

HTRF® Research Reagents

Anti-6HIS-Tb Gold Quality Control

Product number : 61HI2TLA Lot Number : 20RB

Manufacturing date : 08/04/2022 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 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	173A	0.15 nMf à 2.4 nMf
Anti-6HIS-Tb Gold reference	19A	0.33 nMf
Pept-6HIS-Biot	CQ02	0.6 nMf à 9.6 nMf

	CURRENT BATCH LOT NUMBER	ASSAY CONCENTRATION
Anti-6HIS-Tb Gold current batch	20RB	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 :

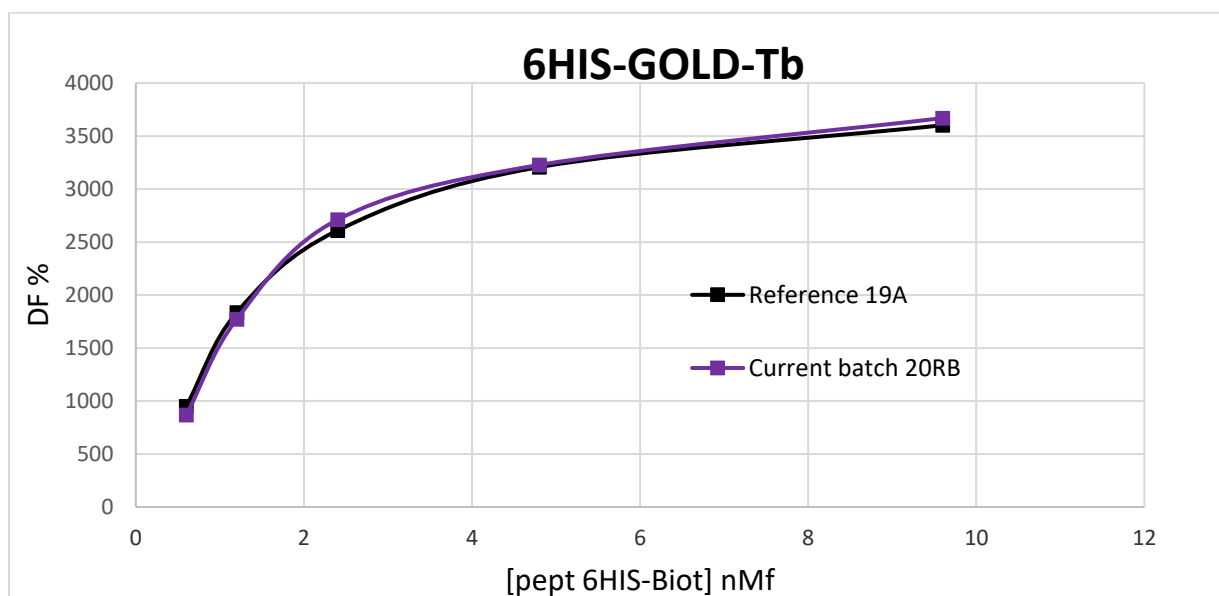
- 10 µL Pept-6HIS-Biotin (10 µL diluent for negative control)
- 5 µL XL conjugate
- 5 µL Tb conjugate

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	950% 2.6%	867% 4.8%	-8.8%	
1.2	% Delta F % CV	1834% 1.0%	1771% 0.9%	-3.4%	-0.6 %
2.4	% Delta F % CV	2609% 1.4%	2710% 0.2%	3.9%	
4.8	% Delta F % CV	3207% 1.0%	3327% 0.4%	3.7%	± 20 %
9.6	% Delta F % CV	3602% 0.8%	3669% 0.8%	1.8%	

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



Anti-6HIS-Tb Gold batch # 20RB

Accepted

Rejected

Operator's initials: ML

Date: 19/04/2022

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