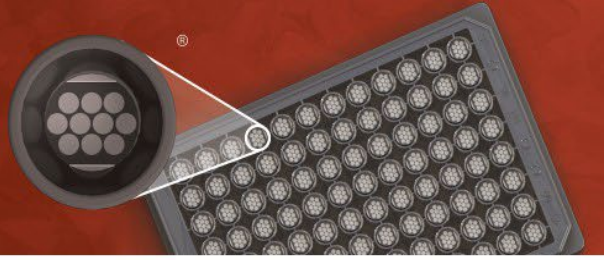
V-PLEX®

T1D Autoantibody Panel 1 (human) Kit

Datasheet



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Products Covered

Kit Name	Type	1-Plate Kit	5-Plate Kit	25-Plate Kit
V-PLEX T1D Autoantibody Panel 1 (human) Kit	SECTOR	K15757D-1	K15757D-2	K15757D-4
	QuickPlex	K15757D-21	K15757D-22	K15757D-24

Product insert and certificates of analysis are available at https://www.mesoscale.com/en/products_and_services/assay_kits.
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Product Introduction

The MESO SCALE DISCOVERY® (MSD) V-PLEX T1D Autoantibody Panel 1 (human) Kit enables simultaneous detection of autoantibodies to insulin, glutamic acid decarboxylase 65 (GAD65), zinc transporter 8 (ZnT8), and insulinoma-associated antigen-2 (IA-2) in serum or plasma, providing a comprehensive assessment of T1D-associated humoral autoimmunity in a single well. By measuring all four autoantibodies simultaneously from a small sample volume, the kit streamlines workflows, conserves precious samples, and supports high-throughput screening — making it well suited for both research studies and large-scale population screening programs.

The electrochemiluminescence (ECL) detection method eliminates the need to dispose of radioactive waste, enabling a broader adoption across laboratory settings. The ECL bridging assay format provides high sensitivity and specificity.

Biotinylated antigens locate to well-defined spots in each well. Autoantibodies bridge SULFO-TAG™ labeled antibodies to the capture antigen, completing the assay. This multiplex assay is provided on MULTI-SPOT® plates.

Analytical Validation Data

Analytical validation of the T1D Autoantibody Panel 1 (human) Kit was performed using three kit lots. The MSD Methodical Mind Enterprise™ analysis software was used to convert electrochemiluminescence signal to analyte concentrations. Validation data is presented in the following sections.

Calibration Curves

For each plate, a calibration curve was generated by fitting signals from 7 calibrators and a blank to a 4-parameter logistic (4PL) model with $1/Y^2$ weighting. Calibrators were prepared by serial dilution of the recommended top calibrator concentration, with the range designed to ensure the lowest calibrator fell below the expected LLOQ to improve accuracy at low analyte concentrations. Representative calibration curves from one kit lot are presented in Figure 1.

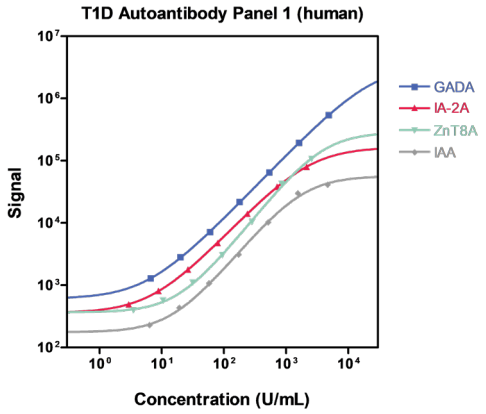

Figure 1. *Representative calibration curves for assays in the V-PLEX T1D Autoantibody Panel 1 (human) Kit.*

Sensitivity

The lower limit of detection (LLOD) is a calculated concentration corresponding to the mean signal 2.5 standard deviations above the background (zero calibrator). The LLOD is calculated across multiple plates per lot; the median and range for a representative kit lot are reported in Table 1.

