

RFE MEMO

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Product Description(s): V-PLEX® and V-PLEX Plus Human IL-22 Kit

Catalog Number(s) / Size(s): K151WV-Series

Lot Number: K0081000

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0081000 has been extended to 31 JUL 2020.

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

Description	Lot Number	Original Expiration Date	New Expiration Date
Anti-hu IL-22 Antibody	D0080895	31 JUL 2019	31 JUL 2020
Diluent 43	M0430021	30 SEP 2019	31 JUL 2020
Diluent 3	M0030076	30 SEP 2019	31 JUL 2020

Function	Name	Signature	Date	
Quality	Karen Hamilla	Harr Hamille	21 JUN 2019	

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

Memo Rev. A CM-00289-B

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Product Description: V-PLEX® and V-PLEX Plus Human IL-22 Kit

Kit Catalog Numbers: K151WV-Series

Kit Lot Number: K0081000 Expiration Date: 31 Jul 2019

Acceptance Data/ Percent Recovery Specifications:

		Calibrator		TH17 Panel 1 (human) Control 1		TH17 Panel 1 (human) Control 2		TH17 Panel 1 (human) Control 3	
Spot	Name	Recovery	CV	Recovery	CV	Recovery	CV	Recovery	CV
1	hu IL-22	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%

		LLOQ				ULOQ	
Spot	Name	Value	Recovery	CV	Value	Recovery	CV
1	hu IL-22	2.78	80% - 120%	< 20%	325	80% - 120%	< 20%

Stock Concentration of Material Tested:

Spot	Name	Item	Conc	Units
	Calibrator	551	pg/mL	
	TH17 Panel 1 (human) Control 1	540	pg/mL	
	TH17 Panel 1 (human) Control 2	103	pg/mL	
		TH17 Panel 1 (human) Control 3	17.2	pg/mL

Controls tested may not be the same lot as shipped.

Standard Curve Data:

hu IL-22 - Spot 1				
Conc. pg/mL	ECL Signal	%CV		
551	157,000	1.8		
138	39,400	1.3		
34.4	10,200	1.2		
8.61	2,750	1.8		
2.15	917	1.1		
0.538	442	2.1		
0.135	330	2.0		
0.00	289	1.5		

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Components:

Description	Lot Number	Storage Temperature	Expiration Date
Human IL-22 Plate	Z0046810	2-8°C	30 Sep 2020
Anti-hu IL-22 Antibody	D0080895	2-8°C	31 Jul 2019
TH17 Panel 1 (human) Calibrator Blend	A0080119	2-8°C	31 Jan 2022
Diluent 43	M0430021	≤ -10°C	30 Sep 2019
Diluent 3	M0030076	≤ -10°C	30 Sep 2019
MSD Read Buffer T	Not Kit Specific	Not Kit Specific	N/A

Additional Components Included in V-PLEX Plus				
Plate Seals	Not Kit Specific			
Wash Buffer (20X), 100 mL	Not Kit Specific			
TH17 Panel 1 (human) Control 1	Not Kit Specific			
TH17 Panel 1 (human) Control 2	Not Kit Specific			
TH17 Panel 1 (human) Control 3	Not Kit Specific			

Statement:

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

	Name	Function	Signature	Date
Review/Approval	Jessica Drolet	Quality Assurance	Jus	14 May 2018