



November 2022

Re: V-PLEX® and V-PLEX Plus Cytokine Panel 2 (human) Kit (Catalog No. K15084-Series; K151WO-Series; K151XED), Kit Lot No. K0082135; IL-17B and TSLP assay nonconformances

Dear Valued Customer,

During QC testing of Kit Lot No. K0082135, the kit failed to pass certain performance criteria for the IL-17B and TSLP assays. Specifications and actual measured values of these nonconformances are provided below. All other analytes released with this kit lot met specification, including signals, control recoveries, and limits of quantitation.

IL-17B LLOQ

- The LLOQ inter-plate concentration CV for IL-17B did not meet specification (< 20%) at the target of 1.12 pg/mL, but was fully conforming at an LLOQ of 1.32 pg/mL.

TSLP LLOQ

- The LLOQ inter-plate concentration CV for TSLP did not meet specification (< 20%) at the target of 0.460 pg/mL, but was fully conforming at an LLOQ of 4.21 pg/mL.

We have investigated these nonconformances via our Corrective and Preventive Action process, and the root causes of the observed nonconformances have not yet been determined.

Given the scope of these nonconformances and potential impact on the use of the kit by our customers, we have placed this kit lot on hold. We recognize that an interruption in supply presents challenges to our customers; therefore, we are offering customers the option of accepting delivery of kits from this nonconforming lot. The kit(s) will be shipped upon confirmation of customer's acceptance of this lot.

If you have any questions or concerns, please contact MSD Scientific Support at +1 240-314-2798 or [scientificsupport@mesoscale.com](mailto:scientificsupport@mesoscale.com).

Sincerely,

MSD Quality Assurance

## CERTIFICATE OF ANALYSIS

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**Product Description:** V-PLEX® and V-PLEX PLUS Cytokine Panel 2 (human) Kit  
**Kit Lot Number:** K0082135  
**Expiration Date:** 31 May 2024  
**Kit Catalog Numbers:** K15084-Series;K151WP-Series; K151WO-Series; K151XC-Series;K151WQ-Series;K151WZ-Series; K151XE-Series

**Precision and Accuracy Specifications:**

Spot	Name	Calibrator		Cytokine Panel 2 (human) Control 1		Cytokine Panel 2 (human) Control 2		Cytokine Panel 2 (human) Control 3	
		Recovery	CV	Recovery	CV	Recovery	CV	Recovery	CV
1	IL-17A/F	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%
2	IL-17B	80% - 120%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%
3	IL-17C	80% - 120%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%
4	IL-17D	80% - 120%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%
6	IL-1RA	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%
7	IL-3	75% - 125%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%
8	IL-9	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%
10	TSLP	80% - 120%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%

Spot	Name	LLOQ			ULOQ		
		Value	Recovery	CV	Value	Recovery	CV
1	IL-17A/F	7.57	80% - 120%	< 20%	3900	80% - 120%	< 20%
2	IL-17B	1.12	75% - 125%	< 20%*	1040	75% - 125%	< 20%
3	IL-17C	3.84	75% - 125%	< 20%	1620	75% - 125%	< 20%
4	IL-17D	11.2	75% - 125%	< 20%	5200	75% - 125%	< 20%
5	IL-1RA	9.19	75% - 125%	< 25%	650	80% - 120%	< 20%
6	IL-3	12.6	75% - 125%	< 20%	1950	80% - 120%	< 20%
7	IL-9	2.23	80% - 120%	< 25%	975	80% - 120%	< 20%
8	TSLP	0.460	75% - 125%	< 20%*	325	75% - 125%	< 20%

\* See Additional Comments.

**Non-Specific Binding Specifications:**

Spot	Name	NSB Spec
1	IL-17A/F	< 1.0%
2	IL-17B	< 1.0%
3	IL-17C	< 1.0%
4	IL-17D	< 1.0%
5	IL-1RA	< 1.0%
6	IL-3	< 1.0%
7	IL-9	< 1.0%
8	TSLP	< 1.0%

## CERTIFICATE OF ANALYSIS

### Stock Concentration of Calibrator:

Spot	Name	Conc.	Units
1	IL-17A/F	6500	pg/mL
2	IL-17B	1130	pg/mL
3	IL-17C	2645	pg/mL
4	IL-17D	8645	pg/mL
5	IL-1RA	1095	pg/mL
6	IL-3	3260	pg/mL
7	IL-9	1575	pg/mL
8	TSLP	502	pg/mL

### Lot-Specific Components:


Description	Lot Number	Storage Temperature	Expiration Date
Cytokine Panel 2 (human) SECTOR Plate	Z0047741	2-8°C	31 Jan 2025
Anti-hu IL-17A/F Antibody	D0081900	2-8°C	28 Feb 2026
Anti-hu IL-17B Antibody	D0081883	2-8°C	31 Dec 2025
Anti-hu IL-17C Antibody	D0081718	2-8°C	30 Jun 2025
Anti-hu IL-17D Antibody	D0081901	2-8°C	28 Feb 2026
Anti-hu IL-1RA Antibody	D0081902	2-8°C	28 Feb 2026
Anti-hu IL-3 Antibody	D0081721	2-8°C	31 Mar 2025
Anti-hu IL-9 Antibody	D0081903	2-8°C	28 Feb 2026
Anti-hu TSLP Antibody	D0081904	2-8°C	28 Feb 2026
Cytokine Panel 2 (human) Calibrator Blend	A0080295	2-8°C	31 May 2026
Diluent 3	M0030114	≤ -10°C	30 Sep 2024
Diluent 43	M0430047	≤ -10°C	31 May 2024

Additional components may be provided to execute the assay. Additional components are not lot-specific.

### Additional Comments:

	Assay	Spot	Specification	Comment
1	IL-17B	2	LLOQ CV	Specification for LLOQ is <20% at target of 1.12pg/mL, was fully confirming at 1.32pg/mL
2	TSLP	10	LLOQ CV	Specification for LLOQ is <20% at target of 0.460pg/mL, was fully confirming at 4.21pg/mL

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

	Name	Function	Signature	Date
Review/Approval	Karen Hamilla	Quality		14 NOV 2022