

#### HTRF® Research Reagents

# FLAGM2-K Quality Control

Product number: 61FG2KLA Lot Number: 28RA

Manufacturing date: 06/03/2017 Document version: 1

### **EXPERIMENTAL CONDITION**

The batch to be controlled was compared to the reference batch currently in use, at increasing Prot-N-Flag-Biot concentrations.

FLAGM2-K is lyophilized in PO4 buffer 100 mM pH7; 0.5% BSA; Stabilizers.

All the reagents involved were diluted in 50 mM Hepes pH 8.0, 0.1% BSA, 0.4M KF.

#### **ASSAY FORMAT**

FLAGM2-K + Prot-N-Flag-Biot + SA-XL

### **REAGENTS**

|                    | REFERENCE LOT NUMBER | ASSAY CONCENTRATION    |  |
|--------------------|----------------------|------------------------|--|
| SA-XL              | 135                  | 0.625 - 1.25 - 2.5 nMf |  |
| FLAGM2-K reference | 25B                  | 70 ng/mLf              |  |
| Prot-N-Flag-Biot   | CQ09                 | 1.25 - 2.5 - 5 nMf     |  |

|                        | CURRENT BATCH LOT<br>NUMBER | ASSAY CONCENTRATION |  |
|------------------------|-----------------------------|---------------------|--|
| FLAGM2-K current batch | 28RA                        | 75 ng/mLf           |  |

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 FLAGM2-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:

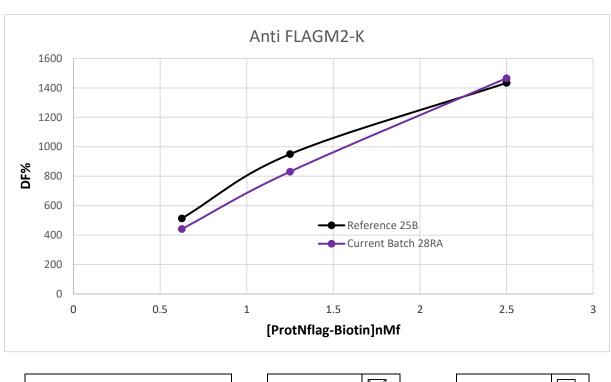
- 5 μL Prot-N-Flag-Biot (5 μL diluent for negative control)
- 10 μL XL conjugate
- 5 μL K conjugate

Incubation took place for 180 min at room temperature. The plate was read on Phera Star ® under standard conditions.

## **RESULTS**

| [Prot-N-Flag-Biot]<br>nMf |                   | FLAGM2-K<br>Reference | FLAGM2-K<br>CURRENT<br>BATCH | VARIATION | MEAN<br>ACCEPTABLE<br>VARIATION |
|---------------------------|-------------------|-----------------------|------------------------------|-----------|---------------------------------|
| 1.25                      | % Delta F<br>% CV | 513%<br>2.0%          | 441%<br>1.0%                 | -14.0%    | -8.1%                           |
| 2.5                       | % Delta F<br>% CV | 950%<br>0%            | 831%<br>0.9%                 | -12.5%    | ± 20 %                          |
| 5                         | % Delta F<br>% CV | 1434%<br>0%           | 1466%<br>1.0%                | 2.2%      |                                 |

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



Operator's initials: MB Date: 06/03/2017

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