

PY20-Cryptate - Quality Control

Product reference: 61Y20KLA

Batch # : 35A

1- Experimental conditions

The batch to be controlled was compared to the reference batch currently in use, at increasing Peptide PO₄-Biotin concentrations and at increasing Streptavidin-XL concentrations.
PY20-Cryptate is lyophilized in Hepes buffer 20 mM pH 7.4 +1% BSA + Stabilizer
All the conjugates involved were diluted in PPI Europium buffer # 61DB9RDF.

2- Assay format

PY20-Cryptate + Peptide-PO₄-Biotin + Streptavidin-XL

3- Reagents

	Reference lot number	Assay Concentration
Streptavidin-XL	166A	0.1 nM _f – 1.2 nM _f
PY20-Cryptate	34A	6.66 nM _f
Peptide-PO ₄ -Biotin	CQ01	0.2 nM _f – 2.4 nM _f

	Current batch lot number	Assay Concentration
PY20-Cryptate	35A	6.66 nM _f

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

If applicable, Streptavidin / Biotin ratio was set up at: 1/2

4- Experimental procedure

Reconstitute PY20-Cryptate vial with 250 µl H₂O .

Reagents were dispensed as follows:

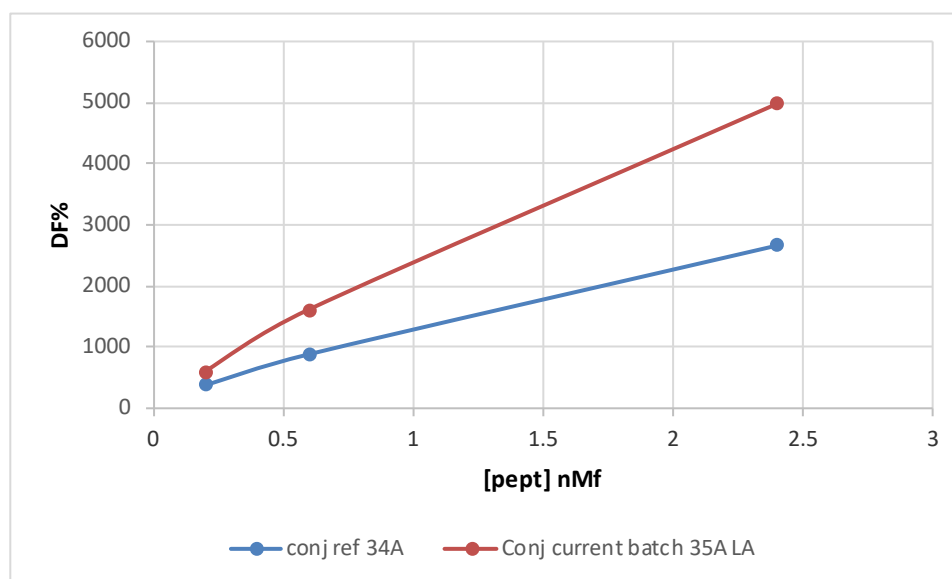
- 5 µl Cryptate conjugate
- 10 µl XL conjugate
- 5 µl Peptide PO₄-Biotin

Incubation took place for 150 min at room temperature. The plate was read on PHERAStar Plus under standard conditions.

5- Results

[Peptide PO ₄ -Biotin] nM _f		PY20-Cryptate Ref	PY20-Cryptate 5,000 tests Current batch	Variation / Ref	Mean Acceptable variation
0.2	% Delta F % CV	373 % 2.9 %	573 % 2.4%	53.6%	74.8% * ± 20% CV < 10 %
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%	

*New batch antibody



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

PY20-K batch # 35A

Accepted ☒

Rejected ☐

Operator's initials: ML

Supervisor's initials and date: **NL 2021-02-17**