

***TrialNet – TN10***

***Central Laboratory Results Data Dictionary - Secondary Manuscript Analytical Datasets***

***Current as of March 19, 2020***

***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 DK units/mL	Negative: <=20; Positive: >20 DK units/mL	
IA-2H	Anti-IA-2 autoantibody (NIDDK Harmonized Assay)	0 to 2000 DK units/mL	Negative: <=5; Positive: >5 DK units/mL	
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	0–25000 JDF units	Negative: <10 JDF units; Positive: >=10 JDF units	Study Start–10MAR2015
ICA	Islet Cell Antigen	0–25000 JDF units, >25000 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
INSTM10	Insulin level at -10 min (TOSOH)	<0.5 µU/mL, 0.5 or greater µU/mL	Normal fasting range: <17 µU/mL	

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INST0	Insulin level at 0 min (TOSOH)	<0.5 µU/mL, 0.5 or greater µU/mL	Normal fasting range: <17 µU/mL	
INST30	Insulin level at 30 min (TOSOH)	<0.5 µU/mL, 0.5 or greater µU/mL		
INST60	Insulin level at 60 min (TOSOH)	<0.5 µU/mL, 0.5 or greater µU/mL		
INST90	Insulin level at 90 min (TOSOH)	<0.5 µU/mL, 0.5 or greater µU/mL		
INST120	Insulin level at 120 min (TOSOH)	<0.5 µU/mL, 0.5 or greater µU/mL		
PEP0	C-Peptide level at 0 min	<0.05 ng/mL, 0.05-100 ng/mL	Normal fasting range: 1.1-3.3 ng/mL	Study Start-05JAN2015
PEP30	C-Peptide level at 30 min	<0.05 ng/mL, 0.05-100 ng/mL		Study Start-05JAN2015
PEP60	C-Peptide level at 60 min	<0.05 ng/mL, 0.05-100 ng/mL		Study Start-05JAN2015
PEP90	C-Peptide level at 90 min	<0.05 ng/mL, 0.05-100 ng/mL		Study Start-05JAN2015
PEP120	C-Peptide level at 120 min	<0.05 ng/mL, 0.05-100 ng/mL		Study Start-05JAN2015
PEP0	C-Peptide level at 0 min	<0.02 ng/mL, 0.02-100 ng/mL	Normal fasting range: 1.1-3.3 ng/mL	06JAN2015-04FEB2016
PEP30	C-Peptide level at 30 min	<0.02 ng/mL, 0.02-100 ng/mL		06JAN2015-04FEB2016
PEP60	C-Peptide level at 60 min	<0.02 ng/mL, 0.02-100 ng/mL		06JAN2015-04FEB2016
PEP90	C-Peptide level at 90 min	<0.02 ng/mL, 0.02-100 ng/mL		06JAN2015-04FEB2016
PEP120	C-Peptide level at 120 min	<0.02 ng/mL, 0.02-100 ng/mL		06JAN2015-04FEB2016
PEP0	C-Peptide level at 0 min	<0.02 ng/mL, 0.02 or greater ng/mL	Normal fasting range: 1.1-3.3 ng/mL	05FEB2016-Present
PEP30	C-Peptide level at 30 min	<0.02 ng/mL, 0.02 or greater ng/mL		05FEB2016-Present
PEP60	C-Peptide level at 60 min	<0.02 ng/mL, 0.02 or greater ng/mL		05FEB2016-Present
PEP90	C-Peptide level at 90 min	<0.02 ng/mL, 0.02 or greater ng/mL		05FEB2016-Present
PEP120	C-Peptide level at 120 min	<0.02 ng/mL, 0.02 or greater ng/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		

