

HTRF® Research Reagents

Anti-6HIS-Tb Quality Control

Product number : 61HISTLF Lot Number : 13RA

Manufacturing date : 05/01/2022 Document version : 1

EXPERIMENTAL CONDITION

The batch to be controlled was compared to the reference batch currently in use, at increasing Pept-6HIS-biotin concentrations.

Anti-6HIS-Tb is lyophilized in PO4 buffer 100 mM pH7 ; 0.1% BSA ; Stabilizers.

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

ASSAY FORMAT

Anti-6HIS-Tb + Pept-6HIS-biot. + Streptavidin-XL665

REAGENTS

	REFERENCE LOT NUMBER	ASSAY CONCENTRATION
Streptavidin-XL665	169A	0.3-0.6-1.2 nMf
Anti-6HIS-Tb reference	11A	0.67 nMf
Pept-6HIS-Biot	CQ02	0.6-1.2-2.4 nMf

	CURRENT BATCH LOT NUMBER	ASSAY CONCENTRATION
Anti-6HIS-Tb current batch	13RA	0.67 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 Anti-6HIS-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 :

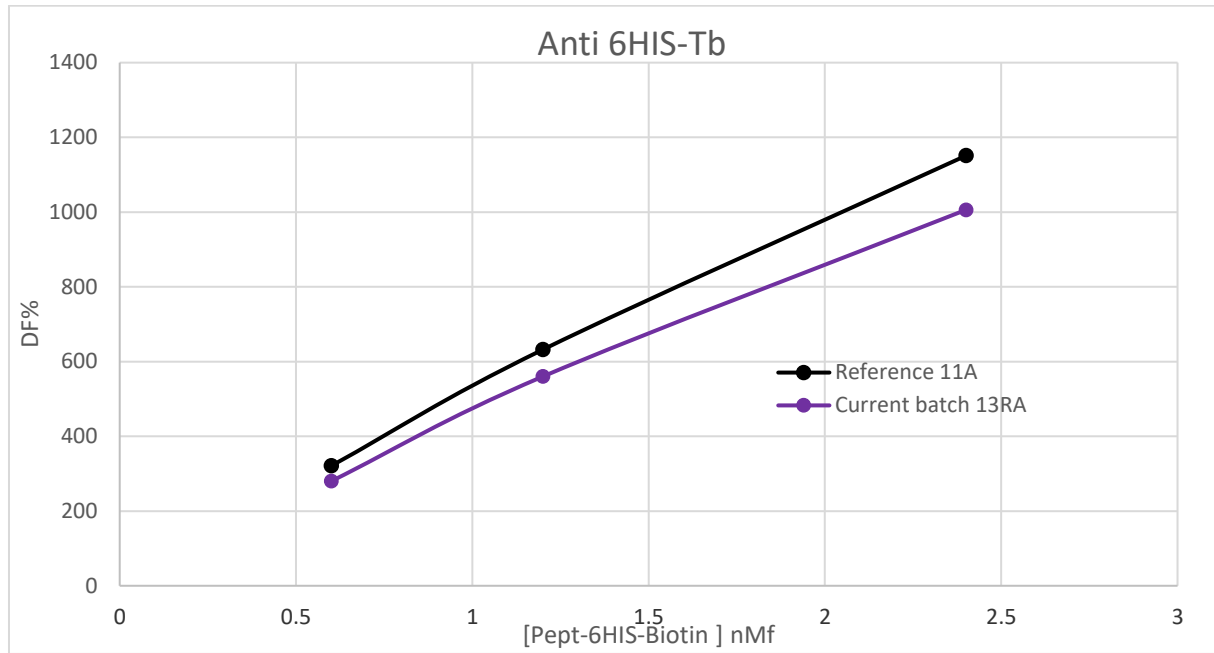
- 5 µL Pept-6HIS-Biotin (5 µL diluent for negative control)
- 10 µL XL conjugate
- 5 µL Tb conjugate

Incubation took place for 150 min at 2-8°C. The plate was read on Phera Star ® under standard conditions.

RESULTS

[Pept-6HIS-Biotin] nMf		Anti-6HIS-Tb Reference	Anti-6HIS-Tb CURRENT BATCH	VARIATION	MEAN ACCEPTABLE VARIATION
0.6	% Delta F % CV	321% 1.25%	280% 2.29%	-13.0 %	-12.3 %
1.2	% Delta F % CV	632% 2.77%	560% 2.93%	-11.3 %	± 20 %
2.4	% Delta F % CV	1 151% 1.59%	1 006% 2.93%	-12.6 %	

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



Anti-6HIS-Tb batch # 13RA

Accepted

Rejected

Operator's initials: AL

Date: 18/01/2022

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