

HTRF® Research Reagents

## Anti-6HIS-Tb Gold Quality Control

Product number : 61HI2TLB Lot Number : 23RA

Manufacturing date : 2023-10-03 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 Gold 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

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

### REAGENTS

	REFERENCE LOT NUMBER	ASSAY CONCENTRATION
Streptavidin-XL665	174A	0.15 nMf à 2.4 nMf
Anti-6HIS-Tb Gold reference	22A	0.33 nMf
Pept-6HIS-Biot	CQ03	0.6 nMf à 9.6 nMf

	CURRENT BATCH LOT NUMBER	ASSAY CONCENTRATION
Anti-6HIS-Tb Gold current batch	23RA	0.33 nMf

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

If applicable, streptavidin / biotin ratio was set up at : 1/4

### EXPERIMENTAL PROCEDURE

Reconstitute Anti-6HIS-Tb Gold 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 :

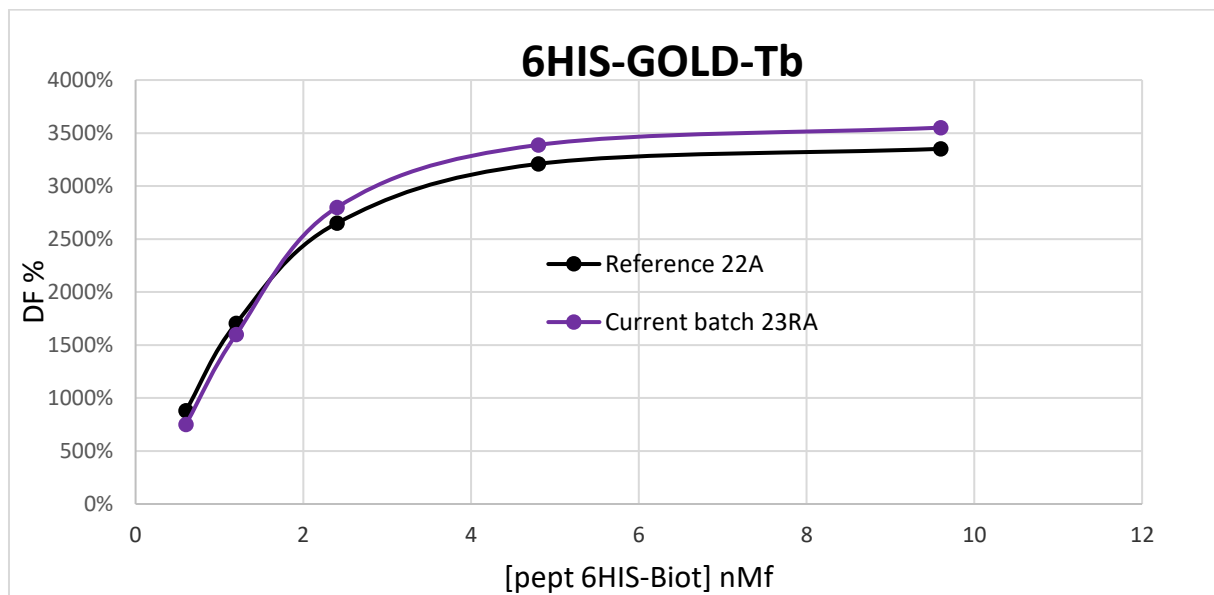
- 10 µL Pept-6HIS-Biotin (10 µL diluent for negative control)
- 5 µL XL conjugate
- 5 µL Tb conjugate

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

## RESULTS

[Pept-6HIS-Biotin] nMf		Anti-6HIS-Tb Gold Reference	Anti-6HIS-Tb Gold CURRENT BATCH	VARIATION	MEAN ACCEPTABLE VARIATION
0.6	% Delta F % CV	880% 6.8%	751% 8.2%	-14.7 %	
1.2	% Delta F % CV	1705% 10.9%	1600% 5.4%	-6.2 %	-0.7 %
2.4	% Delta F % CV	2650% 1.6%	2798% 2.6%	5.6 %	
4.8	% Delta F % CV	3209% 3.9%	3388% 4.1%	5.6 %	± 20 %
9.6	% Delta F % CV	3351% 7.1%	3551% 0.2%	6.0 %	

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



Anti-6HIS-Tb Gold batch # 23RA

Accepted

Rejected

Operator's initials: ML

Date: 18/04/2023

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