

TrialNet – TN10 (Analysis Datasets)
Central Laboratory Results Data Dictionary
Data Through November 30, 2018, Current as of January 31, 2019
Test Name Definitions, Result Values, and Interpretation

Test	Description of Test	Result Values	Interpretation of Result/Outcome	Effective Dates*
GAD65H	Anti-GAD65 autoantibody (NIDDK Harmonized Assay)	0 to 3000 NIDDK units/mL	Negative: ≤ 20 ; Positive: >20 NIDDK units/mL	
IA2H	Anti-IA-2 autoantibody (NIDDK Harmonized Assay)	0 to 2000 NIDDK units/mL	Negative: ≤ 5 ; Positive: >5 NIDDK units/mL	15MAY2015-Present
MIAA	Micro Insulin autoantibody	-0.5 to 7.0, ins-uninhib (index)	Negative: ≤ 0.010 ; Positive: >0.010 ; Uninterpretable: ins-uninhib	Study Start-14MAY2015
MIAA	Micro Insulin autoantibody	-0.5 to 10.0, ins-uninhib (index)	Negative: ≤ 0.010 ; Positive: >0.010 ; Uninterpretable: ins-uninhib	15MAY2015-Present
ZnT8	Zinc transporter autoantibody	-0.5 to 2.0 (index)	Negative: ≤ 0.020 ; Positive: >0.020	Study Start-14MAY2015
ZnT8	Zinc transporter autoantibody	-0.5 to 3.0 (index)	Negative: ≤ 0.020 ; Positive: >0.020	15MAY2015-Present
ICA	Islet Cell Antigen	0-25,000 JDF units	Negative: <10 JDF units; Positive: ≥ 10 JDF units	Study Start-10MAR2015
ICA	Islet Cell Antigen	0-25000; 5×10^2 JDF units, >25000 ; 5×10^2 JDF units	Negative: <10 JDF units; Positive: ≥ 10 JDF units	11MAR2015-Present
GLUM10	Glucose level at -10 min	<2 mg/dL, 2-825 mg/dL	Normal fasting: <110 mg/dL, Borderline fasting: 110 - 125 mg/dL	Study Start-04FEB2016
GLU0	Glucose level at 0 min	<2 mg/dL, 2-825 mg/dL	Normal fasting: <110 mg/dL, Borderline fasting: 110 - 125 mg/dL	Study Start-04FEB2016
GLU30	Glucose level at 30 min	<2 mg/dL, 2-825 mg/dL		Study Start-04FEB2016
GLU60	Glucose level at 60 min	<2 mg/dL, 2-825 mg/dL		Study Start-04FEB2016
GLU90	Glucose level at 90 min	<2 mg/dL, 2-825 mg/dL		Study Start-04FEB2016
GLU120	Glucose level at 120 min	<2 mg/dL, 2-825 mg/dL		Study Start-04FEB2016
GLUM10	Glucose level at -10 min	<2 mg/dL, 2 or greater mg/dL	Normal fasting: <110 mg/dL, Borderline fasting: 110 - 125 mg/dL	05FEB2016-Present
GLU0	Glucose level at 0 min	<2 mg/dL, 2 or greater mg/dL	Normal fasting: <110 mg/dL, Borderline fasting: 110 - 125 mg/dL	05FEB2016-Present
GLU30	Glucose level at 30 min	<2 mg/dL, 2 or greater mg/dL		05FEB2016-Present
GLU60	Glucose level at 60 min	<2 mg/dL, 2 or greater mg/dL		05FEB2016-Present
GLU90	Glucose level at 90 min	<2 mg/dL, 2 or greater mg/dL		05FEB2016-Present
GLU120	Glucose level at 120 min	<2 mg/dL, 2 or greater mg/dL		05FEB2016-Present
PEP0	C-Peptide level at 0 min	<0.0165 pmol/mL, 0.0165-33 pmol/mL**	Normal fasting range: 0.363-1.056 pmol/mL	Study Start-05JAN2015

TrialNet – TN10 (Analysis Datasets)
Central Laboratory Results Data Dictionary
Data Though November 30, 2018, Current as of January 31, 2019
Test Name Definitions, Result Values, and Interpretation

