

HTRF® Research Reagents

GST-XL Quality Control

Product number : 61GSTXLF Lot Number : 41RA

Manufacturing date : 28/04/2023 Document version : 1

EXPERIMENTAL CONDITION

The batch to be controlled was compared to the reference batch currently in use, at increasing antigen concentrations (GST-Biotin).

GST-XL is lyophilized in PO4 buffer 100 mM pH7 ; 0.1% BSA ; Stabilizers.

All the reagents involved were diluted in PPI-Europium detection buffer (#61DB9RDF).

ASSAY FORMAT

SA-Cryptate + GST-Biotin + GST-XL

REAGENTS

	REFERENCE LOT NUMBER	ASSAY CONCENTRATION
SA-Cryptate	CQ02	2.33 nMf
GST-XL reference	40A	6.67 nMf
GST-Biotin	09	0.5 - 2 - 12 nMf

	CURRENT BATCH LOT NUMBER	ASSAY CONCENTRATION
GST-XL current batch	41RA	6.67 nMf

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

EXPERIMENTAL PROCEDURE

Reconstitute GST-XL 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 :

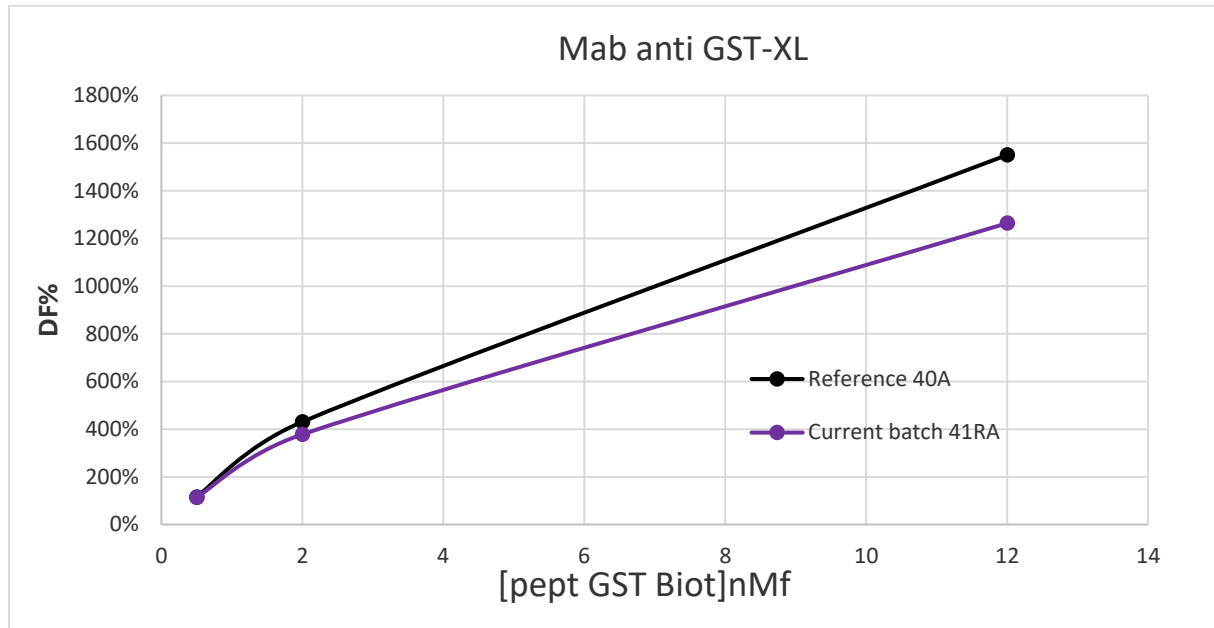
- 5 µL GST-Biotin (5 µL diluent for negative control)
- 10 µL XL conjugate
- 5 µL K conjugate

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

RESULTS

[GST-Biotin] nMf		GST-XL Reference	GST-XL CURRENT BATCH	VARIATION	MEAN ACCEPTABLE VARIATION
0.5	% Delta F % CV	115 % 2.3 %	113 % 4.1%	-2.4%	-11.0 %
2	% Delta F % CV	431 % 8.6 %	378% 12.5 %	-12.2%	± 20 %
12	% Delta F % CV	1 550% 1.5 %	1264 % 1.0 %	-18.5 %	

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



GST-XL batch # 41RA

Accepted



Rejected



Operator's initials: ML

Date: 05/05/2023

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