

TN-01 Pathway to Prevention (Natural History) Specimen Inventory Summary

Guidelines for Table Interpretation:

Subjects indicates the number of subjects with stored samples at a given time point.

Samples indicates the total number of stored samples available at a given time point for the indicated number of subjects. The number of tubes/vials per subject is variable, as collection volumes often depend upon participant age/weight.

Example:

Time Point	PBMC	
	# Subjects	# Samples
Baseline	75	500
6 months	72	486

The table at left indicates that at Baseline, there are 500 PBMC vials from a total of 75 subjects. At 6 months, there are 486 vials from 72 subjects. Subjects with samples at each timepoint may or may not overlap.

Specimen Collection Protocols:

PBMC/PLASMA:

Prior to 2012, PBMCs /plasma extracted locally at clinical sites; up to 24 mL whole blood collected in CPT tubes. As of January 9, 2012, samples processed centrally at Rutgers Infinite Biologics; up to 60 mL whole blood collected in Tempus tubes.

PBMC: “# Samples” represents the total number of PBMC vials in storage. PBMCs aliquoting protocol: 10 x 10⁶ cells per 1 mL aliquot if total if yield ≥ 30 million cells; 5 x 10⁶ cells per 0.5 mL aliquot if total if yield < 30 million cells. Actual cell count per vial varies significantly, particularly for locally-processed samples.

PLASMA: “# Samples” represents the total number of plasma vials in storage. Aliquot protocol prior to 2012: 250 µL per cryovial; actual volume in each vial may vary. Aliquot protocol as of 9 Jan 2012: 500 µL per cryovial/

DNA: 6 mL whole blood collected for DNA extraction. “# Samples” indicates the number of whole blood samples collected for storage. Average yield of per 6 mL whole blood is 60 µg DNA.

RNA: At each indicated time point, 3 or 6 mL whole blood collected for RNA extraction in Tempus tubes. “# Samples” indicates the total number of vials of RNA currently in storage.

SERUM: At each indicated time point, 5 mL whole blooded collection for serum storage. “# Samples” indicates the total number of vials of serum currently in storage. Per protocol, serum was to be aliquoted at 1 mL per 1.8 mL cryovial. Actual volume in each vial may vary.

TN-01 Pathway to Prevention (Natural History) Stored Specimen Inventory Summary

Multiple Autoantibody Positive, Progressed to T1D

Time Point	PBMC		Plasma		Serum		RNA		DNA	
	# Subjects	# Samples	# Subjects	# Samples	# Subjects	# Samples	# Subjects	# Samples	# Subjects	# Samples
Baseline	83	226	87	294	163	462	132	1186	536	767
6 months	112	328	131	413	165	487	150	952	.	.
1 year	93	284	102	345	122	366	111	748	.	.
1 year, 6 months	68	214	80	255	99	285	94	638	.	.
2 years	56	162	62	195	75	209	75	585	.	.
2 years, 6 months	38	108	42	132	58	166	56	476	.	.
3 years	32	111	37	123	46	143	41	358	.	.
3 years, 6 months	20	77	22	75	29	86	26	274	.	.
4 years	14	58	16	51	23	62	20	214	.	.
4 years, 6 months	18	63	18	63	25	70	24	264	.	.
5 years	11	42	13	42	19	57	18	217	.	.
5 years, 6 months	9	30	9	26	15	44	15	180	.	.
6 years	3	11	3	9	12	35	12	144	.	.
6 years, 6 months	4	13	4	12	14	40	14	168	.	.
7 years	1	7	2	6	9	25	9	108	.	.
7 years, 6 months	1	4	1	3	8	24	7	74	.	.
8 years	6	18	6	62	.	.
8 years, 6 months	4	12	4	48	.	.
9 years	1	3	1	12	.	.
9 years, 6 months	1	3	1	2	.	.
PRN*	3	8	13	41	30	105	28	416	154	209

*PRN = Unscheduled or Out-of-Window Visit

TN-01 Pathway to Prevention (Natural History) Stored Specimen Inventory Summary

Single Confirmed Autoantibody Positive, Progressed to T1D

Time Point	PBMC		Plasma		Serum		RNA		DNA	
	# Subjects	# Samples	# Subjects	# Samples	# Subjects	# Samples	# Subjects	# Samples	# Subjects	# Samples
Baseline	10	26	10	30	14	35	13	123	36	65
6 months	10	28	12	34	12	36	11	63	.	.
1 year	6	17	8	24	8	24	8	34	.	.
1 year, 6 months	5	14	5	18	5	13	4	31	.	.
2 years	2	8	2	6	3	9	2	25	.	.
2 years, 6 months	2	4	3	9	4	12	4	45	.	.
3 years	3	6	4	12	4	12	3	36	.	.
3 years, 6 months	2	5	3	8	4	12	4	48	.	.
4 years	2	7	2	6	2	6	2	24	.	.
4 years, 6 months	1	3	1	3	2	6	2	24	.	.
5 years	1	3	1	12	.	.
5 years, 6 months	1	3	1	12	.	.
PRN*	.	.	1	6	.	.	1	12	6	8

