

RFE MEMO

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Product Description(s): V-PLEX® and V-PLEX Plus NHP IL-10 Kit **Catalog Number(s) / Size(s):** K156QU-series **Lot Number:** K0080354

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0080354 has been extended to 31 Jan 2018.

Description	Lot Number	Original Expiration Date	New Expiration Date
Human IL-10 Plate	Z0045754	30 Nov 2017	31 Jan 2018
Anti-hu IL-10 Antibody	D0080531	30 Sep 2017	31 Jan 2018
Proinflammatory Panel 1 (human) Calibrator Blend	A0080058	31 May 2020	31 May 2020
Diluent 2	M0020085	31 Jan 2017	31 Jan 2018
Diluent 3	M0030066	30 Sep 2017	31 Jan 2018

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

Function	Name	Signature	Date
Quality Assurance	Dawn Stollar	Dawn Stollar	08 FEB 2017

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



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Product Description:	NHP IL-10 Kit V-PLEX [®] and V-PLEX Plus
Kit Catalog Numbers:	K156QUD-1, K156QUD-2, K156QUD-4, K156QUG-1, K156QUG-2, K156QUG-4
Kit Lot Number:	K0080354
Expiration Date:	31 Jan 2017

Acceptance Data/ Percent Recovery Specifications:

		Calibrator		Proinflammatory Panel 1 (human) Control 1		Proinflammatory Panel 1 (human) Control 2		Proinflammatory Panel 1 (human) Control 3	
Spot	Name	Recovery	CV	Recovery	CV	Recovery	CV	Recovery	CV
1	NHP IL-10	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%

		LLOQ				ULOQ	
Spot	Name	Value	Recovery	CV	Value	Recovery	CV
1	NHP IL-10	0.680	80% - 120%	< 20%	233	80% - 120%	< 20%

Stock Concentration of Material Tested :

Spot	Name	Item	Conc	Units
1 NHP		Calibrator	317	pg/mL
		Proinflammatory Panel 1 (human) Control 1	95.8	pg/mL
		Proinflammatory Panel 1 (human) Control 2	24.7	pg/mL
		Proinflammatory Panel 1 (human) Control 3	3.69	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.



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Standard Curve Data:

NHP IL-10 - Spot 1					
Conc. pg/mL	ECL Signal	%CV			
317	126,192	1.9			
79.3	33,463	1.7			
19.8	8,516	1.9			
4.95	2,157	2.2			
1.24	577	2.3			
0.310	192	1.9			
0.0774	98	3.2			
0	65	5.9			

Components:

Description	Lot Number	Storage Temperature	Expiration Date
Human IL-10 Plate	Z0045754	2-8°C	30 Nov 2017
Anti-hu IL-10 Antibody	D0080531	2-8°C	30 Sep 2017
Proinflammatory Panel 1 (human) Calibrator Blend	A0080058	2-8°C	31 May 2020
Diluent 2	M0020085	\leq -10°C	31 Jan 2017
Diluent 3	M0030066	\leq -10°C	30 Sep 2017
MSD Read Buffer T (4X)	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			
Proinflammatory Panel 1 (human) Control 1	Not Kit Specific			
Proinflammatory Panel 1 (human) Control 2	Not Kit Specific			
Proinflammatory Panel 1 (human) Control 3	Not Kit Specific			

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.

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	Name	Function	Signature	Date
Review/Approval	Anastasia Belilovets	Quality Assurance	ABellon	15 Jul 2015