

TN01 - Natural History Summary of Mechanistic Samples
Data Current as of February 11, 2011

		Risk < 25%		Risk >= 25%		Risk >= 50%		Risk Missing or TBD		Overall	
Time Point	Type	# Subjects	Total # Samples	# Subjects	Total # Samples	# Subjects	Total # Samples	# Subjects	Total # Samples	# Subjects	Total # Samples
Baseline (Phase 2)	DNA	365	379	109	114	299	303	123	123	895	919
	HLA	456	2832	129	811	307	1852	167	781	1059	6276
	PBMC	324	1063	105	324	254	767	64	212	747	2366
	PLASMA	329	987	107	328	256	777	64	190	756	2282
	SERUM	346	987	112	324	273	769	66	188	797	2268
Baseline (Phase 3)	PBMC	222	699	75	244	154	506	65	206	516	1655
	PLASMA	223	681	75	231	157	487	63	194	518	1593
	SERUM	234	682	75	223	163	484	66	188	538	1577
6 months	PBMC	173	619	60	209	109	357	51	174	393	1359
	PLASMA	175	580	61	202	111	362	50	154	397	1298
	SERUM	179	564	62	192	112	348	52	147	405	1251
1 year	PBMC	130	448	42	130	83	283	38	127	293	988
	PLASMA	130	407	42	132	86	273	39	123	297	935
	SERUM	133	394	44	127	87	260	39	113	303	894
1 year, 6 months	PBMC	121	419	45	141	61	216	26	94	253	870
	PLASMA	123	386	45	141	61	197	26	85	255	809
	SERUM	123	370	45	130	59	173	26	69	253	742
2 years	PBMC	91	308	29	94	54	179	52	152	226	733
	PLASMA	93	282	30	90	54	165	52	160	229	697
	SERUM	95	283	31	88	53	151	51	138	230	660
2 year, 6 months	PBMC	70	249	24	72	42	156	22	78	158	555
	PLASMA	70	222	25	81	42	141	22	71	159	515
	SERUM	71	216	27	84	42	135	23	65	163	500
3 years	PBMC	49	163	17	67	22	77	23	88	111	395
	PLASMA	49	158	17	60	22	72	22	75	110	365
	SERUM	51	160	18	61	23	68	23	71	115	360
3 year, 6 months	PBMC	30	98	13	44	19	66	16	55	78	263
	PLASMA	32	102	13	39	19	60	17	53	81	254
	SERUM	33	102	13	39	19	53	17	48	82	242
4 years	PBMC	21	79	5	15	15	56	18	64	59	214
	PLASMA	23	70	5	15	15	51	18	57	61	193

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	SERUM	23	68	5	15	15	46	18	48	61	177
4 year, 6 months	PBMC	16	57	5	16	7	13	8	28	36	114
	PLASMA	16	48	5	15	7	21	8	27	36	111
	SERUM	16	47	5	15	7	21	8	21	36	104
5 years	PBMC	11	37	2	3	6	21	9	25	28	86
	PLASMA	10	30	2	6	6	17	9	26	27	79
	SERUM	12	36	2	6	6	17	10	27	30	86
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	50	66	17	32	61	91	59	85	187	274
	HLA	324	2984	110	1049	320	3018	101	617	855	7668
	PBMC	18	54	4	10	6	20	10	37	38	121
	PLASMA	17	54	4	12	6	18	10	33	37	117
	SERUM	18	54	4	11	7	17	10	30	39	112

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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 PBMCs 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.