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| **Oral Glucose Tolerance Test** | |
| **Protocol Id** | 141001 |
| **Version #** | 1 |
| **Description of Protocol** | Participants are asked to fast for at least 9 hours (generally overnight) prior to the Oral Glucose Tolerance test. Participants are asked a series of exclusionary questions and then have an initial blood draw to determine Fasting Plasma Glucose levels. Participants are next asked to drink a calibrated dose (generally 75 grams / 10 ounces) of a dextrose solution (e.g., Trutol®) and have a second venipuncture 2 hours (plus or minus 15 minutes) after the first venipuncture. The plasma is separated from the blood via centrifugation and glucose concentration is determined via the hexokinase method. |
| **Specific Instructions** | The Oral Glucose Tolerance Test includes a Fasting Plasma Glucose assay as the first step. Therefore performing the Oral Glucose Tolerance Test and the Fasting Plasma Glucose Assay for Diabetes Screening together will result collecting in the Fasting Plasma Glucose Assay twice.  The Diabetes Working Group notes that an alternative to the single two-hour post load value is to establish a catheter and obtain samples for Serum Glucose concentrations at 0, 30, 60, 90 and 120 minutes. There are also protocols for more rapid sampling of Serum Glucose concentrations.  In addition, the Diabetes Working Group notes that there are also protocols to collect samples for Serum Insulin concentrations at 0, 30, 60, 90 and 120 minutes and that this could be done at the same time as the Oral Glucose Tolerance Test. Such protocols would give extra specificity and information but would increase the burden on both the participant and investigator. |
| **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 Oral Glucose Tolerance Test Procedures can be found here: [2007-2008 NHANES Oral Glucose Tolerance 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. The SP is **excluded** from the Oral Glucose Tolerance test if the 9-hour fast is not met and will not be met with 1 hour and 40 minutes left in the session.  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  3. Are you currently pregnant?  **1**  [ ]  Yes  **2**  [ ]  No  **3**  [ ]  Don’t Know  If answer is "Yes", then the SP is blocked from the Oral Glucose Tolerance Test.  If answer is "No" or "Don’t Know," the SP drinks the Trutol® and receives the venipuncture for the Oral Glucose Tolerance 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 Oral Glucose Tolerance Test.  If answer is "No" or "Don’t Know," the SP drinks the Trutol® and receives the venipuncture for the Oral Glucose Tolerance 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 Oral Glucose Tolerance Test.  If SP answer "No" or "Don’t Know," the SP drinks the Trutol® and receives the venipuncture for the Oral Glucose Tolerance Test.  6. Do you have hemophilia?  **1**  [ ]  Yes  **2**  [ ]  No  **7**  [ ]  Refused  **9**  [ ]  Don’t Know  If the SP answers, "Yes," the SP is excluded from the Oral Glucose Tolerance Test.  If SP answer "No" or "Don’t Know," the SP drinks the Trutol® and receives the venipuncture for the Oral Glucose Tolerance Test.  7. Have you received cancer chemotherapy in the past four weeks or do you anticipate such therapy in the next four weeks?  **1**  [ ]  Yes  **2**  [ ]  No  **7**  [ ]  Refused  **9**  [ ]  Don’t Know  If the SP answers, "Yes," the SP is excluded from the Oral Glucose Tolerance Test.  If SP answer "No" or "Don’t Know," the SP drinks the Trutol® and receives the venipuncture for the Oral Glucose Tolerance Test.  *Note from the Diabetes Working Group: The investigator should record the reason a person is excluded from the Oral Glucose Tolerance Test.*  **First Venipuncture**  A fasting glucose blood test is performed on all participants 12 years and older who are examined in the morning session after a 9-hour fast.  *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 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.*  **Administering the Trutol® (Dextrose Solution)**  SPs who weigh more than 100 pounds will drink 10 ounces of Trutol®. SPs who weigh less than 94 pounds must have a calibrated dose of Trutol®.   |  |  |  |  | | --- | --- | --- | --- | | **Body Weight** | | **75 g Concentration** | | | **lb.** | **kg** | **oz.