



RFE MEMO

Page 1 of 1

Product Description(s): V-PLEX® and V-PLEX Plus Metabolic Panel 1 (human) kit
Catalog Number(s) / Size(s): K15325-Series; K151X5-Series; K150T5-Series; K151Y5-Series;
K15334-Series; K15335-Series; K15332-Series; K15333-Series
Lot Number: K0081315

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0081315 has been extended to 28 FEB 2023.

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

Description	Lot Number	Original Expiration Date	New Expiration Date
Metabolic Panel 1 Plate	Z0047163	28 FEB 2022	28 FEB 2023
Diluent 56	M0560001	30 Apr 2022	28 FEB 2023
Diluent 11	M0110042	28 Feb 2022	28 FEB 2023

Function	Name	Signature	Date
Quality	Karen Hamilla		28 JAN 2022

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

CERTIFICATE OF ANALYSIS

Product Description: V-PLEX Metabolic Panel 1 (human) kit
Kit Catalog Numbers: K15325-Series; K151X5-Series; K150T5-Series; K151Y5-Series; K15334-Series; K15335-Series; K15332-Series; K15333-Series
Kit Lot Number: K0081315
Expiration Date: 28 Feb 2022

Acceptance Data/ Percent Recovery Specifications:

Spot	Name	Calibrator		Metabolic Panel 1 Control 1		Metabolic Panel 1 Control 2		Metabolic Panel 1 Control 3	
		Recovery	CV	Recovery	CV	Recovery	CV	Recovery	CV
1	Insulin	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%
2	C-peptide	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%
3	GLP-1 (active)	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%
7	GIP (active)	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%
8	Glucagon	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%
9	PP	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%
10	Leptin	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%

Spot	Name	Value	LLOQ		Value	ULOQ	
			Recovery	CV		Recovery	CV
1	Insulin	0.0690	80% - 120%	< 20%	19.5	80% - 120%	< 20%
2	C-peptide	19.0	80% - 120%	< 20%	3150	80% - 120%	< 20%
3	GLP-1 (active)	0.0960	80% - 120%	< 20%	39.0	80% - 120%	< 20%
7	GIP (active)	3.18	80% - 120%	< 20%	390	80% - 120%	< 20%
8	Glucagon	0.329	80% - 120%	< 20%	52.0	80% - 120%	< 20%
9	PP	0.405	80% - 120%	< 20%	325	80% - 120%	< 20%
10	Leptin	37.7	80% - 120%	< 20%	7150	80% - 120%	< 20%

Acceptance Data/ Non Specific Binding Specifications:

Spot	Name	NSB Spec
1	Insulin	< 1.0%
2	C-peptide	< 1.0%
3	GLP-1 (active)	< 1.0%
7	GIP (active)	< 1.0%
8	Glucagon	< 1.0%
9	PP	< 1.0%
10	Leptin	< 1.0%

CERTIFICATE OF ANALYSIS

Page 2 of 4

Stock Concentration of Material Tested :

Spot	Name	Item	Conc	Units
1	Insulin	Calibrator	30.6	μIU/mL
		Metabolic Panel 1 Control 1	12	μIU/mL
		Metabolic Panel 1 Control 2	1.65	μIU/mL
		Metabolic Panel 1 Control 3	0.293	μIU/mL
2	C-peptide	Calibrator	11300	pg/mL
		Metabolic Panel 1 Control 1	4990	pg/mL
		Metabolic Panel 1 Control 2	581	pg/mL
		Metabolic Panel 1 Control 3	82.3	pg/mL
3	GLP-1 (active)	Calibrator	67.7	pM
		Metabolic Panel 1 Control 1	22.7	pM
		Metabolic Panel 1 Control 2	2.78	pM
		Metabolic Panel 1 Control 3	0.336	pM
7	GIP (active)	Calibrator	551	pg/mL
		Metabolic Panel 1 Control 1	227	pg/mL
		Metabolic Panel 1 Control 2	22.5	pg/mL
		Metabolic Panel 1 Control 3	9.61	pg/mL
8	Glucagon	Calibrator	77.4	pM
		Metabolic Panel 1 Control 1	28.2	pM
		Metabolic Panel 1 Control 2	3.76	pM
		Metabolic Panel 1 Control 3	1.11	pM
9	PP	Calibrator	443	pg/mL
		Metabolic Panel 1 Control 1	157	pg/mL
		Metabolic Panel 1 Control 2	22.2	pg/mL
		Metabolic Panel 1 Control 3	1.42	pg/mL
10	Leptin	Calibrator	9930	pg/mL
		Metabolic Panel 1 Control 1	3290	pg/mL
		Metabolic Panel 1 Control 2	458	pg/mL
		Metabolic Panel 1 Control 3	104	pg/mL

Controls tested may not be the same lot as shipped.

