***Note: for all lab testing we recommend utilizing the same assay for all participants and list the reference ranges and assay used in the study methods. If a study is at multiple sites, we recommend a central lab is used for consistency.***

Table 1 Diabetes diagnostic evaluation, including oral glucose tolerance test (OGTT).

| CDE | General Comments | Purpose | Classification |
| --- | --- | --- | --- |
| Glycosylated Hemoglobin (Hemoglobin A1c) value | %, 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 value | Test for available diabetes-related autoimmunity (may include GAD 65, IA2, insulin, ZnT8).**2,3** | Diagnosis | Supplemental – Highly Recommended for individuals with diagnosed DM |
| Fasting glucose value | Measured in mg/dL (U.S.) or mmol/L (outside U.S.) | Diagnosis | Supplemental – Highly Recommended |
| 2-hour glucose (OGTT) value | Measured in mg/dL (U.S.) or mmol/L (outside U.S.) | Diagnosis | Supplemental |
| Fasting insulin value | Measured in mIU/L (U.S.) or pmol/L (outside U.S.) | Diagnosis, Monitoring | Supplemental |
| Fasting C-peptide value | Measured in ng/mL (U.S.) or nmol/L (outside U.S.) | Monitoring | Supplemental |
| Random glucose value (consider if unable to obtain fasting labs) | Measured in mg/dL (U.S.) or mmol/L (outside U.S.) | Diagnosis | Supplemental |

Table 2 Diabetes-related comorbidities.

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

Recorder Signature:

General Instructions

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

Important note: None of the data elements included on this CRF Module are classified as Core (i.e., strongly recommended for all mitochondrial disease studies to collect). Data elements are classified as Supplemental – Highly Recommended (i.e., essential information for specified conditions, study types, or designs), Supplemental or Exploratory, as indicated in the table.

Please see the Data Dictionary for element classifications.

Specific Instructions

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

Date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in an unambiguous format acceptable to the study database like DD-MMM-YYYY. When date/time data are prepared for aggregation or sharing, they should be converted to the format specified by [ISO 8601](https://www.iso.org/iso-8601-date-and-time-format.html);  YYYY-MM-DD T:hh:mm:ss.

*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 participant 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.

## References

1. American Diabetes Association. Standards of medical care in diabetes--2014. Diabetes Care. 2014 Jan;37 Suppl 1:S14-80.
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.
3. Ziegler AG, Rewers M, Simell O, Simell T, Lempainen J, Steck A, Winkler C, Ilonen J, Veijola R, Knip M, Bonifacio E, Eisenbarth GS. Seroconversion to multiple islet autoantibodies and risk of progression to diabetes in children. JAMA. 2013 Jun 19;309(23):2473-9.