



RFE MEMO

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Product Description(s): Kidney Injury Panel 3 (human) Kit

Catalog Number(s) / Size(s): K15189D-Series

Lot Number: K0040495

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0040495 has been extended to 30 NOV 2022.

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

Description	Lot Number	Original Expiration Date	New Expiration Date
Kidney Injury Panel 3 (human) Plate	Z0056695	30 SEP 2022	30 NOV 2022
Diluent 37	M0370025	30 NOV 2021	30 NOV 2022

Function	Name	Signature	Date
Quality	Karen Hamilla		16 MAR 2022

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

CERTIFICATE OF ANALYSIS

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Product Description: Kidney Injury Panel 3 (human) Kit
Kit Lot Number: K0040495
Expiration Date: 30 Nov 2021
Kit Catalog Numbers: K15189D-Series

Precision and Accuracy Specifications:

Spot	Name	Calibrator		KIP-3 Control 1		KIP-3 Control 2	
		Recovery	CV	Recovery	CV	Recovery	CV
1	αGST	80% - 120%	< 20%*	75% - 125%*	< 20%*	75% - 125%*	< 20%*
2	Calbindin	80% - 120%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%
3	Clusterin	80% - 120%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%
4	KIM-1	80% - 120%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%
5	Osteoactivin	80% - 120%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%
6	TFF3	80% - 120%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%
7	VEGF	80% - 120%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%

* See Additional Comments.

Non-Specific Binding Specifications:

Spot	Name	NSB Spec
1	αGST	< 1.0%
2	Calbindin	< 1.0%
3	Clusterin	< 1.0%
4	KIM-1	< 1.0%
5	Osteoactivin	< 1.0%
6	TFF3	< 1.0%
7	VEGF	< 1.0%

Stock Concentration of Calibrator:

Spot	Name	Conc.	Units
1	αGST	662000	pg/mL
2	Calbindin	418000	pg/mL
3	Clusterin	3880000	pg/mL
4	KIM-1	450000	pg/mL
5	Osteoactivin	694000	pg/mL
6	TFF3	37200	pg/mL
7	VEGF	43600	pg/mL

CERTIFICATE OF ANALYSIS

Lot-Specific Components:


Description	Lot Number	Storage Temperature	Expiration Date
Kidney Injury Panel 3 (human) Plate	Z0056695	2-8°C	30 Sep 2022
Anti-hu αGST Antibody	D0040912	2-8°C	31 Mar 2024
Anti-hu Calbindin Antibody	D0040913	2-8°C	30 Sep 2023
Anti-hu Clusterin Antibody	D0040914	2-8°C	31 Dec 2023
Anti-hu KIM-1 Antibody	D0040915	2-8°C	30 Sep 2023
Anti-hu Osteoactivin Antibody	D0040916	2-8°C	30 Sep 2023
Anti-hu TFF3 Antibody	D0040917	2-8°C	31 Dec 2023
Anti-hu VEGF Antibody	D0040918	2-8°C	30 Sep 2023
Kidney Injury Panel 3 (human) Calibrator Blend	A0040251	≤ -70°C	28 Feb 2023
Diluent 37	M0370025	≤ -10°C	30 Nov 2021

Additional components may be provided to execute the assay. Additional components are not lot-specific.

Additional Comments:

	Assay	Spot	Specification	Comment
1	αGST	1	Calibrator CV	Cal-5 CV 20.4% (specifications NMT 20%)
2	αGST	1	Control Conc.	Control-1 recovery 298.4% Control-2 recovery 161.0% (Specifications 75-125%)
3	αGST	1	Control CV	Control-2 CV 22.4% (Specifications NMT 20%)

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

	Name	Function	Signature	Date
Review/Approval	Karen Hamilla	Quality		03 FEB 2021