

HTRF® Research Reagents

## SA-Tb Quality Control

Product number : 610SATLF

Lot Number : 26A

Manufacturing date : 30/08/2024

Document version : 1

### EXPERIMENTAL CONDITION

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

GST-Biotin + GST-d2 + SA-Tb

### REAGENTS

	REFERENCE LOT NUMBER	ASSAY CONCENTRATION
SA-Tb Ref	25A	20 ng/mLf
GST-Biot	10	2.5 nMf
GST-D2	16A	1.5 – 0.75 – 0.375 – 0.1 nMf

	CURRENT BATCH LOT NUMBER	ASSAY CONCENTRATION
SA-Tb current batch	26A	20 ng/mLf

*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 :

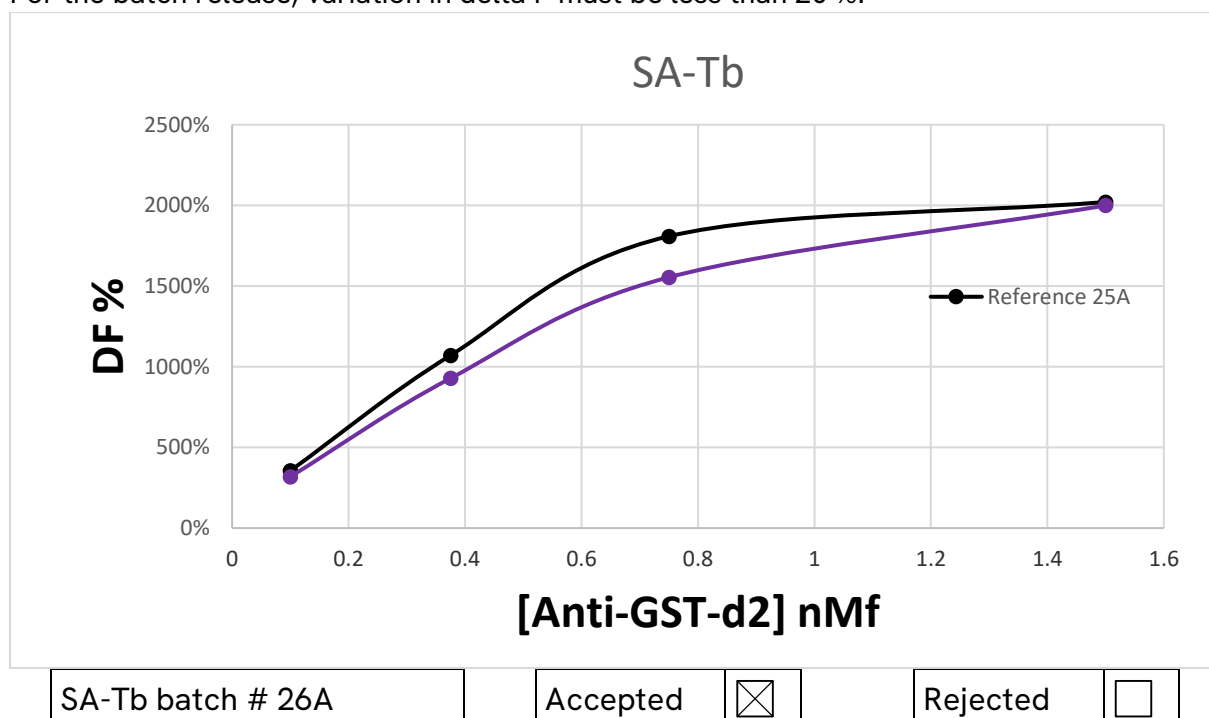
- 5 µL GST-Biotin (5 µL diluent for negative control)
- 10 µL d2 conjugate
- 5 µL Tb conjugate

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

## RESULTS

[Pept-PO4-Biotin] nMf		SA-Tb Ref	SA-Tb CURRENT BATCH	VARIATION	ACCEPTABLE VARIATION
0.1	% Delta F % CV	356% 1.8 %	319 % 3.9 %	-10.40 %	-9.7%
0.375	% Delta F % CV	1070 % 3.2 %	928 % 5.0 %	-13.3%	
0.75	% Delta F % CV	1809 % 3.5 %	1554 % 4.8 %	-14.05%	± 20 %
1.5	% Delta F % CV	2021 % 2.2 %	1999 % 0.4 %	-1.07%	

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



Operator's initials: ML

Date :03/09/24

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