



Mab Anti GST-Tb Quality Control

Product reference: 61GSTTLB

Batch # : 17AR

EXPERIMENTAL CONDITION

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

Mab Anti GST-Tb is lyophilized in PO4 buffer 100 mM pH7; 0.1% BSA + Stabilizer.

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

ASSAY FORMAT

Pep GST-Biotin + Mab Anti GST-Tb crytate + Streptavidin-XL

REAGENTS

	REFERENCE LOT NUMBER	ASSAY CONCENTRATION
Streptavidin -XL	178A	0.2 – 2.4 nMf
Mab Anti GST-Tb Ref	16A	0.5 nMf
Pept-GST-Biotin	CQ09	0.2 – 2.4 nMf

	CURRENT BATCH LOT NUMBER	ASSAY CONCENTRATION
Mab Anti GST-Tb current batch	17AR	0.5 nMf

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

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

EXPERIMENTAL PROCEDURE

Reconstitute GST-Tb vial with 250 µL H2O (if packaged under 5,000 tests or 1,000 tests) or 1 mL H2O (if packaged under 20,000 tests).

Reagents were dispensed as follows :

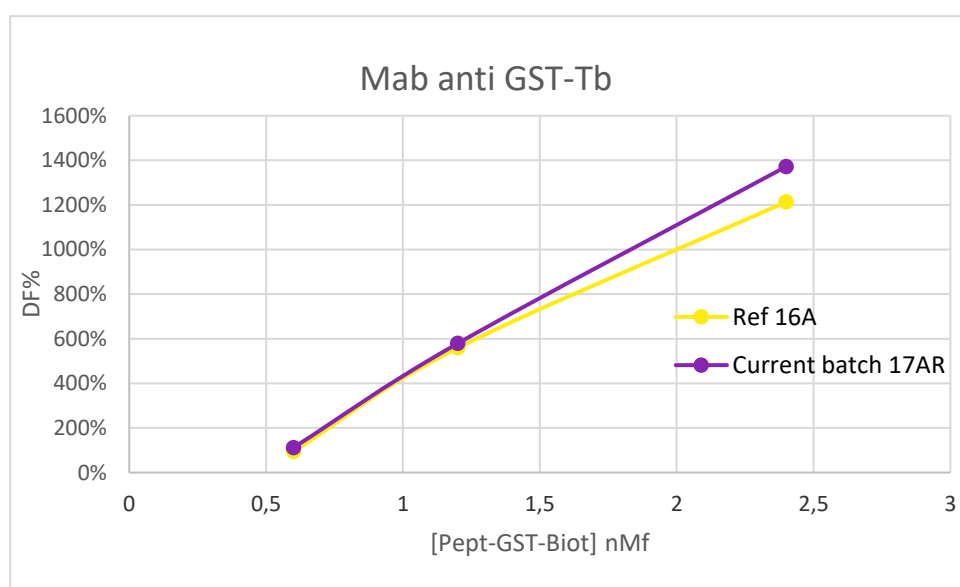
- 5 µL Pept-GST -Biotin (5 µL diluent for negative control)
- 10 µL XL conjugate
- 5 µL Tb conjugate

Incubation took place for 120 min at room temperature. The plate was read on Phera Star ® under standard conditions.

RESULTS

[Pept-GST -Biotin] nMf		GST-Tb Ref	GST-Tb CURRENT BATCH	VARIATION	ACCEPTABLE VARIATION
0.2	% Delta F % CV	95 % 4.5 %	112 % 1.2 %	17.4 %	11.3 %
0.8	% Delta F % CV	559 % 1.9 %	579 % 2.8 %	3.5 %	
2.4	% Delta F % CV	1214 % 1.3 %	1372 % 1.1 %	13.0 %	± 20 %

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



GST-Tb batch # 17AR

Accepted



Rejected



Operator's initials: ML

Date :04/07/2023