



SA-Tb Quality Control

Product reference: 610SATLF

Batch # : 21CR

EXPERIMENTAL CONDITION

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 buffer 100 mM pH7; 0.1% BSA + Stabilizer.

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

ASSAY FORMAT

Pept-PO4-Biotin + SA-Tb + Mab anti GST-d2

REAGENTS

	REFERENCE LOT NUMBER	ASSAY CONCENTRATION
Mab anti GST-d2	16 A	0.1-0.375-0.75-1.5 nMf
SA-Tb Ref	14 A	333 nMf
Pept-PO4-Biotin	CQ 09	2.5 nMf

	CURRENT BATCH LOT NUMBER	ASSAY CONCENTRATION
SA-d2 current batch	21CR	333 nMf

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

If applicable, streptavidin / biotin ratio was set up at : 1/2

EXPERIMENTAL PROCEDURE

Reconstitute SA-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 :

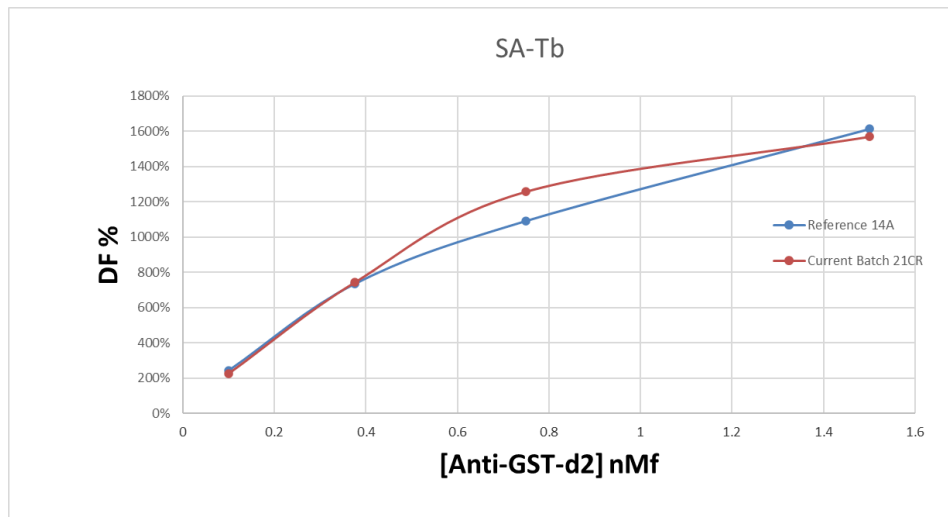
- 5 µL Pept-GST-Biot
- 10 µL d2 conjugate
- 5 µL Tb conjugate

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

RESULTS

[Anti GST-D2] nMf		SA-Tb Ref	SA-Tb CURRENT BATCH	VARIATION	ACCEPTABLE VARIATION
0.1	% Delta F % CV	243 % 3.8 %	227% 1.5 %	-7.2 %	1.65 %
0.375	% Delta F % CV	735 % 13.2 %	743 % 2.1 %	1.1 %	
0.75	% Delta F % CV	1092 % 5.5 %	1259 % 2.2 %	15.3 %	± 20 %
1.5	% Delta F % CV	1613 % 4.5 %	1570 % 1.0 %	-2.7 %	

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



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Accepted

Rejected

Operator's initials: ML

Date : 10/07/2023