

HTRF® Research Reagents

SA-K Quality Control

Product number : 610SAKLA Lot Number : 37RA

Manufacturing date : 03/05/2023 Document version : 1

EXPERIMENTAL CONDITION

The batch to be controlled was compared to the reference batch currently in use, at increasing GST-D2 concentrations.

SA-K is lyophilized in PO4 buffer 100 mM pH7 ; 0.5% BSA ; Stabilizers.

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

ASSAY FORMAT

SA-K + GST-D2 + Pept-GST-Biotin

REAGENTS

	REFERENCE LOT NUMBER	ASSAY CONCENTRATION
SA-K reference	36A	110 ng/mLf
GST-D2	15A	0.1 - 1.5 nMf
Pept-GST-Biotin	09	2.4 nMf

	CURRENT BATCH LOT NUMBER	ASSAY CONCENTRATION
SA-K current batch	37RA	110 ng/mLf

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

EXPERIMENTAL PROCEDURE

Reconstitute SA-K 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 :

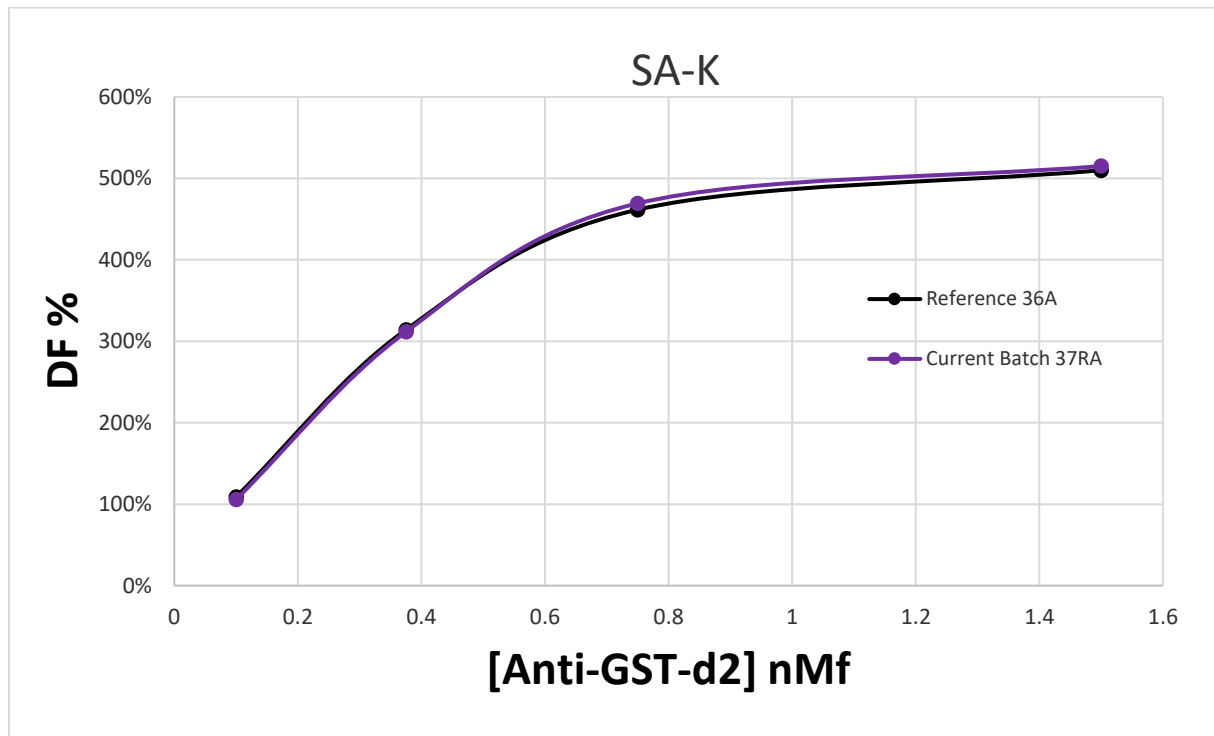
- 5 µL Pept-GST-Biotin (5 µL diluent for negative control)
- 10 µL D2 conjugate
- 5 µL K conjugate

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

RESULTS

[Anti GST-D2] nMf		SA-K Reference	SA-K CURRENT BATCH	VARIATION	MEAN ACCEPTABLE VARIATION
0.1	% Delta F % CV	109 % 1.0 %	106 % 0.1 %	-2.9 %	-0.3 %
0.375	% Delta F % CV	314 % 1.7 %	312 % 0.6 %	-0.8 %	
0.75	% Delta F % CV	462 % 1.4 %	469 % 2.5 %	1.7 %	± 20 %
1.5	% Delta F % CV	510% 1.0 %	515 % 1.8 %	1.0 %	

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



SA-K batch # 37RA

Accepted

Rejected

Operator's initials: AL

Date: 11/05/2023

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