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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 $\alpha$	####\$####\$####	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 $\beta$	####\$####\$####	List of 4-digit alleles for DRB1\$ DQA1\$ DQB1 (\$ = separator between alleles). Eg. DRB1*0101,DQA*0101 DQB1*0501 = 0101\$0101\$0501	
CMVVL	Cytomegalovirus Viral Load by PCR	[99] [100-500] 1000-1000000 copies/mL (numeric value between 1000 & 1000000, inclusive) [>1000000]	<ul style="list-style-type: none"> <li>– 99: No viral replication=Negative;</li> <li>– 100-500: &lt;1000 copies/mL=Qualitative positive but below level of quantitation;</li> <li>– 1000-1000000: 1,000 copies/mL–1,000,000 copies/mL=Quantitative positive;</li> <li>– &gt;1000000: &gt;1,000,000 copies/mL=Greater than maximum quantitative range</li> </ul>	Study Start-05JAN2012
CMVVL	Cytomegalovirus Viral Load by PCR	[<250] [250-1000] 1000-1000000 copies/mL (numeric value between 1000 & 1000000, inclusive) [>1000000]	<ul style="list-style-type: none"> <li>– &lt;250: No viral replication=Negative;</li> <li>– 250-1000: &lt;1000 copies/mL=Qualitative positive but below level of quantitation;</li> <li>– 1000-1000000: 1,000 copies/mL–1,000,000 copies/mL=Quantitative positive;</li> <li>– &gt;1000000: &gt;1,000,000 copies/mL=Greater than maximum quantitative range</li> </ul>	06JAN2012-28JAN2014
CMVVL	Cytomegalovirus Viral Load by PCR	[TND] [POS<1000] 1000-1000000 copies/mL (numeric value between 1000 & 1000000, inclusive) [>1000000]	<ul style="list-style-type: none"> <li>– TND: No viral replication=Negative;</li> <li>– POS&lt;1000: &lt;1000 copies/mL=Qualitative positive but below level of quantitation;</li> <li>– 1000-1000000: 1,000 copies/mL–1,000,000 copies/mL=Quantitative positive;</li> <li>– &gt;1000000: &gt;1,000,000 copies/mL=Greater than maximum quantitative range</li> </ul>	29JAN2014-04FEB2016
CMVVL	Cytomegalovirus Viral Load by PCR	[0] [500] 1000-1000000 IU/mL (numeric value between 1000 & 1000000, inclusive)	<ul style="list-style-type: none"> <li>– 0: No viral replication=Negative;</li> <li>– 500: &lt;1000 IU/mL=Qualitative positive but below level of quantitation;</li> </ul>	05FEB2016-ACTIVE

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		[2000000]	<ul style="list-style-type: none"> <li>– 1000-1000000: 1,000 IU/mL–1,000,000 IU/mL= Quantitative positive;</li> <li>– 2000000: &gt;1,000,000 IU/mL=Greater than maximum quantitative range</li> </ul>	
EBVVL	Epstein-Barr Virus Viral Load by PCR	[99] [100-500] 1000-1000000 copies/mL ( <i>numeric value between 1000 &amp; 1000000, inclusive</i> ) [>1000000]	<ul style="list-style-type: none"> <li>– 99: No viral replication=Negative;</li> <li>– 100-500: &lt;1000 copies/mL=Qualitative positive but below level of quantitation;</li> <li>– 1000-1000000: 1,000 copies/mL–1,000,000 copies/mL=Quantitative positive;</li> <li>– &gt;1000000: &gt;1,000,000 copies/mL=Greater than maximum quantitative range</li> </ul>	Study Start-05JAN2012
EBVVL	Epstein-Barr Virus Viral Load by PCR	[<500] [500-1000] 1000-1000000 copies/mL ( <i>numeric value between 1000 &amp; 1000000, inclusive</i> ) [>1000000]	<ul style="list-style-type: none"> <li>– &lt;500: No viral replication=Negative;</li> <li>– 500-1000: &lt;1000 copies/mL=Qualitative positive but below level of quantitation;</li> <li>– 1000-1000000: 1,000 copies/mL–1,000,000 copies/mL=Quantitative positive;</li> <li>– &gt;1000000: &gt;1,000,000 copies/mL=Greater than maximum quantitative range</li> </ul>	06JAN2012-28JAN2014
EBVVL	Epstein-Barr Virus Viral Load by PCR	[TND] [POS<1000] 1000-1000000 copies/mL ( <i>numeric value between 1000 &amp; 1000000, inclusive</i> ) [>1000000]	<ul style="list-style-type: none"> <li>– TND: No viral replication=Negative;</li> <li>– POS&lt;1000: &lt;1000 copies/mL=Qualitative positive but below level of quantitation;</li> <li>– 1000-1000000: 1,000 copies/mL–1,000,000 copies/mL=Quantitative positive;</li> <li>– &gt;1000000: &gt;1,000,000 copies/mL=Greater than maximum quantitative range</li> </ul>	29JAN2014-19SEP2016
EBVVL	Epstein-Barr Virus Viral Load by PCR	[0] [500] 1000-1000000 IU/mL ( <i>numeric value between 1000 &amp; 1000000, inclusive</i> ) [2000000]	<ul style="list-style-type: none"> <li>– 0: No viral replication=Negative;</li> <li>– 500: &lt;1000 IU/mL=Qualitative positive but below level of quantitation;</li> <li>– 1000-1000000: 1000 IU/mL–1,000,000 IU/mL= Quantitative positive;</li> <li>– 2000000: &gt;1,000,000 IU/mL=Greater than maximum quantitative range</li> </ul>	20SEP2016-ACTIVE
*Effective dates are listed if reportable test result values and/or interpretations changed during the study.				

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Variable Name	Values	Definition
ResultType	RPTD	Result reported
	NORPTD	Result not reported (confirmed unavailable by lab)
	RVSD	Result revised