

HTRF® Research Reagents

SA-K Quality Control

Product number : 610SAKLA Lot Number : 36RA

Manufacturing date : 04/08/2022 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	35A	90 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	36RA	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 :

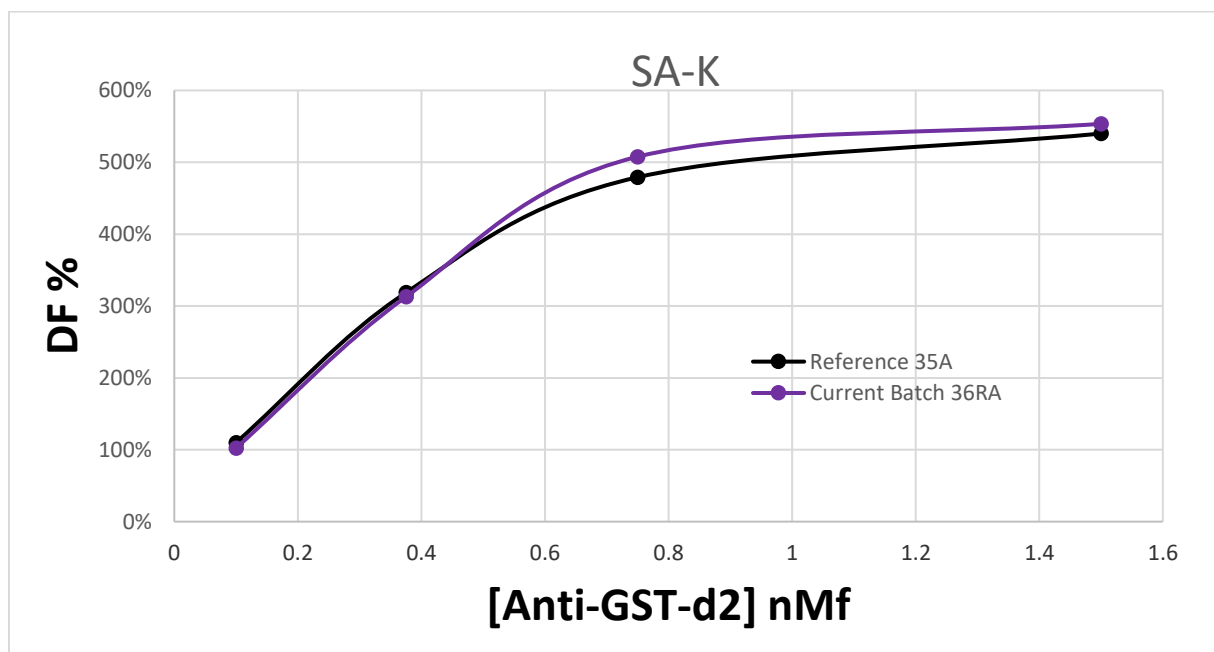
- 5 µL Pept-GST-Biotin (5 µL diluent for negative control)
- 10 µL D2 conjugate
- 5 µL K conjugate

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	110 % 2.7 %	102 % 1.4 %	- 6.9 %	-0.1 %
0.375	% Delta F % CV	319 % 1.3 %	313 % 0.5 %	- 1.8 %	
0.75	% Delta F % CV	479 % 0.9 %	508 % 1.5 %	6.0 %	± 20 %
1.5	% Delta F % CV	540% 1.8 %	554 % 2.0 %	2.5 %	

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



SA-K batch # 36RA

Accepted



Rejected



Operator's initials: AL

Date: 10/08/2022

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