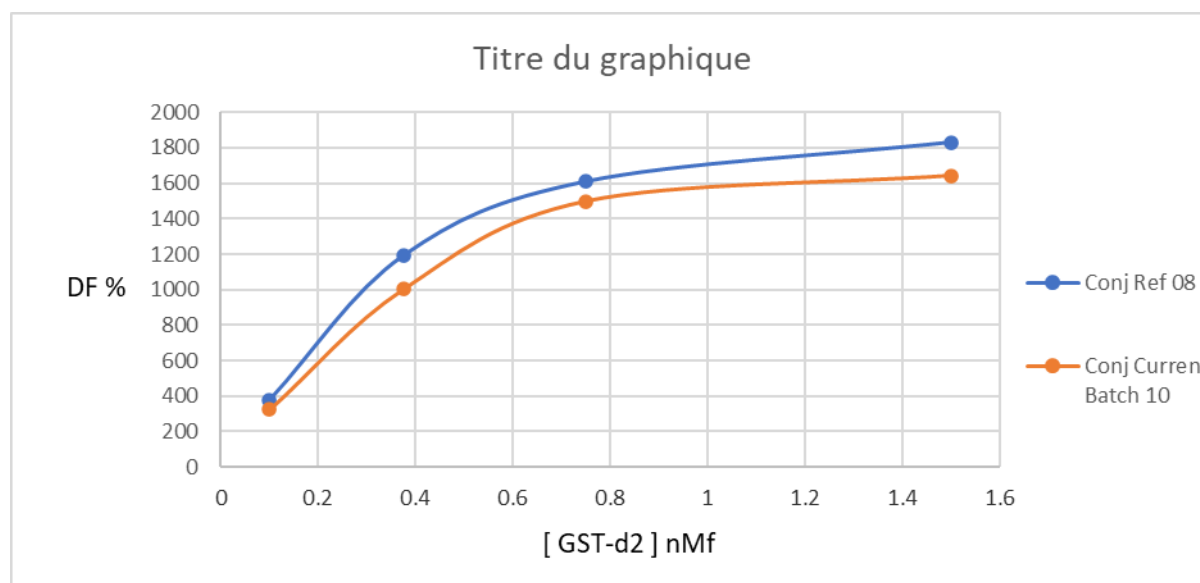
- 5 µl Pept-GST-Biot.
- 10 µl d2 conjugate
- 5 µl Tb conjugate

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

5- Results

[Anti GST-d2] nM _i		SA-Tb Ref	SA-Tb Current batch	Variation / Ref	Mean Variation / Ref
0.1	% Delta F % CV	377 % 0.9 %	325 % 1.9 %	-14 %	-11.7 %
0.375	% Delta F % CV	1 191 % 0.2 %	1 002% 2.1 %	-16 %	
0.75	% Delta F % CV	1 609 % 2.8 %	1 498% 3.2%	-6.8 %	Mean acceptable variation ± 20%
1.5	% Delta F % CV	1830 % 0.8 %	1 642 % 2.0%	-10 %	

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



SA-Tb batch # 10A

Accepted

Rejected

Operator's initials **ML**

Supervisor's initials and date