

HTRF® Research Reagents

Anti-6HIS-Tb Gold Quality Control

Product number : 61HI2TLA Lot Number : 22RA

Manufacturing date : 01/09/2022 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	20A	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	22RA	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 :

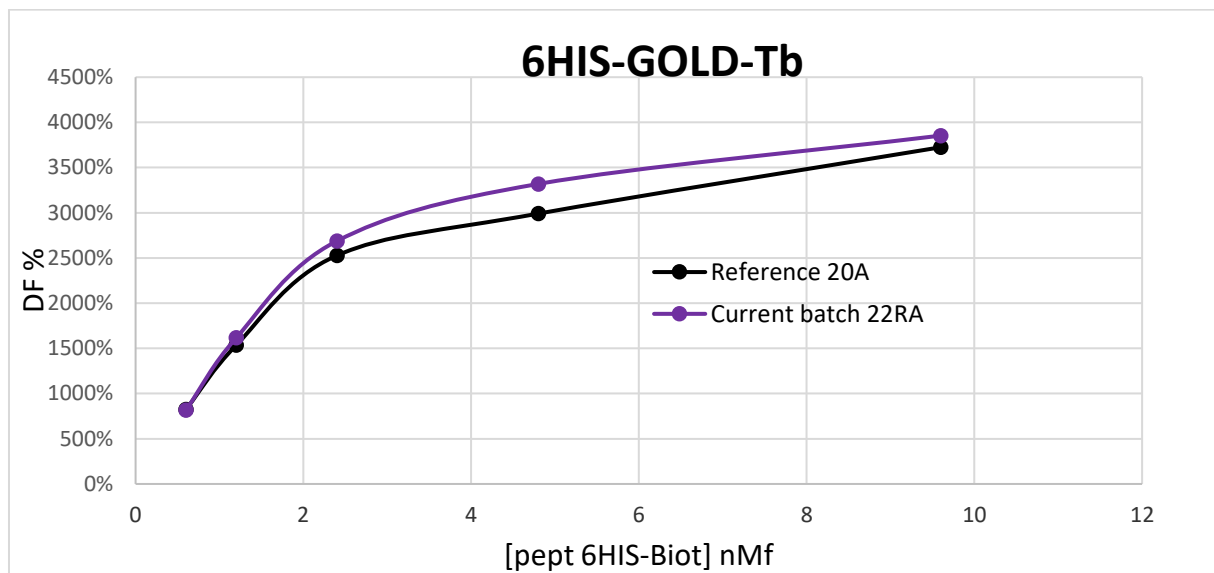
- 10 µL Pept-6HIS-Biotin (10 µL diluent for negative control)
- 5 µL XL conjugate
- 5 µL Tb conjugate

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	824% 1.5%	817% 1.0%	-0.9%	
1.2	% Delta F % CV	1535% 0.6%	1616% 4.3%	5.3%	5.0 %
2.4	% Delta F % CV	2527% 0.6%	2687% 0.7%	6.3%	
4.8	% Delta F % CV	2990% 1.7%	3319% 0.6%	11%	± 20 %
9.6	% Delta F % CV	3725% 0.4%	3854% 1.2%	3.5%	

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



Anti-6HIS-Tb Gold batch # 22RA

Accepted

Rejected

Operator's initials: ML

Date: 06/09/2022

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