** | **mL** | | 94+ | 42.7+ | 10.0 | 295 | | 90-93 | 40.9 | 9.5 | 283 | | 85-89 | 38.6 | 9.0 | 267 | | 80-84 | 36.4 | 8.5 | 251 | | 75-79 | 34.1 | 8.0 | 235 | | 70-74 | 31.8 | 7.4 | 220 | | 65-69 | 29.5 | 6.9 | 204 | | 60-64 | 27.3 | 6.4 | 188 |   Note: The investigator should record the calibrated amount of Trutol® given to the sample person.  Ask the SP to indicate a preference for one of the three flavors. Choose the flavor that matches the preference of the soft drink flavor that he or she prefers. Follow the instructions; remove the correct amount of Trutol® from the bottle before handing the bottle to the SP. Use a small medicine cup to measure the correct amount to remove and discard the excess Trutol®. Hand the SP a cold bottle of Trutol® (containing the calibrated dose) and a straw. SPs MUST consume the entire calibrated dose of the Trutol within 10 minutes.  Recite the script "Please drink this solution within 10 minutes" and start the timer. The timer counts down from 10:00 minutes.  When the SP has finished drinking the entire calibrated dose of Trutol®, or cannot continue drinking the Trutol, then stop the timer.  The choices for the amount of solution that the SP consumed are "All," "Some," or "None."  Record the amount of solution the SP drank. If the SP drank "some" or "none" of the Trutol® solution, then the section status is Not Done.  If the total time is 00:10:00, then "Solution not consumed in 10 minutes."  **Second Venipuncture**  If an SP consumed the entire calibrated dose of the Trutol® solution in 10 minutes, then he or she is eligible to have a 2-ml gray top tube drawn 2 hours, -20 or +15 minutes, after he or she finished consuming the Trutol®. (He or she must maintain the fast until the second blood draw is completed.)  *Editor’s Note:**Please review chapter 4 of the Laboratory Procedures Manual from the National Health and Nutrition Examination Survey 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)*.*  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 Samples for the 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 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.*  **Laboratory Assay for 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 Oral Glucose Tolerance Test Lab Assay](file:///C:\Users\hpan\Downloads\toolkit_content\supplemental_info\diabetes\additional_info\Fasting_Glucose_Lab_Assay.pdf)*.*  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:**  Non-fasting glucose concentration normally ranges between 60-139 mg/dL  Fasting plasma glucose concentration normally ranges between 60-100 mg/dL  Trutol® a registered trademark, Thermo Fisher Scientific Inc. |
| **Selection Rationale** | The National Health and Nutrition Examination Survey 2007-2008 protocol was selected as the best practice methodology and one of the most widely used protocols to measure Glucose Tolerance. |
| **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 5 and 6) |
| **Language** | English, Spanish |
| **Participant** | Participant aged 12 years and older |
| **Personnel and Training Required** | Phlebotomist Medical Technologist to administer dextrose solution Lab which can perform hexokinase-mediated reaction |
| **Equipment Needs** | Phlebotomy supplies Supplies to administer the dextrose solution |
| **Standards** | |  |  |  |  | | --- | --- | --- | --- | | **Standard** | **Name** | **ID** | **Source** | | Common Data Elements (CDE) | Person Glucose Tolerance Test Laboratory Result Value in mg/Dl | 3070859 | [CDE Browser](https://cdebrowser.nci.nih.gov/CDEBrowser/search?elementDetails=9&FirstTimer=0&PageId=ElementDetailsGroup&publicId=3070859&version=1.0) | | Logical Observation Identifiers Names and Codes (LOINC) | Oral glucose tolerance test proto | 62856-0 | [LOINC](http://s.details.loinc.org/LOINC/62856-0.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 plasma glucose concentrations 2 hours after a 75 gram glucose challenge for the scoring (+/-) of prediabetes and diabetes are updated yearly by the American Diabetes Association and can be found in the journal Diabetes Care.  Pre-diabetes 2 hour post challenge plasma glucose concentration between 140-199 mg/dl (7.8-11.0 mmol/l) Fasting plasma glucose concentration between 100-125 mg/dl (5.6 - 6.9 mmol/l)  Diabetes 2 hour post challenge plasma glucose concentration greater than or equal to 200 mg/dl (11.1 mmol/l) Fasting plasma glucose concentration greater than or equal to 126 mg/dl (7.0 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 | |