

***TN01 - Natural History Summary of Mechanistic Samples  
Participants that do NOT 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	356	370	100	104	195	199	117	117	767	790
	HLA	447	2770	121	750	232	1352	157	732	957	5604
	PBMC	315	1029	96	298	174	531	58	192	643	2050
	PLASMA	320	960	98	301	174	524	58	172	650	1957
	SERUM	335	960	102	296	179	507	60	170	676	1933
Baseline (Phase 3)	PBMC	213	669	67	216	107	343	53	168	440	1396
	PLASMA	214	654	67	207	107	334	52	161	440	1356
	SERUM	225	659	67	200	110	325	55	158	457	1342
6 months	PBMC	167	595	51	176	77	241	44	143	339	1155
	PLASMA	169	562	52	169	78	254	43	131	342	1116
	SERUM	172	545	52	159	79	244	45	126	348	1074
1 year	PBMC	124	430	37	114	62	208	34	112	257	864
	PLASMA	124	390	37	117	63	204	35	111	259	822
	SERUM	127	381	38	110	64	193	35	103	264	787
1 year, 6 months	PBMC	116	400	40	127	46	172	22	80	224	779
	PLASMA	118	368	40	126	46	152	22	75	226	721
	SERUM	118	357	40	117	43	128	22	61	223	663
2 years	PBMC	88	298	26	85	45	148	49	138	208	669
	PLASMA	90	273	26	78	45	138	49	148	210	637
	SERUM	92	275	27	76	44	126	48	132	211	609
2 year, 6 months	PBMC	66	231	20	61	37	136	20	74	143	502
	PLASMA	66	207	21	69	37	123	20	65	144	464
	SERUM	67	203	23	72	37	118	21	62	148	455
3 years	PBMC	47	153	15	61	19	62	22	85	103	361
	PLASMA	47	150	15	54	19	60	21	72	102	336
	SERUM	49	152	16	55	20	58	22	70	107	335
3 year, 6 months	PBMC	29	96	13	44	18	60	15	53	75	253
	PLASMA	31	99	13	39	18	57	16	50	78	245
	SERUM	32	99	13	39	18	52	16	47	79	237
4 years	PBMC	21	79	5	15	12	41	17	63	55	198
	PLASMA	23	70	5	15	12	36	17	54	57	175

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		# Subjects	Total # Samples	# Subjects	Total # Samples	# Subjects	Total # Samples	# Subjects	Total # Samples	# Subjects	Total # Samples
	SERUM	23	68	5	15	12	36	17	46	57	165
4 year, 6 months	PBMC	16	57	5	16	7	13	7	26	35	112
	PLASMA	16	48	5	15	7	21	7	24	35	108
	SERUM	16	47	5	15	7	21	7	20	35	103
5 years	PBMC	11	37	2	3	5	18	9	25	27	83
	PLASMA	10	30	2	6	5	14	9	26	26	76
	SERUM	12	36	2	6	5	15	10	27	29	84
5 year, 6 months	PBMC	0	0	2	6	2	6	7	21	11	33
	PLASMA	0	0	2	6	2	6	8	24	12	36
	SERUM	0	0	2	6	2	5	7	20	11	31
6 years	PBMC	0	0	0	0	1	3	4	11	5	14
	PLASMA	0	0	0	0	1	3	4	12	5	15
	SERUM	0	0	0	0	1	3	4	9	5	12
6 year, 6 months	PBMC	0	0	0	0	0	0	2	5	2	5
	PLASMA	0	0	0	0	0	0	2	6	2	6
	SERUM	0	0	0	0	0	0	2	4	2	4
PRN	DNA	47	63	13	27	44	66	54	79	158	235
	HLA	314	2883	95	907	194	1811	98	601	701	6202
	PBMC	18	54	3	6	5	17	10	37	36	114
	PLASMA	17	54	3	9	5	15	10	33	35	111
	SERUM	18	54	3	9	5	14	10	30	36	107

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<b>KEY</b>	
<b># of Subjects:</b>	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).
<b>Total # Samples:</b>	The total number of vials collected at each time point, for all subjects. (i.e. A total of 1077 vials of PBMCs were collected at the Baseline Phase 2 visit, from 319 subjects.)
<b>Risk:</b>	Risk of development of T1D within 5 years.
<b>Risk &lt; 25%:</b>	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.
<b>Risk &gt;= 25%:</b>	Two confirmed autoantibody tests and a normal OGTT.
<b>Risk &gt;= 50%:</b>	An abnormal OGTT regardless of the number of positive autoantibodies, OR three or more confirmed positive autoantibody tests with a normal OGTT.