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| **Fasting Plasma Glucose for Diabetes Screening - blood draw** | |
| **Protocol Id** | 140801 |
| **Version #** | 1 |
| **Description of Protocol** | Participants are asked to fast for at least 9 hours (generally overnight) prior to the Fasting Plasma Glucose test. Participants are asked a series of exclusionary questions and then have blood drawn. The plasma is separated from the blood via centrifugation and glucose concentration is determined via a hexokinase-mediated reaction. |
| **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 the protocol for casual glucose reference ranges for screening plus/minus Diabetes).  The Diabetes Working Group refers users to the Fasting Plasma Proinsulin assay in Diabetes Supplemental Information to obtain more information about insulin resistance. |
| **Protocol Text** | The following is a summary version of the full National Health and Nutrition Examination Survey 2007-2008 protocol.  The full National Health and Nutrition Examination Survey 2007-2008 Fasting Plasma Glucose Test Procedures are part of the Oral Glucose Tolerance Test Procedure and can be found here: [2007-2008 NHANES Oral Glucose Tolerane Test Manual](file:///C:\Users\hpan\Downloads\toolkit_content\supplemental_info\diabetes\additional_info\NHANES_OGTT.pdf)  **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.*  **Venipuncture**  *Note from the Diabetes Working Group:**Blood should be collected in an appropriate 10-mL EDTA tube. Invert the tube 3 to 4 times to mix, store on ice and centrifuge within 30 minutes. Processing should yield ~ 4.5 mL of plasma which can then be separated into several 0.5 mL aliquots for multiple different tests.*  Venipuncture should generally be performed using the median cubital, cephalic, or basilic veins in the left arm unless this arm is unsuitable. If the veins in the left arm are unsuitable, look for suitable veins on the right arm. If the veins in the antecubital space on both arms are not suitable, then look for veins in the forearm or dorsal side of the hand on the left arm/hand and then the right arm/hand.  *Editor’s Note: Please review chapter 4 of the Laboratory Procedures Manual from the National Health and Nutrition Examination Survey 2007-2008 for a full description of Phlebotomy procedures:*[2007-2008 NHANES Lab Manual](file:///C:\Users\hpan\Downloads\toolkit_content\supplemental_info\diabetes\additional_info\NHANES_Lab_Manual.pdf)*.*  **Recording the Results of the Venipuncture Procedure**  Immediately after completing the venipuncture, record the results of the blood draw, the reasons for a tube not being drawn according to the protocol, and any comments about the venipuncture.  *Note from the Diabetes Working Group: The Diabetes Working Group recommends that the investigator record whether the blood was drawn and whether the full amount was obtained.*  **Process the Sample for the Fasting Plasma Glucose Test**  *Editor’s Note: Please review chapter 8 of the Laboratory Procedures Manual from the National Health and Nutrition Examination Survey 2007-2008 for a full description of Blood Processing procedures:*[2007-2008 NHANES Lab Manual](file:///C:\Users\hpan\Downloads\toolkit_content\supplemental_info\diabetes\additional_info\NHANES_Lab_Manual.pdf).  Centrifuge and separate the plasma from the 10-mL tube as soon as possible. Process the specimen even if the contents of the gray tube clot.  • Separate the plasma by centrifugation.  • Use a calibrated plastic transfer pipette to transfer at least 0.5 mL plasma.  • Determine if the plasma is hemolyzed, turbid, lipemic, or icteric. If so, enter a comment to describe the plasma.  • Close all vessels secured to prevent leakage and evaporation.  *Note from the Diabetes Working Group: Plasma should be stored at -80°C until testing and shipped on dry ice to prevent thawing.*  **Lab Assay for Fasting Plasma Glucose**  The Diabetes Working Group recommends that glucose concentration be determined according to a hexokinase-mediated reaction such as the one developed by the University of Minnesota for use in the National Health and Nutrition Examination Survey: [2007-2008 NHANES Fasting Glucose Lab Assay](file:///C:\Users\hpan\Downloads\toolkit_content\supplemental_info\diabetes\additional_info\Fasting_Glucose_Lab_Assay.pdf)*.*  Note from the Diabetes Working Group: To aid comparability, the Diabetes Working Group recommends that the investigator record the make and manufacturer of equipment used and the repeatability and coefficients of variation for the assay.  **Reference Ranges:**  Fasting plasma glucose concentration normally ranges between 60-100 mg/dL  Non-fasting glucose concentration normally ranges between 60-139 mg/dL |
| **Selection Rationale** | The National Health and Nutrition Examination Survey 2007-2008 protocol was selected as the best practice methodology and most widely used protocol to measure Fasting Plasma Glucose concentration. |
| **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  Centers for Disease Control and Prevention (CDC). National Center for Health Statistics (NCHS). National Health and Nutrition Examination Survey Questionnaire. Laboratory Procedures Manual. Hyattsville, MD: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2007-2008  Centers for Disease Control and Prevention (CDC). National Center for Health Statistics (NCHS). National Health and Nutrition Examination Survey Questionnaire.Shared Exclusion Questions for the MEC Examination. Hyattsville, MD: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2002. (questions 6 and 7) |
| **Language** | English, Spanish |
| **Participant** | Participant aged 12 years and older |
| **Personnel and Training Required** | Phlebotomist Medical Technologist Laboratory which can perform hexokinase-mediated reaction |
| **Equipment Needs** | Phlebotomy supplies |
| **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 blood draw proto | 62851-1 | [LOINC](http://s.details.loinc.org/LOINC/62851-1.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. |
| **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 | |