

HTRF® Research Reagents

PY20-K Quality Control

Product number : 61Y20KLA

Lot Number : 35RA

Manufacturing date : 10/02/2021

Document version : 1

EXPERIMENTAL CONDITION

The batch to be controlled was compared to the reference batch currently in use, at increasing Pept-PO4-biotin concentrations and SA-XL665 concentrations.

PY20-K is lyophilized in Hepes buffer 20 mM pH 7.4 + 1% BSA + Stabilizers.

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

ASSAY FORMAT

Pept-PO4-Biotin + SA-XL665 + PY20-K

REAGENTS

	REFERENCE LOT NUMBER	ASSAY CONCENTRATION
SA-XL665	166A	0.1 nMf - 1.2 nMf
PY20-K reference	34A	6.66 nMf
Pept-PO4-Biotin	CQ01	0.2 nMf - 2.4 nMf

	CURRENT BATCH LOT NUMBER	ASSAY CONCENTRATION
PY20-K current batch	35RA	6.66 nMf

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 PY20-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-PO4-Biotin (5 µL diluent for negative control)
- 10 µL XL conjugate
- 5 µL K conjugate

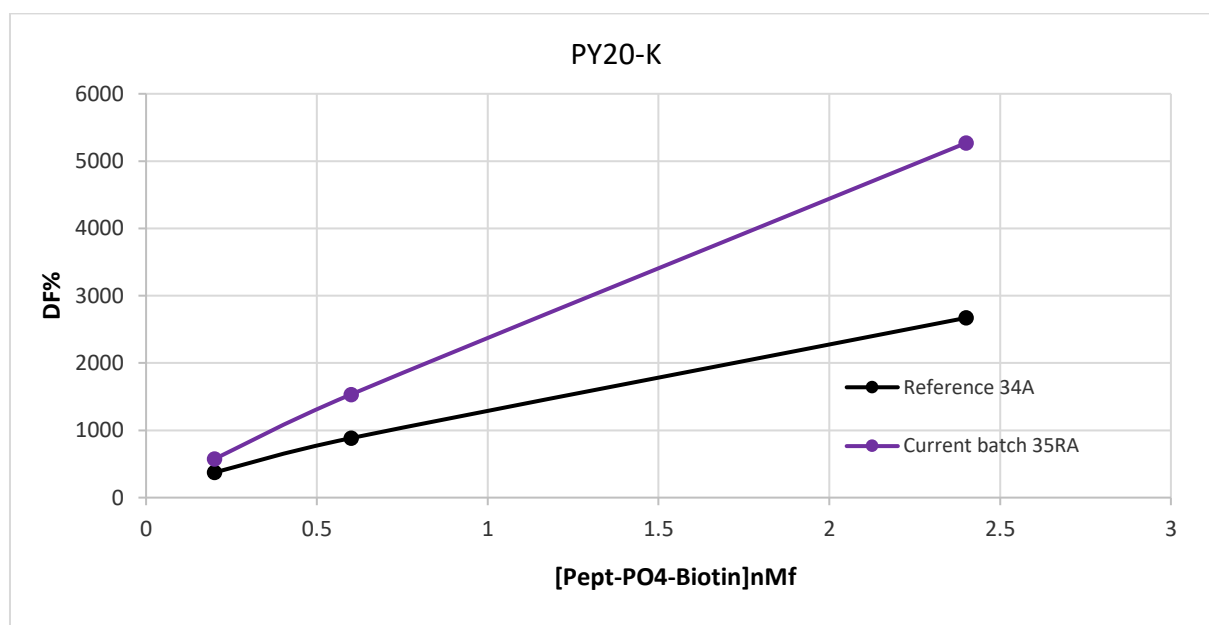
Incubation took place for 150 min at room temperature. The plate was read on Phera Star ® under standard conditions.

RESULTS

[Pept-PO4-Biotin] nMf		PY20-K Reference	PY20-K CURRENT BATCH	VARIATION	MEAN ACCEPTABLE VARIATION
0.2	% Delta F % CV	373 % 2.9 %	573 % 2.4 %	53.6 %	74.8 %*
0.6	% Delta F % CV	884 % 1.2 %	1 533 % 3.4 %	73.5 %	
2.4	% Delta F % CV	2 670 % 5.9 %	5 268 % 2.1 %	97.3 %	± 20 %

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

*New batch antibody



PY20-K batch # 35RA

Accepted



Rejected



Operator's initials: ML

Date: 17/02/2021

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