Table 1. *LLOD, LLOQ, and ULOQ for each analyte in the T1D Autoantibody Panel 1 (human) Kit*

Analyte	Median LLOD (U/mL)	LLOQ (U/mL)	ULOQ (U/mL)	Dynamic Range (U/mL)
GADA	0.40	9.0	2,000	0.40 – 2,000
IA-2A	0.55	7.0	900	0.55 – 900
IAA	2.8	18	1,200	2.8 – 1,200
ZnT8A	1.6	16	800	1.6 – 800

The lower limit of quantification (LLOQ) and upper limit of quantification (ULOQ) are established by measuring independent samples near the bottom and top of the calibration range, respectively. Each limit is set at the concentration where the %CV of back-calculated concentration value is less than 25% and concentration recovery is within 75–125% of the nominal value. Both limits were established across multiple kit lots, are verified for each kit lot, and are reported on the lot-specific Certificate of Analysis available at www.mesoscale.com.

The dynamic range of each assay spans from the LLOD to the ULOQ, typically covering 2–4 log units. The quantitative range, defined as the interval between the LLOQ and ULOQ, typically spans 2–3 log units.

Precision

Independent quality control samples at three different concentrations for each analyte were run on every plate to assess performance of the kit. Precision was based on 36 runs performed by 3 operators. Each control was tested in quadruplicate over multiple days (2).

Table 2. Intra-run and inter-run %CVs for each analyte in the T1D Autoantibody Panel 1 (human) Kit

Analyte	Control	Average Conc. (U/mL)	Average Intra-run %CV	Inter-run %CV	Inter-lot %CV
GADA	1	405	4.2	6.4	7.3
	2	60	4.5	7.6	8.0
IA-2A	1	305	4.2	5.6	8.4
	2	33	3.9	6.3	8.1
IAA	1	510	3.3	4.5	5.7
	2	118	4.2	5.1	6.7
ZnT8A	1	421	3.4	4.5	5.6
	2	127	3.7	5.2	6.2

The intra-run concentration %CV was computed using the quadruplicate replicates within a plate. The inter-run concentration %CV was computed using all the replicates across the 36 runs. The inter-lot concentration %CV was computed from the average concentration measured within each kit lot. The results show that the average intra-run %CV and inter-lot %CV are all less than 10%. The inter-run %CV is typically less than 10%, well below the acceptance specification of 20%.

Accuracy and precision of controls are measured as part of lot release for each kit lot. Results are reported on the lot-specific Certificate of Analysis available at www.mesoscale.com and meet typical acceptance criteria of %CV less than 25% and recovery between 75–125%.

Tested Samples: Normal and T1D Diseased Samples

Normal human serum and serum from new-onset T1D donors from the Islet Autoantibody Standardization Program (IASP) were tested. The results for each sample are displayed in Table 3. Samples were added directly to the assay mixture without dilution. The median and range are calculated from samples with concentrations at or above the LLOD. The percentage detected is the percentage of samples with concentrations at or above the LLOD.

Table 3. Normal (Control) and New Onset T1D human samples tested using the T1D Autoantibody Panel 1 (human) Kit

Analyte	Statistic	Normal Serum (N=97)	New Onset T1D Serum (N=50)
GADA	Median (U/mL)	1.7	109
	Range (U/mL)	ND – 20	ND – 5,460
	% Detected	94	94
IA-2A	Median (U/mL)	2.6	548
	Range (U/mL)	ND – 7.0	0.50 – 2,140
	% Detected	97	100
ZnT8A	Median (U/mL)	3.5	209
	Range (U/mL)	ND – 8.2	ND – 2,540
	% Detected	49	72
IAA	Median (U/mL)	ND	9
	Range (U/mL)	NA	ND – 402
	% Detected	0	44

ND = not detectable, NA = not applicable

Representative sample data from 20 non-diabetic controls and 20 new-onset T1D samples from the IASP 2024 sample set are presented in Table 4. Measured concentrations above or below the assay limits of detection were reported as > top calibrator concentration or < lower limit of detection (LLOD), respectively. Positive samples were defined as concentrations above the 99th percentile of the concentration distribution of the non-diabetic controls. The total number of positive assays (from 0 to 4) for each sample are reported.

