

HTRF® Research Reagents

Anti-6HIS-Tb Quality Control

Product number : 61HISTLA

Lot Number : 16A

Manufacturing date : 09/08/2024

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	182A	0.3-0.6-1.2 nMf
Anti-6HIS-Tb reference	15A	0.67 nMf
Pept-6HIS-Biot	CQ03	0.6-1.2-2.4 nMf

	CURRENT BATCH LOT NUMBER	ASSAY CONCENTRATION
Anti-6HIS-Tb current batch	16A	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 :

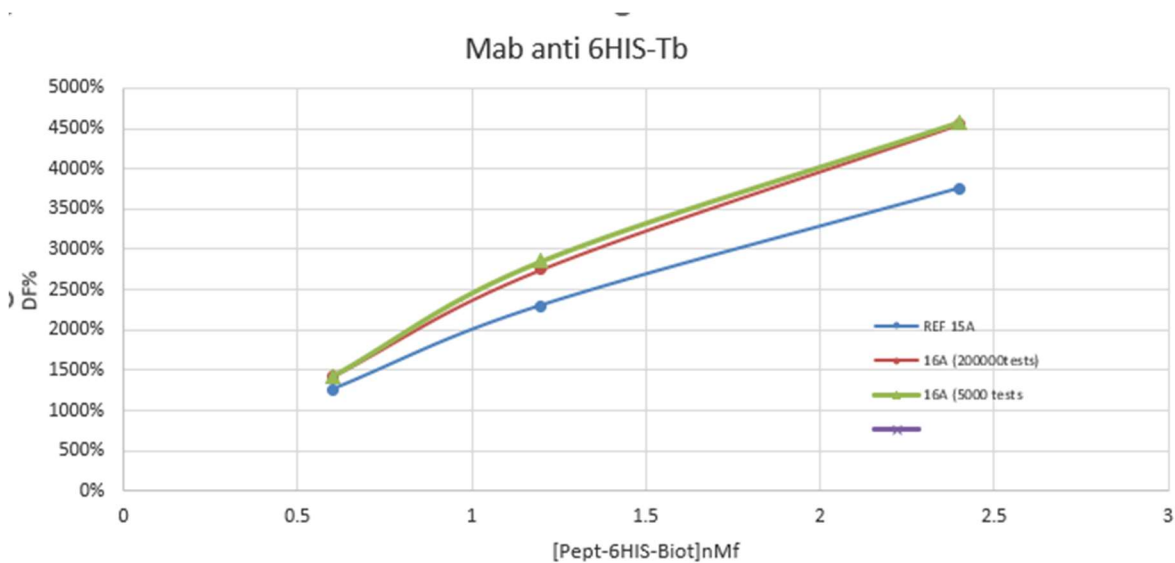
- 5 µL Pept-6HIS-Biotin (5 µL diluent for negative control)
- 10 µL XL conjugate
- 5 µL Tb conjugate

Incubation took place for 150 min at 2-8°C. The plate was read on ENVISION® 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	1256% 4.5%	1430% / %	13.9%	19.9%
1.2	% Delta F % CV	2301% 13.6%	2854% 2.1%	24.1 %	± 20 %
2.4	% Delta F % CV	3756% 2.1%	4575% 0.3%	21.8%	

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



Anti-6HIS-Tb batch # 16A

Accepted

Rejected

Operator's initials: AC

Date: 09/08/2024

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