

TN01 - Natural History Summary of Mechanistic Samples
Participants that have Type 1 Diabetes
Data Current as of February 11, 2011

Time Point	Type	Risk < 25%		Risk >= 25%		Risk >= 50%		Risk Missing or TBD		Overall	
		# Subjects	Total # Samples	# Subjects	Total # Samples	# Subjects	Total # Samples	# Subjects	Total # Samples	# Subjects	Total # Samples
Baseline (Phase 2)	DNA	9	9	9	10	104	104	6	6	128	129
	HLA	9	62	8	61	75	500	10	49	102	672
	PBMC	9	34	9	26	80	236	6	20	104	316
	PLASMA	9	27	9	27	82	253	6	18	106	325
	SERUM	11	27	10	28	94	262	6	18	121	335
Baseline (Phase 3)	PBMC	9	30	8	28	47	163	12	38	76	259
	PLASMA	9	27	8	24	50	153	11	33	78	237
	SERUM	9	23	8	23	53	159	11	30	81	235
6 months	PBMC	6	24	9	33	32	116	7	31	54	204
	PLASMA	6	18	9	33	33	108	7	23	55	182
	SERUM	7	19	10	33	33	104	7	21	57	177
1 year	PBMC	6	18	5	16	21	75	4	15	36	124
	PLASMA	6	17	5	15	23	69	4	12	38	113
	SERUM	6	13	6	17	23	67	4	10	39	107
1 year, 6 months	PBMC	5	19	5	14	15	44	4	14	29	91
	PLASMA	5	18	5	15	15	45	4	10	29	88
	SERUM	5	13	5	13	16	45	4	8	30	79
2 years	PBMC	3	10	3	9	9	31	3	14	18	64
	PLASMA	3	9	4	12	9	27	3	12	19	60
	SERUM	3	8	4	12	9	25	3	6	19	51
2 year, 6 months	PBMC	4	18	4	11	5	20	2	4	15	53
	PLASMA	4	15	4	12	5	18	2	6	15	51
	SERUM	4	13	4	12	5	17	2	3	15	45
3 years	PBMC	2	10	2	6	3	15	1	3	8	34
	PLASMA	2	8	2	6	3	12	1	3	8	29
	SERUM	2	8	2	6	3	10	1	1	8	25
3 year, 6 months	PBMC	1	2	0	0	1	6	1	2	3	10
	PLASMA	1	3	0	0	1	3	1	3	3	9
	SERUM	1	3	0	0	1	1	1	1	3	5
4 years	PBMC	0	0	0	0	3	15	1	1	4	16
	PLASMA	0	0	0	0	3	15	1	3	4	18
	SERUM	0	0	0	0	3	10	1	2	4	12

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		# Subjects	Total # Samples	# Subjects	Total # Samples	# Subjects	Total # Samples	# Subjects	Total # Samples	# Subjects	Total # Samples
4 year, 6 months	PBMC	0	0	0	0	0	0	1	2	1	2
	PLASMA	0	0	0	0	0	0	1	3	1	3
	SERUM	0	0	0	0	0	0	1	1	1	1
5 years	PBMC	0	0	0	0	1	3	0	0	1	3
	PLASMA	0	0	0	0	1	3	0	0	1	3
	SERUM	0	0	0	0	1	2	0	0	1	2
PRN	DNA	3	3	4	5	17	25	5	6	29	39
	HLA	10	101	15	142	126	1207	3	16	154	1466
	PBMC	0	0	1	4	1	3	0	0	2	7
	PLASMA	0	0	1	3	1	3	0	0	2	6
	SERUM	0	0	1	2	2	3	0	0	3	5

KEY	
# of Subjects:	Number of subjects who had a given sample collected at a given time point. (i.e. 319 subjects had PMBCs collected at the Baseline Phase 2 visit).
Total # Samples:	The total number of vials collected at each time point, for all subjects. (i.e. A total of 1077 vials of PMBCs were collected at the Baseline Phase 2 visit, from 319 subjects.)
Risk:	Risk of development of T1D within 5 years.
Risk < 25%:	A normal OGTT and no more than one confirmed positive autoantibody (biochemical or ICA), OR two or more autoantibodies positive on the first sample with no autoantibodies on subsequent samples and a normal OGTT. Also includes those who are positive for autoantibodies on two different tests, but who do not confirm positive for any specific autoantibody.
Risk >= 25%:	Two confirmed autoantibody tests and a normal OGTT.
Risk >= 50%:	An abnormal OGTT regardless of the number of positive autoantibodies, OR three or more confirmed positive autoantibody tests with a normal OGTT.