Test	Description of Test	Result Values	Interpretation of Result/Outcome	Effective Dates*
PEP30	C-Peptide level at 30 min	<0.0165 pmol/mL, 0.0165-33 pmol/mL**		Study Start-05JAN2015
PEP60	C-Peptide level at 60 min	<0.0165 pmol/mL, 0.0165-33 pmol/mL**		Study Start-05JAN2015
PEP90	C-Peptide level at 90 min	<0.0165 pmol/mL, 0.0165-33 pmol/mL**		Study Start-05JAN2015
PEP120	C-Peptide level at 120 min	<0.0165 pmol/mL, 0.0165-33 pmol/mL**		Study Start-05JAN2015
PEP0	C-Peptide level at 0 min	<0.0066 pmol/mL, 0.0066-33 pmol/mL**	Normal fasting range: 0.363-1.056 pmol/mL	06JAN2015-04FEB2016
PEP30	C-Peptide level at 30 min	<0.0066 pmol/mL, 0.0066-33 pmol/mL**		06JAN2015-04FEB2016
PEP60	C-Peptide level at 60 min	<0.0066 pmol/mL, 0.0066-33 pmol/mL**		06JAN2015-04FEB2016
PEP90	C-Peptide level at 90 min	<0.0066 pmol/mL, 0.0066-33 pmol/mL**		06JAN2015-04FEB2016
PEP120	C-Peptide level at 120 min	<0.0066 pmol/mL, 0.0066-33 pmol/mL**		06JAN2015-04FEB2016
PEP0	C-Peptide level at 0 min	<0.0066 pmol/mL, 0.0066 or greater pmol/mL**	Normal fasting range: 0.363-1.056 pmol/mL	05FEB2016-Present
PEP30	C-Peptide level at 30 min	<0.0066 pmol/mL, 0.0066 or greater pmol/mL**		05FEB2016-Present
PEP60	C-Peptide level at 60 min	<0.0066 pmol/mL, 0.0066 or greater pmol/mL**		05FEB2016-Present
PEP90	C-Peptide level at 90 min	<0.0066 pmol/mL, 0.0066 or greater pmol/mL**		05FEB2016-Present
PEP120	C-Peptide level at 120 min	<0.0066 pmol/mL, 0.0066 or greater pmol/mL**		05FEB2016-Present
HbA1c	Glucosylated Hemoglobin (%)	3.0-20.7%	<6.0%	Study Start-04FEB2016
HbA1c	Glucosylated Hemoglobin (%)	3.2 or greater %	<6.0%	05FEB2016-Present
HLA	Absence/Presence of DQA1*0102, DQB1*0602	Absent, Present		
DR3	Absence Presence DRB*0301 DQA*0501DQB0201	Absent, Present		
DR4	Absence Presence DRB*0401, 0402, 0403, etc. DQA*0301 DQB*0302	Absent, Present		
HLAA	HLA Haplotype α	####\$####\$####	List of 4-digit alleles for DRB1\$ DQA1\$ DQB1 (\$ = separator between alleles). Eg. DRB1*0101,DQA*0101 DQB1*0501 = 0101\$0101\$0501	
HLAB	HLA Haplotype β	####\$####\$####	List of 4-digit alleles for DRB1\$ DQA1\$ DQB1 (\$ = separator between alleles). Eg.	

TrialNet – TN10 (Analysis Datasets)
Central Laboratory Results Data Dictionary
Data Though November 30, 2018, Current as of January 31, 2019
Test Name Definitions, Result Values, and Interpretation

