Table Diabetes Diagnostic evaluation, including oral glucose tolerance test (OGTT).

| CDE | General Comments | Purpose | Classification |
| --- | --- | --- | --- |
| Glycosylated Hemoglobin (Hemoglobin A1c) | %, performed using a method certified by the National Glycohemoglobin Standardization Program (NGSP) and standardizable to the Diabetes Control and Complications Trial (DCCT) reference.**1** | Diagnosis, Monitoring | Supplemental - Highly Recommended |
| Anti-pancreatic autoantibodies | Test for available diabetes-related autoimmunity (can include GAD 65, IA2, insulin).**2,3** | Diagnosis | Supplemental - Highly Recommended |
| Fasting glucose | Measured in mg/dL (U.S.) or mmol/L (outside U.S.) | Diagnosis | Supplemental - Highly Recommended |
| 2-hour glucose (OGTT) | Measured in mg/dL (U.S.) or mmol/L (outside U.S.) | Diagnosis | Supplemental - Highly Recommended |
| Fasting insulin | Meausred in mIU/L (U.S.) or pmol/L (outside U.S.) | Diagnosis, Monitoring | Supplemental |
| Fasting C-peptide | Measured in ng/mL (U.S.) or nmol/L (outside U.S.) | Monitoring | Supplemental |

Table 2 Diabetes-related comorbidities.

| CDE | General Comments | Purpose | Classification |
| --- | --- | --- | --- |
| Cholesterol - HDL\* | Measured in mg/dL (U.S.) or mmol/L (outside U.S.) | Safety | Supplemental |
| Cholesterol - LDL | Measured in mg/dL (U.S.) or mmol/L (outside U.S.) | Safety | Supplemental |
| Cholesterol, total | Measured in mg/dL (U.S.) or mmol/L (outside U.S.) | Safety | Supplemental |
| Cholesterol - VLDL | Measured in mg/dL (U.S.) or mmol/L (outside U.S.) | Safety | Supplemental |
| Triglycerides | Measured in mg/dL (U.S.) or mmol/L (outside U.S.) | Safety | Supplemental |
| Vitamin D, 25-hydroxy | Measured in ng/mL or nmol/L (U.S.) or mmol/L (outside U.S.) | Diagnosis, Monitoring | Exploratory |
| Microalbumin, urine | Measured in mg/dL (U.S) or mmol/L (outside U.S.) | Diagnosis | Supplemental |

## General Instructions

Laboratory tests are routinely administered in observational studies and clinical trials to diagnose, monitor disease, and also to assess participant/subject safety.

Laboratory tests may also be used to determine an individual’s eligibility for a study.

Laboratory results may be received via electronic files directly from central study laboratories or recorded manually on case report forms if the study is using a local lab. In either scenario, it is recommended that a Laboratory Test Tracking form be used to record when samples were collected (date and time) so that the laboratory tests results can be matched with the samples collected for each participant/subject.

## Specific Instructions

*Diagnosis of diabetes.* The diagnosis of diabetes can either be made by 1) hemoglobin A1c greater than or equal to 6.5 in a NGSP certified laboratory, standardized to the DCCT OR 2) fasting (no caloric intake for at least 8 hours) plasma glucose greater than or equal to 126 mg/dL (7.0 mmol/L) OR 3) two-hour plasma glucose greater than or equal to 200 mg/dL (11.1 mMol/L) after an oral glucose tolerance test (OGTT) ingestion of a glucose load containing 75 g anhydrous glucose dissolved in water OR 4) in a patient with classic symptoms of hyperglycemia or hyperglycemic crisis, a random plasma glucose of greater than or equal to 200 mg/dL (11.1 mmol/L). Additional details can be found in the reference cited below.

## CITATIONS

1. Standards of medical care in diabetes--2014. Diabetes care. 2014;37 Suppl 1:S14-80. Epub 2013/12/21. doi: 10.2337/dc14-S014. PubMed PMID: 24357209.
2. Vehik K, Beam CA, Mahon JL, Schatz DA, Haller MJ, Sosenko JM, et al. Development of autoantibodies in the TrialNet Natural History Study. Diabetes care. 2011;34(9):1897-901. Epub 2011/07/14. doi: 10.2337/dc11-0560. PubMed PMID: 21750277; PubMed Central PMCID: PMC3161292.
3. Ziegler AG, Rewers M, Simell O, Simell T, Lempainen J, Steck A, et al. Seroconversion to multiple islet autoantibodies and risk of progression to diabetes in children. JAMA : the journal of the American Medical Association. 2013;309(23):2473-9. Epub 2013/06/20. doi: 10.1001/jama.2013.6285. PubMed PMID: 23780460.