Wednesday, May 02, 2018

Protocol 7

Test Name Definitions; Result Value Ranges and Interpretation

Variable Name	Description of Test	Result Values	Interpretation of Result/Outcome	Effective Dates*
GAD65	Anti-GAD65 autoantibody titer value	-0.5 to 2.0	Negative ≤ 0.032, Positive: >0.032	Study Start-14MAY2015
GAD65	Anti-GAD65 autoantibody titer value	-0.5 to 3.0	Negative ≤ 0.032, Positive: >0.032	15MAY2015-Present
GAD65H	Anti-GAD65 autoantibody titer value (NIDDK Harmonized Assay)	0 to 3000 NIDDK units/mL	Negative: ≤ 20; Positive: >20 NIDDK units/mL	
ICA512	Anti-ICA512 (IA-2) autoantibody titer value	-0.5 to 2.0	Negative: ≤ 0.049; Positive: >0.049	Study Start-14MAY2015
ICA512	Anti-ICA512 (IA-2) autoantibody titer value	-0.5 to 3.0	Negative: ≤ 0.049; Positive: >0.049	15MAY2015-Present
IA2H	Anti-IA-2 autoantibody titer value (NIDDK Harmonized Assay)	0 to 2000 NIDDK units/mL	Negative: ≤ 5; Positive: >5 NIDDK units/mL	
MIAA	Micro Insulin autoantibody titer value	-0.5 to 7.0, ins-uninhib	Negative: ≤ 0.010; Positive: >0.010; Uninterpretable: ins-uninhib	Study Start-14MAY2015
MIAA	Micro Insulin autoantibody titer value	-0.5 to 10.0, ins-uninhib	Negative: ≤ 0.010; Positive: >0.010; Uninterpretable: ins-uninhib	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; $5*2^N$ JDF units, >25000; $5*2^N$ JDF units	Negative: <10 JDF units; Positive: ≥ 10 JDF units	11MAR2015-Present
GLU-10	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

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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
HbA1c	Glucosylated Hemoglobin (%)	3.0-20.7%	<6.0%	Study Start-04FEB2016
HbA1c	Glucosylated Hemoglobin (%)	3.2 or greater %	<6.0%	05FEB2016-Present
INS1	Insulin level at 1 min (RIA)	<3 µU/mL, 3 or greater µU/mL		
INS3	Insulin level at 3 min (RIA)	<3 µU/mL, 3 or greater µU/mL		
INST1	Insulin level at 1 min (TOSOH)	<0.5 µU/mL, 0.5 or greater µU/mL		
INST3	Insulin level at 3 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

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Variable Name	Description of Test	Result Values	Interpretation of Result/Outcome	Effective Dates*
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
HLA	Absence/Presence of DQA1*0102, DQB1*0602	ABSENT, PRESENT		
DR3	Absence/Presence of DRB1*0301, DQA1*0501, DQB1*0201	ABSENT, PRESENT		
DR4	Absence/Presence of DRB1*04##, DQA1*0301 *or* 0303, DQB1*0302	ABSENT, PRESENT		
HLAa	HLA Haplotype α (DRB1, DQA1, DQB1)	####$####$####	List of 4-digit alleles for DRB1$ DQA1$ DQB1 ($ = separator between alleles). Eg. DRB1*0101,DQA*0101 DQB1*0501 = 0101$0101$0501	
HLAb	HLA Haplotype β (DRB1, DQA1, DQB1)	####$####$####	List of 4-digit alleles for DRB1$ DQA1$ DQB1 ($ = separator between alleles). Eg. DRB1*0101,DQA*0101 DQB1*0501 = 0101$0101$0501	
*Effective dates are listed if reportable test result values and/or interpretations changed during the study.				