

RFE MEMO

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Product Description(s): V-PLEX® and V-PLEX Plus NHP IL-5 Kit

Catalog Number(s) / Size(s): K156QS-Series

Lot Number: K0081028

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0081028 has been extended to 31 JUL 2020.

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

Description	Lot Number	Original Expiration New Expira Date Date	
Anti-hu IL-5 Antibody	D0080887	31 JUL 2019	31 JUL 2020

Function	Name	Signature	Date
Quality Assurance	Dawn Stollar	Dawn Stollan	29 MAR 2019

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

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Product Description: V-PLEX® and V-PLEX Plus NHP IL-5 Kit

Kit Catalog Numbers: K156QS-Series

Kit Lot Number: K0081028
Expiration Date: 31 Jul 2019

Acceptance Data/ Percent Recovery Specifications:

		Calibrator		Cytokine Panel 1 (human) Control 1		Cytokine Panel 1 (human) Control 2		Cytokine Panel 1 (human) Control 3	
Spot	Name	Recovery	CV	Recovery	CV	Recovery	CV	Recovery	CV
1	NHP IL-5	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%

		LLOQ			LLOQ				ULOQ	
Spot	Name	Value	Recovery	cv	Value	Recovery	CV			
1	NHP IL-5	4.41	80% - 120%	< 20%	562	80% - 120%	< 20%			

Stock Concentration of Material Tested:

Spot	Name	Item	Conc	Units
1 NHP IL-5	Calibrator	844	pg/mL	
	NIIID II 5	Cytokine Panel 1 (human) Control 1	310	pg/mL
	NHP IL-3	Cytokine Panel 1 (human) Control 2	110	pg/mL
		Cytokine Panel 1 (human) Control 3	34	pg/mL

Controls tested may not be the same lot as shipped.

The calibrator and controls for this assay contain a human recombinant cytokine calibrator sequence that is highly homologous to the non-human primate cytokine. This assay has been verified to cross-react with homologs of rhesus and cynomolgus monkeys. See Product Insert for experimental data.

Standard Curve Data:

NHP IL-5 - Spot 1				
Conc. pg/mL	ECL Signal	%CV		
844	269,000	1.6		
211	72,900	2.5		
52.8	18,900	2.4		
13.2	4,790	2.7		
3.30	1,280	1.3		
0.824	380	2.1		
0.206	147	3.0		
0.00	66	6.5		

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Components:

Description	Lot Number	Storage Temperature	Expiration Date
Human IL-5 Plate	Z0046849	2-8°C	30 Nov 2020
Anti-hu IL-5 Antibody	D0080887	2-8°C	31 Jul 2019
Cytokine Panel 1 (human) Calibrator Blend	A0080121	2-8°C	28 Feb 2022
Diluent 43	M0430026	≤ -10°C	31 Aug 2020
Diluent 3	M0030082	≤ -10°C	31 Oct 2020
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), 100mL	Not Kit Specific			
Cytokine Panel 1 (human) Control 1	Not Kit Specific			
Cytokine Panel 1 (human) Control 2	Not Kit Specific			
Cytokine 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	Dawn Stollar	Quality Assurance	Dawn Stollar	20 JUL 2018