Table 4. *Sample concentrations and positivity from 20 normal controls and 20 new onset T1D samples from the IASP 2024 sample set.*

Sample Type	Sample Number	Concentration (U/mL)				Negative (0) or Positive (1)				Number Positive
		GADA	IA-2A	ZnT8A	IAA	GADA	IA-2A	ZnT8A	IAA	
Control	1	1.5	3.4	<1.4	<3.4	0	0	0	0	0
	2	1.5	2.8	4.1	<3.4	0	0	0	0	0
	3	1.0	2.0	<1.4	<3.4	0	0	0	0	0
	4	5.2	2.8	3.1	<3.4	0	0	0	0	0
	5	1.2	2.1	<1.4	<3.4	0	0	0	0	0
	6	1.5	1.7	1.5	<3.4	0	0	0	0	0
	7	<0.5	2.6	<1.4	<3.4	0	0	0	0	0
	8	1.6	2.7	4.1	<3.4	0	0	0	0	0
	9	1.3	4.8	<1.4	<3.4	0	0	0	0	0
	10	1.6	2.2	2.7	<3.4	0	0	0	0	0
	11	1.7	3.1	<1.4	<3.4	0	0	0	0	0
	12	1.3	2.3	<1.4	<3.4	0	0	0	0	0
	13	1.6	1.5	<1.4	<3.4	0	0	0	0	0
	14	1.4	1.8	<1.4	<3.4	0	0	0	0	0
	15	1.0	1.9	<1.4	<3.4	0	0	0	0	0
	16	1.0	1.1	<1.4	<3.4	0	0	0	0	0
	17	1.3	1.2	<1.4	<3.4	0	0	0	0	0
	18	0.9	1.8	<1.4	<3.4	0	0	0	0	0
	19	1.7	2.6	4.2	<3.4	0	0	0	0	0
	20	1.4	1.7	<1.4	<3.4	0	0	0	0	0
New Onset T1D	21	2,597	136	202	4.6	1	1	1	1	4
	22	63	>2,140	1,092	58	1	1	1	1	4
	23	295	1,997	70	3.4	1	1	1	0	3
	24	371	>2,140	586	8.0	1	1	1	1	4
	25	41	>2,140	72	3.9	1	1	1	1	4
	26	884	3.7	3.1	3.4	1	0	0	0	1
	27	18	>2,140	>2,540	9.0	1	1	1	1	4
	28	765	>2,140	>2,540	41	1	1	1	1	4
	29	394	>2,140	2.6	9.3	1	1	0	1	3
	30	>5,460	>2,140	1,565	20	1	1	1	1	4
	31	3,436	>2,140	31	7.2	1	1	1	1	4
	32	11	0.7	1.4	3.4	1	0	0	0	1
	33	748	580	111	21	1	1	1	1	4
	34	12	9.2	49	4.0	1	1	1	1	4
	35	438	>2,140	2,454	11	1	1	1	1	4
	36	16	675	53	3.4	1	1	1	0	3
	37	4,746	2.2	2.1	5.3	1	0	0	1	2
	38	33	365	263	3.4	1	1	1	0	3
	39	82	>2,140	131	7.2	1	1	1	1	4
	40	2,221	>2,140	209	5.8	1	1	1	1	4

The Islet Autoantibody Standardization Program (IASP) is an international effort with the aim to improve the measurement of islet autoantibodies associated with Type 1 diabetes (T1D). IASP coordinates the distribution of a set of blinded samples to participating laboratories world-wide. Results and inter-laboratory comparisons were presented at The Immunology of Diabetes Congress, Bruges, Belgium, November 2024 (Figure 2).

