



RFE MEMO

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Product Description(s): Rat NT-proBNP Kit
Catalog Number(s) / Size(s): K153JKD-Series
Lot Number: K0040474

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0040474 has been extended to 30 SEP 2021.

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

Description	Lot Number	Original Expiration Date	New Expiration Date
Rat NT-proBNP Calibrator	A0040207	30 SEP 2020	30 SEP 2021

Function	Name	Signature	Date
Quality	Karen Hamilla		22 MAY 2020

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

CERTIFICATE OF ANALYSIS

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Product Description: Rat NT-proBNP Kit
Kit Catalog Numbers: K153JKD-Series
Kit Lot Number: K0040474
Expiration Date: 30 Sep 2020

Acceptance Data/ Percent Recovery Specifications:

Spot	Name	Calibrator		Rat NT-proANP/BNP Control 1		Rat NT-proANP/BNP Control 2		Rat NT-proANP/BNP Control 3	
		Recovery	CV	Recovery	CV	Recovery	CV	Recovery	CV
1	NT-proBNP	80% - 120%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%

Stock Concentration of Material Tested :

Spot	Name	Item	Conc	Units
1	NT-proBNP	20X Calibrator	90200	pg/mL
		Rat NT-proANP/BNP Control 1	7901	pg/mL
		Rat NT-proANP/BNP Control 2	990	pg/mL
		Rat NT-proANP/BNP Control 3	186	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:

NT-proBNP - Spot 1		
Conc. pg/mL	ECL Signal	%CV
4510	323,000	1.6
1130	63,000	3.4
282	10,400	3.0
70.5	1,540	3.2
17.6	352	2.2
4.40	150	3.5
1.10	107	4.4
0.00	94	5.9


CERTIFICATE OF ANALYSIS

Components:

Description	Lot Number	Storage Temperature	Expiration Date
Rat NT-proBNP Plate	Z0056527	2-8°C	30 Nov 2021
Anti-rat NT-proBNP Antibody	D0040862	2-8°C	30 Nov 2022
Rat NT-proBNP Calibrator	A0040207	≤ -70°C	30 Sep 2020
Diluent 34	M0340016	≤ -10°C	31 Dec 2021
Protease Inhibitor Solution	Not Kit Specific	Not Kit Specific	N/A
MSD Read Buffer T	Not Kit Specific	Not Kit Specific	N/A

Statement:

The above product is intended for Research Use Only. Not for use in Diagnostic Procedures.

	Name	Function	Signature	Date
Review/Approval	Karen Hamilla	Quality		22 OCT 2019