CERTIFICATE OF ANALYSIS

Page 3 of 4

Standard Curve Data:

Insulin - Spot 1		
Conc. $\mu\text{IU/mL}$	ECL Signal	%CV
30.6	710,000	1.7
7.65	180,000	1.5
1.91	42,200	2.4
0.478	10,300	2.3
0.120	2,980	2.5
0.0299	1,120	3.1
0.00747	656	3.9
0.00	503	3.8

C-peptide - Spot 2		
Conc. pg/mL	ECL Signal	%CV
11300	606,000	4.5
2830	320,000	3.4
706	73,200	2.6
177	10,300	3.5
44.1	2,060	2.7
11.0	662	4.8
2.76	369	5.9
0.00	283	7.7

GLP-1 (active) - Spot 3		
Conc. pM	ECL Signal	%CV
67.7	816,000	3.4
16.9	196,000	1.8
4.23	42,600	2.7
1.06	9,970	3.0
0.264	2,840	3.0
0.0661	975	4.1
0.0165	506	5.6
0.00	347	5.8

GIP (active) - Spot 7		
Conc. pg/mL	ECL Signal	%CV
551	606,000	2.7
138	132,000	4.0
34.4	26,100	4.9
8.61	5,540	3.8
2.15	1,800	3.3
0.538	765	6.7
0.135	502	6.9
0.00	407	3.9

Glucagon - Spot 8		
Conc. pM	ECL Signal	%CV
77.4	668,000	3.4
19.4	179,000	2.5
4.84	44,000	3.6
1.21	11,500	4.6
0.302	3,710	4.1
0.0756	1,730	6.2
0.0189	1,200	5.4
0.00	1,040	5.0

PP - Spot 9		
Conc. pg/mL	ECL Signal	%CV
443	640,000	2.2
111	190,000	1.9
27.7	50,700	2.3
6.92	12,700	2.3
1.73	3,510	1.7
0.433	1,070	4.5
0.108	476	5.1
0.00	267	8.0

Leptin - Spot 10		
Conc. pg/mL	ECL Signal	%CV
9930	680,000	3.0
2480	139,000	4.2
621	22,700	2.7
155	4,180	4.9
38.8	1,210	3.9
9.70	501	7.6
2.42	398	14.0
0.00	285	9.6

CERTIFICATE OF ANALYSIS

Page 4 of 4


Components:

Description	Lot Number	Storage Temperature	Expiration Date
Metabolic Panel 1 Plate	Z0047163	2-8°C	28 Feb 2022
Anti-Insulin Antibody	D0081371	2-8°C	31 Mar 2023
Anti-C-peptide Antibody	D0081372	2-8°C	31 Mar 2023
Anti-GLP-1 (active) Antibody	D0081373	2-8°C	31 Mar 2023
Anti-GIP (active) Antibody	D0081374	2-8°C	31 Mar 2023
Anti-Glucagon Antibody	D0081375	2-8°C	30 Apr 2023
Anti-PP Antibody	D0081376	2-8°C	30 Apr 2023
Anti-Leptin Antibody	D0081377	2-8°C	31 Mar 2023
Metabolic Panel 1 Calibrator Blend	A0080230	2-8°C	30 Sep 2024
Diluent 56	M0560001	≤ -10°C	30 Apr 2022
Diluent 11	M0110042	≤ -10°C	28 Feb 2022
MSD Gold Read Buffer B	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
Metabolic Panel 1 Control 1	Not Kit Specific
Metabolic Panel 1 Control 2	Not Kit Specific
Metabolic Panel 1 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		03 MAR 2022