

HTRF® Research Reagents

Streptavidin-Tb Quality Control

Product number : 610SATLA Lot Number : 14RA

Manufacturing date : 30/03/2022 Document version : 1

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 ; 0.5% BSA ; Stabilizers.

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

ASSAY FORMAT

SA-Tb + Pept-GST-biot. + Anti GST-D2

REAGENTS

	REFERENCE LOT NUMBER	ASSAY CONCENTRATION
Anti GST-d2	12A	0.1 - 0.375 - 0.75 - 1.5 nMf
SA-Tb reference	13A	0.333 nMf
Pept-GST-Biot	CQ09	2.5 nMf

	CURRENT BATCH LOT NUMBER	ASSAY CONCENTRATION
SA-Tb current batch	14RA	0.333 nMf

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

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 :

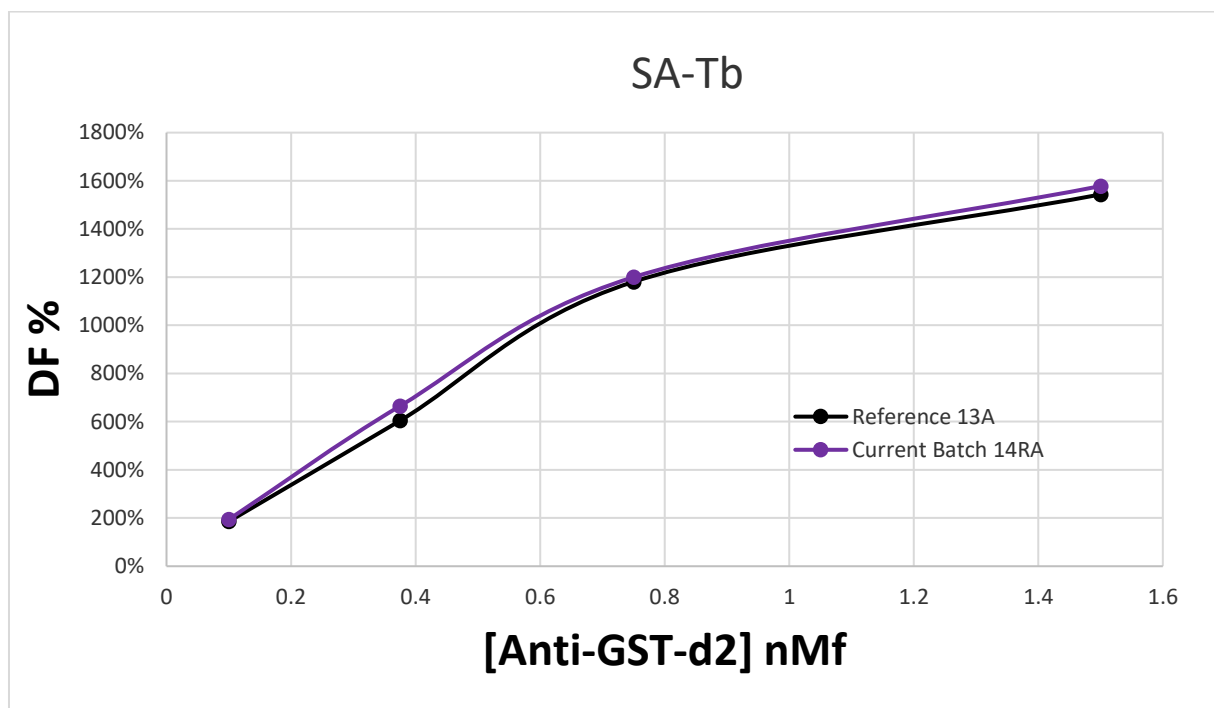
- 5 µL Pept-GST-Biotin (5 µL diluent for negative control)
- 10 µL D2 conjugate
- 5 µL Tb conjugate

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 Reference	SA-Tb CURRENT BATCH	VARIATION	MEAN ACCEPTABLE VARIATION
0.1	% Delta F % CV	185 % 1.5 %	194% 0.9 %	4.5 %	4.7 %
0.375	% Delta F % CV	604 % -- %	665 % 0.9 %	10.2 %	
0.75	% Delta F % CV	1181 % 0.5 %	1200% 1.5 %	1.7 %	± 20 %
1.5	% Delta F % CV	1543 % 4.7 %	1578 % 2.0%	2.3 %	

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



SA-Tb batch # 14RA

Accepted



Rejected



Operator's initials: MB

Date : 01/04/2022

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