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| **Fasting Plasma Glucose for Diabetes Screening - glucometer** | |
| **Protocol Id** | 140802 |
| **Version #** | 1 |
| **Description of Protocol** | This protocol provides basic information for measuring blood glucose concentrations using a glucose meter or glucometer. Participants are asked to fast for at least 9 hours (generally overnight) prior to the test. |
| **Specific Instructions** | If the 9-hour fast is not met, the Diabetes Working Group recommends that the test can still be completed as a "casual" glucose concentration (see protocol for casual glucose reference ranges for screening plus/minus Diabetes). |
| **Protocol Text** | **Exclusion Criteria:**  Persons will be **excluded**from this component if they:  • Report that they are taking oral medications for diabetes;  • Report that they are taking insulin;  • Report that they are pregnant;  • Report that they have hemophilia;  • Report that they have received cancer chemotherapy in the last 3 weeks; and  • Report that they have not fasted at least 9 hours.  *SP= Sample Person.*  1. Did you eat or drink anything other than plain water after [Insert time at 9 hours prior to sample collection] last night?           [ ] Yes           [ ] No           [ ] Refused           [ ] Don’t Know  If answer is "No" then he or she **has met**the 9-hour fast.  If answer is "Yes", "Don’t know", or "Refused", then the actual fasting time is unknown.  Confirmation Question:  2. Have you had any of the following since {insert time from 1 here}?  Coffee or tea with cream and sugar? [Include milk or non-dairy creamers.]           [ ] Yes If Yes, record time and date\_\_\_\_\_\_\_\_\_\_\_\_\_           [ ] No  Alcohol, such as beer, wine, or liquor?           [ ] Yes If Yes, record time and date\_\_\_\_\_\_\_\_\_\_\_\_\_           [ ] No  Gum, breath mints, lozenges, or cough drops, or other cough or cold remedies?           [ ] Yes If Yes, record time and date\_\_\_\_\_\_\_\_\_\_\_\_\_           [ ] No  Antacids, laxatives, or anti-diarrheals?           [ ] Yes If Yes, record time and date\_\_\_\_\_\_\_\_\_\_\_\_\_           [ ] No  Dietary Supplements such as vitamins and minerals? [Include multivitamins and single nutrient supplements.]           [ ] Yes If Yes, record time and date\_\_\_\_\_\_\_\_\_\_\_\_\_           [ ] No  *Note from the Diabetes Working Group: Rather than asking if the subject had anything to eat or drink after 11:30, the Working Group notes that is acceptable to record the current time and time when the subject last had anything other than plain water.*  3. Are you currently pregnant?  **1**  [ ]  Yes  **2**  [ ]  No  **3**  [ ]  Don’t Know  If answer is "Yes", then the SP is blocked from the Fasting Plasma Glucose test.  If answer is "No" or "Don’t Know," the SP completes Fasting Plasma Glucose test.  4. {Is SP/Are you} now taking insulin?  **1**  [ ]  Yes  **2**  [ ]  No  **7**  [ ]  Refused  **9**  [ ]  Don’t Know  If the SP answers, "Yes," the SP is excluded from the Fasting Plasma Glucose test. If answer is "No" or "Don’t Know," the SP completes Fasting Plasma Glucose test.  5. {Is SP/Are you} now taking diabetic pills to lower {his/her}/your} blood sugar? These are sometimes called oral agents or oral hypoglycemic agents  **1**  [ ]  Yes  **2**  [ ]  No  **7**  [ ]  Refused  **9**  [ ]  Don’t Know  If the SP answers, "Yes," the SP is excluded from the Fasting Plasma Glucose test. If SP answer "No" or "Don’t Know," the SP completes Fasting Plasma Glucose test.  6. Do you have hemophilia? (exclusion from Phlebotomy)  **1**  [ ]  Yes  **2**  [ ]  No  **7**  [ ]  Refused  **9**  [ ]  Don’t Know  If the SP answers, "Yes," the SP is excluded from the Fasting Plasma Glucose test. If SP answer "No" or "Don’t Know," the SP completes Fasting Plasma Glucose test.  7. Have you received cancer chemotherapy in the past four weeks or do you anticipate such therapy in the next four weeks? (exclusion from Phlebotomy)  **1**  [ ]  Yes  **2**  [ ]  No  **7**  [ ]  Refused  **9**  [ ]  Don’t Know  If the SP answers, "Yes," the SP is excluded from the Fasting Plasma Glucose test. If SP answer "No" or "Don’t Know," the SP completes Fasting Plasma Glucose test.  *Note from the Diabetes Working Group: The investigator should record the reason(s) a sample person is excluded from the Fasting Plasma Glucose test.*  **Using the Glucometer**  There are many types of glucose meters available that are appropriate for this protocol. Follow manufacturers recommendations for a finger stick (or other site), calibration and measurement.  *Note from the Diabetes Working Group:* *To aid comparability, the Diabetes Working Group recommends that the investigator record the make and manufacturer of glucometer used and the repeatability and coefficients of variation for the assay.*  **Reference Ranges:**  Fasting plasma glucose concentration between 60-100 mg/dL  Non-fasting glucose concentration between 60-139 mg/dL |
| **Selection Rationale** | While not as accurate as the hexokinase-mediated reaction, glucose meters can be used to obtain approximate glucose concentrations. This might be performed if venipuncture is not done and is preferable to not taking the measure at all. |
| **Source** | Centers for Disease Control and Prevention (CDC). National Center for Health Statistics (NCHS). National Health and Nutrition Examination Survey Questionnaire. Oral Glucose Tolerance Test (OGTT) Procedures Manual. Hyattsville, MD: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2005-2006 |
| **Language** | Not Applicable |
| **Participant** | All ages. |
| **Personnel and Training Required** | None |
| **Equipment Needs** | Glucose meter (glucometer) |
| **Standards** | |  |  |  |  | | --- | --- | --- | --- | | **Standard** | **Name** | **ID** | **Source** | | Common Data Elements (CDE) | Person Fasting Plasma Glucose Assay Concentration Value | 3070691 | [CDE Browser](https://cdebrowser.nci.nih.gov/CDEBrowser/search?elementDetails=9&FirstTimer=0&PageId=ElementDetailsGroup&publicId=3070691&version=1.0) | | Logical Observation Identifiers Names and Codes (LOINC) | Fast plasma gluc glucometer proto | 62852-9 | [LOINC](http://s.details.loinc.org/LOINC/62852-9.html?sections=Web) | |
| **General References** | American Diabetes Association. (2009). Diagnosis and classification of diabetes mellitus. *Diabetes Care*, 32(Supplement 1), S62 - S67.  American Diabetes Association. (2008). Standards of medical care in diabetes - 2008. *Diabetes Care*, 31(Supplement 1), S12 - S54.  American Diabetes Association. (2010). Diagnosis and classification of diabetes mellitus. *Diabetes Care*, 33 (Supplement 1), S11 - S61. |
| **Protocol Type** | Bioassay |
| **Derived Variables** | The threshold fasting plasma glucose concentrations for the scoring (+/-) of prediabetes and diabetes are updated yearly by the American Diabetes Association and can be found in the journal Diabetes Care.  Prediabetes Fasting plasma glucose concentration between 100-125 mg/dl (5.6 - 6.9 mmol/l)  Diabetes Fasting plasma glucose concentration greater than or equal to 126 mg/dl (7.0 mmol/l) Casual glucose concentration greater than or equal to 200 mg/dl (11.1 mmol/l)   American Diabetes Association. (2010). Diagnosis and classification of diabetes mellitus. Diabetes Care, 33 (Supplement 1), S11 - S61. |
| **Requirements** | |  |  | | --- | --- | | **Requirement Category** | **Required** | | Average time of greater than 15 minutes in an unaffected individual  Average time of greater than 15 minutes in an unaffected individual | **Yes** | | Major equipment  This measure requires a specialized measurement device that may not be readily available in every setting where genome wide association studies are being conducted. Examples of specialized equipment are DEXA, Echocardiography, and Spirometry | No | | Specialized requirements for biospecimen collection  This protocol requires that blood, urine, etc. be collected from the study participants. | No | | Specialized training  This measure requires staff training in the protocol methodology and/or in the conduct of the data analysis. | No | |