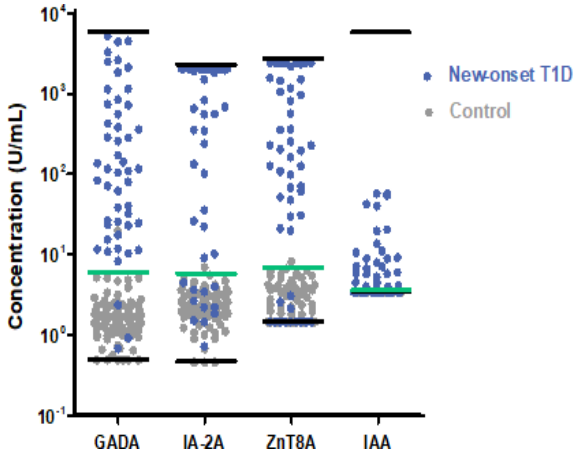

Figure 2. MSD testing results from the Islet Autoantibody Standardization Program (IASP) 2024 proficiency evaluation. The IASP 2024 sample set consisted of 50 samples from individuals with new-onset T1D (blue symbols) and 97 samples from non-diabetic control individuals (grey symbols). Calculated concentrations were thresholded to the assay limits of detection (black lines) for measurements above or below those values. The green line represents the 99th percentile of the concentration distribution of the non-diabetic controls. GADA and IA-2A concentrations were calibrated to the Islet Cell Antibodies WHO Reference Reagent (NIBSC code: 97/550). ZnT8A and IAA concentrations are presented in arbitrary units (U/mL).

Parallelism

To assess linearity, commercially sourced serum samples were diluted 2-fold, 4-fold, 8-fold, and 16-fold before testing. Percent recovery at each dilution level was normalized to the dilution-adjusted, 4-fold diluted concentration (Table 5).

Table 5. Percent recovery at different dilutions tested using the T1D Autoantibody Panel 1 (human) Kit, normalized to the dilution-adjusted, 4-fold diluted concentration

		GADA (n=4)		IA-2A (n=4)		IAA (n=4)		ZnT8A (n=2)	
Sample Type	Fold Dilution	Average % Recovery	% Recovery Range	Average % Recovery	% Recovery Range	Average % Recovery	% Recovery Range	Average % Recovery	% Recovery Range
Serum	2	96	43 – 117	101	48 – 128	86	45 – 109	93	91 – 94
	8	96	88 – 108	97	85 – 122	108	95 – 119	109	104 – 113
	16	104	90 – 116	85	86 – 110	108	76 – 153	128	126 – 131

Specificity

To assess specificity, each assay in the panel was tested with individual calibrators. Nonspecific binding was less than 1% for all assays in the kit. Non-specificity reported in the COA for this panel is measured using the following formula:

$$\%\ Nonspecificity = \frac{nonspecific\ signal}{specific\ signal} * 100$$

Assay Components

Calibrators

Calibrators are recombinant monoclonal antibodies that are detected by the human antigens.

Table 6. Antibodies used in the calibrator blend for the T1D Autoantibody Panel 1 (human) Kit

Calibrator	Source
GADA	Recombinant Monoclonal Anti-GAD2/GAD-65 Antibody
IA-2A	Recombinant Monoclonal Anti-IA-2/R-PTP-N Antibody
IAA	Recombinant Monoclonal Anti-Insulin Antibody
ZnT8A	Recombinant Monoclonal Anti-ZnT8 Antibody

Antigens

Table 7. Antigen expression systems for the T1D Autoantibody Panel 1 (human) Kit

Antigen	Capture	Detection
GAD2/GAD-65	HEK-293	HEK-293
IA-2/R-PTP-N	Insect	Insect
Insulin	Yeast	Yeast
ZnT8	E. coli	E. coli

Reference Materials and Assay Specificity

GADA and IA-2A were calibrated against the WHO Reference Reagent, Islet Cell Antibodies, NIBSC code: 97/550 in Units of biological activity per mL (U/mL). ZnT8A and IAA are assigned units per mL.

References

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2. Bingley PJ, et al. Prediction of IDDM in the general population: strategies based on combinations of autoantibody markers. Diabetes 1997;46:1701–1710
3. Greenbaum CJ, Sears KL, Kahn SE, Palmer JP. Relationship of beta-cell function and autoantibodies to progression and non-progression of subclinical type 1 diabetes: a follow-up of the Seattle Family Study. Diabetes 1999;48:170–175
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