

#### HTRF<sup>®</sup> Research Reagents

# Anti DNP-K Quality Control

Product number :	61DNPKLA	Lot Number :	15RA	
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Manufacturing date :	06/04/2017	Document version :	1	

## EXPERIMENTAL CONDITION

The batch to be controlled was compared to the reference batch currently in use, at increasing Peptide DNP-Biotin concentrations.

Anti DNP-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

Anti DNP-K + DNP-Biotin + SA-XL665

#### REAGENTS

	REFERENCE LOT NUMBER	ASSAY CONCENTRATION	
SA-XL665	137A	0.26 nMf - 1.04 nMf	
Anti DNP-K Reference	11X	1.57 nMf	
DNP-Biotin	CQ06	0.52 nMf - 1.04nMf - 2.08nMf	

	CURRENT BATCH LOT NUMBER	ASSAY CONCENTRATION	
Anti DNP-K current batch	15RA	1.33 nMf	
<b>•</b> ••			

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

If applicable, streptavidin / biotin ratio was set up at : 1/2

### EXPERIMENTAL PROCEDURE

Reconstitute Anti DNP-K vial with 250  $\mu$ L 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 :

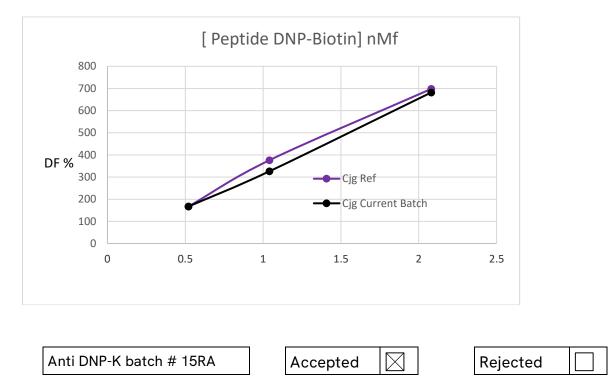
- 5 µL DNP-Biotin (5 µL diluent for negative control)
- 10 µL XL conjugate
- 5 µL K conjugate

Incubation took place for 45 min at room temperature. The plate was read on Phera Star  $\ensuremath{\mathbb{R}}$  under standard conditions.

# RESULTS

[DNP-Biotin] nMf		Anti DNP-K Reference	Anti DNP-K CURRENT BATCH	VARIATION	MEAN ACCEPTABLE VARIATION
0.52	% Delta F % CV	167 % 3.3 %	167 % 0.4 %	0 %	-5.32 %
1.04	% Delta F % CV	376 % 1.4 %	326 % 2.7 %	-13.2 %	± 20 %
2.08	% Delta F % CV	698 % 5.7 %	682 % 0.3 %	-2.29 %	

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



Operator's initials: FTV Date : 06/04/2017

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