*PRN = Unscheduled or Out-of-Window Visit

TN-01 Pathway to Prevention (Natural History) Stored Specimen Inventory Summary

Multiple Autoantibody Positive, Non-Progressor

Time Point	PBMC		Plasma		Serum		RNA		DNA	
	# Subjects	# Samples	# Subjects	# Samples	# Subjects	# Samples	# Subjects	# Samples	# Subjects	# Samples
Baseline	175	567	175	528	437	1271	312	3086	1470	1754
6 months	224	686	230	701	358	1052	299	2337	.	.
1 year	176	557	185	589	303	913	253	2094	.	.
1 year, 6 months	124	400	127	396	221	655	205	1680	.	.
2 years	116	389	120	392	229	682	212	1839	.	.
2 years, 6 months	84	272	86	255	180	523	165	1386	.	.
3 years	63	220	70	225	157	470	144	1370	.	.
3 years, 6 months	56	191	59	194	137	412	119	1109	.	.
4 years	49	166	51	156	116	342	104	924	.	.
4 years, 6 months	30	103	30	88	90	261	85	829	.	.
5 years	30	95	31	93	78	225	75	750	.	.
5 years, 6 months	36	123	36	107	74	212	71	752	.	.
6 years	20	68	21	63	55	163	56	636	.	.
6 years, 6 months	10	32	10	30	47	137	48	516	.	.
7 years	4	14	4	12	53	153	55	530	.	.
7 years, 6 months	37	111	36	326	.	.
8 years	31	91	31	292	.	.
8 years, 6 months	24	72	23	206	.	.
9 years	19	57	19	108	.	.
9 years, 6 months	14	42	13	75	.	.
10 years	8	24	9	18	.	.
10 years, 6 months	1	3	1	2	.	.
PRN*	1	3	33	102	145	587	138	2009	383	468

*PRN = Unscheduled or Out-of-Window Visit

TN-01 Pathway to Prevention (Natural History) Stored Specimen Inventory Summary

Single Confirmed Autoantibody Positive, Non-Progressor

Time Point	PBMC		Plasma		Serum		RNA		DNA	
	# Subjects	# Samples	# Subjects	# Samples	# Subjects	# Samples	# Subjects	# Samples	# Subjects	# Samples
Baseline	144	467	146	432	404	1164	264	2739	1222	1499
6 months	187	614	194	599	249	735	227	1813	.	.
1 year	143	504	148	485	191	587	169	1374	.	.
1 year, 6 months	112	389	113	351	163	488	140	1282	.	.
2 years	86	289	90	277	135	402	127	1151	.	.
2 years, 6 months	77	254	81	253	121	363	112	1053	.	.
3 years	81	275	80	245	119	348	116	1178	.	.
3 years, 6 months	62	215	62	195	104	318	95	972	.	.
4 years	47	175	47	147	86	254	80	862	.	.
4 years, 6 months	30	99	33	102	77	223	70	754	.	.
5 years	21	78	21	63	58	171	56	626	.	.
5 years, 6 months	14	44	14	42	52	153	51	562	.	.
6 years	9	24	10	30	51	150	48	516	.	.
6 years, 6 months	4	14	6	17	44	128	43	430	.	.
7 years	1	2	1	3	32	95	34	307	.	.
7 years, 6 months	19	56	21	142	.	.
8 years	12	36	12	114	.	.
8 years, 6 months	8	24	8	66	.	.
9 years	5	15	5	40	.	.
9 years, 6 months	4	12	4	18	.	.
10 years	4	12	4	8	.	.
10 years, 6 months	1	3	1	2	.	.
PRN*	.	.	22	86	90	372	91	1281	259	308

*PRN = Unscheduled or Out-of-Window Visit

TN-01 Pathway to Prevention (Natural History) Stored Specimen Inventory Summary

Autoantibody Negative (1° or 2° Relatives with T1D)

Time Point	PBMC		Plasma		Serum		RNA		DNA	
	# Subjects	# Samples	# Subjects	# Samples	# Subjects	# Samples	# Subjects	# Samples	# Subjects	# Samples
Baseline	2	2	1	3	36	108	1	12	98	144
6 months	6	17	2	6	2	6	2	24	.	.
1 year	8	32	5	21	5	19	5	60	.	.
1 year, 6 months	2	6
2 years	29	56	36	108	37	109	39	457	.	.
2 years, 6 months	1	4
3 years	33	83	34	102	39	113	39	468	.	.
3 years, 6 months	2	8	.	.	2	6	2	24	.	.
4 years	1	4	.	.	35	105	35	420	.	.
4 years, 6 months	2	6
5 years	22	66	18	210	.	.
5 years, 6 months	1	3	1	2	.	.
6 years	22	66
6 years, 6 months
7 years	2	5	.	.	16	47
7 years, 6 months	1	4
8 years	1	4
8 years, 6 months	.	.	12	36	20	75	15	206	15	24
PRN*	2	2	1	3	36	108	1	12	98	144

*PRN = Unscheduled or Out-of-Window Visit