

RFE MEMO

Page 1 of 1

Product Description(s): V-PLEX® and V-PLEX Plus Mouse IL-31 Kit **Catalog Number(s) / Size(s):** K152XA-Series **Lot Number:** K0080781

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0080781 has been extended to 30 SEP 2020.

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

Description	Lot Number	Original Expiration Date	New Expiration Date
Mouse IL-31 Plate	Z0046471	30 SEP 2019	30 SEP 2020
Anti-ms IL-31 Antibody	D0080953	30 NOV 2019	30 SEP 2020
Diluent 41	M0410018	30 NOV 2019	30 SEP 2020
Diluent 45	M0450019	31 DEC 2019	30 SEP 2020

Function	Name	Signature	Date
Quality	Karen Hamilla	Haven Hamille	21 OCT 2019

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

Meso Scale Diagnostics, LLC. CERTIFICATE OF ANALYSIS

Page 1 of 2

Product Description:	V-PLEX® and V-PLEX Plus Mouse IL-31 Kit
Kit Catalog Numbers:	K152XA-Series
Kit Lot Number:	K0080781
Expiration Date:	30 Sep 2019

Acceptance Data/ Percent Recovery Specifications:

		Calibrator		TH17 Panel 1 (mouse) Control 1		TH17 Panel 1 (mouse) Control 2		TH17 Panel 1 (mouse) Control 3	
Spot	Name	Recovery	CV	Recovery	CV	Recovery	CV	Recovery	CV
1	IL-31	80% - 120%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%

		LLOQ				ULOQ	
Spot	Name	Value	Recovery	CV	Value	Recovery	CV
1	IL-31	22.6	75% - 125%	< 20%	21000	75% - 125%	< 20%

Stock Concentration of Material Tested :

Spot	Name	Item	Conc	Units
	Calibrator	28500	pg/mL	
1	II 21	TH17 Panel 1 (mouse) Control 1	22600	pg/mL
1		TH17 Panel 1 (mouse) Control 2	4470	pg/mL
		TH17 Panel 1 (mouse) Control 3	975	pg/mL

Controls tested may not be the same lot as shipped.

Standard Curve Data:

IL-31 - Spot 1				
Conc. ECL %C pg/mL Signal				
28500	450,000	1.9		
7130	102,000	3.1		
1780	19,200	1.9		
445	4,010	3.5		
111	1,140	3.3		
27.8	317	2.4		
6.96	129	3.8		
0.00	66	3.9		



CERTIFICATE OF ANALYSIS

Page 2 of 2

Components:

Description	Lot Number	Storage Temperature	Expiration Date
Mouse IL-31 Plate	Z0046471	2-8°C	30 Sep 2019
Anti-ms IL-31 Antibody	D0080953	2-8°C	30 Nov 2019
TH17 Panel 1 (mouse) Calibrator	A0080146	2-8°C	31 Aug 2022
Diluent 41	M0410018	\leq -10°C	30 Nov 2019
Diluent 45	M0450019	\leq -10°C	31 Dec 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 (mouse) Control 1	Not Kit Specific			
TH17 Panel 1 (mouse) Control 2	Not Kit Specific			
TH17 Panel 1 (mouse) 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	Karen Hamilla	Quality	Haven Hamille	21 OCT 2019