Test	Description of Test	Result Values	Interpretation of Result/Outcome	Effective Dates*
			DRB1*0101,DQA*0101 DQB1*0501 = 0101\$0101\$0501	
CMVVL	Cytomegalovirus Viral Load by PCR	[99] [100-500] 1000-1000000 copies/mL (<i>numeric value between 1000 & 1000000, inclusive</i>) [>1000000]	<ul style="list-style-type: none"> – 99: No viral replication=Negative; – 100-500: <1000 copies/mL=Qualitative positive but below level of quantitation; – 1000-1000000: 1,000 copies/mL–1,000,000 copies/mL=Quantitative positive; – >1000000: >1,000,000 copies/mL=Greater than maximum quantitative range 	Study Start-05JAN2012
CMVVL	Cytomegalovirus Viral Load by PCR	[<250] [250-1000] 1000-1000000 copies/mL (<i>numeric value between 1000 & 1000000, inclusive</i>) [>1000000]	<ul style="list-style-type: none"> – <250: No viral replication=Negative; – 250-1000: <1000 copies/mL=Qualitative positive but below level of quantitation; – 1000-1000000: 1,000 copies/mL–1,000,000 copies/mL=Quantitative positive; – >1000000: >1,000,000 copies/mL=Greater than maximum quantitative range 	04JAN2012-28JAN2014
CMVVL	Cytomegalovirus Viral Load by PCR	[TND] [POS<1000] 1000-1000000 copies/mL (<i>numeric value between 1000 & 1000000, inclusive</i>) [>1000000]	<ul style="list-style-type: none"> – TND: No viral replication=Negative; – POS<1000: <1000 copies/mL=Qualitative positive but below level of quantitation; – 1000-1000000: 1,000 copies/mL–1,000,000 copies/mL=Quantitative positive; – >1000000: >1,000,000 copies/mL=Greater than maximum quantitative range 	29JAN2014-04FEB2016
CMVVL	Cytomegalovirus Viral Load by PCR	[0] [500] 1000-1000000 IU/mL (<i>numeric value between 1000 & 1000000, inclusive</i>) [2000000]	<ul style="list-style-type: none"> – 0: No viral replication=Negative; – 500: <1000 IU/mL=Qualitative positive but below level of quantitation; – 1000-1000000: 1,000 IU/mL–1,000,000 IU/mL=Quantitative positive; – 2000000: >1,000,000 IU/mL=Greater than maximum quantitative range 	05FEB2016-ACTIVE
EBVVL	Epstein-Barr Virus Viral Load by PCR	[99] [100-500] 1000-1000000 copies/mL (<i>numeric value between 1000 & 1000000, inclusive</i>) [>1000000]	<ul style="list-style-type: none"> – 99: No viral replication=Negative; – 100-500: <1000 copies/mL=Qualitative positive but below level of quantitation; – 1000-1000000: 1,000 copies/mL–1,000,000 copies/mL=Quantitative positive; – >1000000: >1,000,000 copies/mL=Greater than maximum quantitative range 	Study Start-05JAN2012

TrialNet – TN10 (Analysis Datasets)
Central Laboratory Results Data Dictionary
Data Through November 30, 2018, Current as of January 31, 2019
Test Name Definitions, Result Values, and Interpretation

Test	Description of Test	Result Values	Interpretation of Result/Outcome	Effective Dates*
EBVVL	Epstein-Barr Virus Viral Load by PCR	[<500] [500-1000] 1000-1000000 copies/mL (<i>numeric value between 1000 & 1000000, inclusive</i>) [>1000000]	<ul style="list-style-type: none"> – <500: No viral replication=Negative; – 500-1000: <1000 copies/mL=Qualitative positive but below level of quantitation; – 1000-1000000: 1,000 copies/mL–1,000,000 copies/mL=Quantitative positive; – >1000000: >1,000,000 copies/mL=Greater than maximum quantitative range 	06JAN2012-28JAN2014
EBVVL	Epstein-Barr Virus Viral Load by PCR	[TND] [POS<1000] 1000-1000000 copies/mL (<i>numeric value between 1000 & 1000000, inclusive</i>) [>1000000]	<ul style="list-style-type: none"> – TND: No viral replication=Negative; – POS<1000: <1000 copies/mL=Qualitative positive but below level of quantitation; – 1000-1000000: 1,000 copies/mL–1,000,000 copies/mL=Quantitative positive; – >1000000: >1,000,000 copies/mL=Greater than maximum quantitative range 	29JAN2014-19SEP2016
EBVVL	Epstein-Barr Virus Viral Load by PCR	[0] [500] 1000-1000000 IU/mL (<i>numeric value between 1000 & 1000000, inclusive</i>) [2000000]	<ul style="list-style-type: none"> – 0: No viral replication=Negative; – 500: <1000 IU/mL=Qualitative positive but below level of quantitation; – 1000-1000000: 1000 IU/mL–1,000,000 IU/mL=Quantitative positive; – 2000000: >1,000,000 IU/mL=Greater than maximum quantitative range 	20SEP2016-ACTIVE
EBVVCAIGG	Epstein-Barr Virus Viral Capsid Antigen IgG	POS, NEG, EQU	POS = Positive; NEG = Negative; EQU = Equivocal	
EBVVCAIGM	Epstein-Barr Virus Viral Capsid Antigen IgM	POS, NEG, EQU	POS = Positive; NEG = Negative; EQU = Equivocal	
EBNA	Epstein-Barr Virus-determined nuclear antigen	POS, NEG, EQU	POS = Positive; NEG = Negative; EQU = Equivocal	
CMVIGG	Cytomegalovirus IgG	POS, NEG, EQU	POS = Positive; NEG = Negative; EQU = Equivocal	
CMVIGM	Cytomegalovirus IgM	POS, NEG, EQU	POS = Positive; NEG = Negative; EQU = Equivocal	
*Effective dates are listed if reportable test result values and/or interpretations changed during the study.				
**C-peptide results reported by central laboratory in ng/mL. Values converted to pmol/mL for analysis.				