

# **RFE MEMO**

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**Product Description(s):** Rat BNP Kit **Catalog Number(s) / Size(s):** K153KFD-series **Lot Number:** K0040364

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0040364 has been extended to 31 MAR 2019.

The expiration dates for the following kit components have also been extended:

Description	Lot Number	Original Expiration Date	New Expiration Date
MSD Gold Plate	Z0021196	31 OCT 2018	31 MAR 2019
Anti-rat BNP Antibody	D0040633	30 NOV 2018	31 MAR 2019
Anti-rat BNP Biotinylated Capture Antibody	D0040634	30 NOV 2018	31 MAR 2019
Rat BNP Calibrator	A0040149	31 MAR 2018	31 MAR 2019
Diluent 8	M0080029	31 DEC 2018	31 MAR 2019

Function	Name	Signature	Date
Quality Assurance	Dawn Stollar	Dawn Stollar	12 MAR 2019

This memo supersedes all other statements regarding date of expiration for this product.

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COA-07114

Product Description:	Rat BNP Kit
Kit Catalog Numbers:	K153KFD-1, K153KFD-2, K153KFD-4
Kit Lot Number:	K0040364
Expiration Date:	31 Mar 2018

## Acceptance Data/ Percent Recovery Specifications:

		Calibrator		Control 1		Control 2		Control 3	
Spot	Name	Recovery	CV	Recovery	CV	Recovery	CV	Recovery	CV
1	BNP	80% - 120%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%

### **Stock Concentration of Material Tested :**

Spot	Name	Item	Conc	Units
		20X Calibrator	30600	pg/ml
1	1 BNP	Control 1	1196	pg/ml
1		Control 2	252	pg/ml
		Control 3	75.3	pg/ml

Control data was generated utilizing internal reference controls.

Concentrations provided in this table refer to the stock concentration of the calibrators. For top of the standard curve concentrations, please refer to the Standard Curve Data

#### **Standard Curve Data:**

BNP - Spot 1					
Conc. pg/ml	ECL Signal	%CV			
1530	35,200	1.5			
510	11,300	1.3			
170	3,730	1.2			
56.7	1,290	1.6			
18.9	495	1.2			
6.30	243	2.0			
2.10	163	2.7			
0.00	127	2.2			

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## **Components:**

Description	Lot Number	Storage Temperature	Expiration Date
MSD Gold Plate	Z0021196	2-8°C	31 Oct 2018
Anti-rat BNP Antibody	D0040633	2-8°C	30 Nov 2018
Anti-rat BNP Biotinylated Capture Antibody	D0040634	2-8°C	30 Nov 2018
Rat BNP Calibrator	A0040149	$\leq$ -70°C	31 Mar 2018
Blocker A	Not Kit Specific	Room Temperature	N/A
Diluent 8	M0080029	$\leq$ -10°C	31 Dec 2018
Protease Inhibitor	Not Kit Specific	2-8°C	N/A
Read Buffer T(4X)	Not Kit Specific	Room Temperature	N/A

#### Statement:

The above kit was tested using MSD procedures and it conforms to MSD's specifications. The above product is intended for Research Use Only. Not for use in Diagnostic Procedures.

	Name	Function	Signature	Date
<b>Review/Approval</b>	Dawn Stollar	Quality Assurance	Dawn Stollan	12 MAR 2019