

**NHANES 2001–2002 Data Release  
February 2005  
Documentation for Laboratory Results**

**Laboratory 40 – Thyroid-Stimulating Hormone and Thyroxine (TSH & T4)**

**(1) Documentation File Date – February 25, 2005**

**(2) Documentation File Name – Laboratory 40 - Thyroid-Stimulating Hormone (TSH) and Thyroxine (T4)**

**(3) Survey Years Included in this File Release – 2001–2002**

**(4) Component Description**

Serum TSH and T4 levels will be used to assess thyroid function and will provide population-based reference information on these hormone levels. Thyroid function will be examined in relation to measures of exposure to endocrine-disrupting substances, which are hypothesized to affect the thyroid.

**(5) Sample Description:**

**5.1 Eligible Sample**

Participants aged 12 years and older on a 1/3 sample were tested.

**(6) Description of the Laboratory Methodology**

Coulston Foundation:

- 1) IMx Ultrasensitive hTSH II is a Microparticle Enzyme Immunoassay (MEIA) for the quantitative determination of human TSH in serum or plasma on the IMx analyzer.
- 2) T4 specimens were measured on the Hitachi 704 chemistry analyzer.

Collaborative Laboratory Services:

- 1) The Access hTSH Assay is a two-site (sandwich), paramagnetic particle, and chemiluminescent immunoassay for the quantitative determination of human thyroid-stimulating hormone in human serum, using the Access Immunoassay System. A sample is added to a reaction vessel with goat anti-hTSH-alkaline phosphatase conjugate, buffered protein solution, and paramagnetic particles coated with immobilized mouse monoclonal anti-hTSH antibody. (Goat anti-mouse antibody is used to immobilize the mouse anti-hTSH antibody.) The serum hTSH binds to the immobilized monoclonal anti-hTSH on the solid phase while the goat anti-hTSH-alkaline phosphatase conjugate reacts with a different antigenic site on the serum hTSH. Separation in a magnetic field and washing removes materials not bound to the solid phase. A chemiluminescent

substrate, Lumi-Phos 530, is added to the reaction vessel, and light generated by the reaction is measured with a luminometer. The photon production is proportional to the amount of enzyme conjugate bound to the solid support. The amount of analyte in the sample is determined by means of a stored, multi-point calibration curve.

- 2) The Access Total T4 assay is a paramagnetic particle, chemiluminescent, competitive binding enzyme immunoassay for the quantitative determination of total thyroxine (T4) in human serum, using the Access Immunoassay System. A sample was added to a reaction vessel with anti-thyroxine antibody, thyroxine-alkaline phosphatase conjugate, and paramagnetic particles coated with goat anti-mouse capture antibody and a stripping agent to dissociate all T4 from serum-binding proteins. Thyroxine in the sample competed with the thyroxine-alkaline phosphatase conjugate for binding sites on a limited amount of specific anti-thyroxine antibody. Resulting antigen:antibody complexes bound to the capture antibody on the solid phase. Separation in a magnetic field and washing removed materials not bound to the solid phase. A chemiluminescent substrate, Lumi-Phos 530, was added to the reaction vessel, and light generated by the reaction was measured with a luminometer. The photon production was inversely proportional to the concentration of T4 in the sample. The amount of analyte in the sample was determined by means of a stored calibration curve.

## **(7) Laboratory Quality Control and Monitoring**

The NHANES quality control and quality assurance protocols (QA/QC) meet the 1988 Clinical Laboratory Improvement Act mandates. Detailed quality control and quality assurance instructions are discussed in the NHANES Laboratory/Medical Technologists Procedures Manual (LPM). Read the LABDOC file for detailed QA/QC protocols.

## **(8) Data Processing and Editing**

Specimens were processed, stored and shipped to Coulston Foundation, Alamogordo, New Mexico in 2001 and Collaborative Laboratory Services, Ottumwa, Iowa in 2002. Detailed specimen collection and processing instructions are discussed in the NHANES Laboratory/Medical Technologists Procedures Manual (LPM). Read the LABDOC file for detailed data processing and editing protocols. The analytical methods are described in the Description of the Laboratory Methodology section.

## **(9) Data Access:**

All data are publicly available.

## **(10) Analytic Notes for Data Users:**

10.1 Measures of TSH and T4 were assessed in participants aged 12 years and older on a one-third sample. Use the special weights included in this data file when analyzing data.

**Read section 10.3 below before beginning analysis.**

10.2 The analysis of NHANES 2001–2002 laboratory data must be conducted with the key survey design and basic demographic variables. The NHANES 2001–2002 Household

Questionnaire Data Files contain demographic data, health indicators, and other related information collected during household interviews. They also contain all survey design variables and sample weights for these age groups. The phlebotomy file includes auxiliary information such as the conditions precluding venipuncture. The household questionnaire and phlebotomy files may be linked to the laboratory data file using the unique survey participant identifier SEQN.

All data are publicly available.

**(11) Subsample Weight Notes:**

Special sample weights are required to analyze these data properly.

**(12) References**

1. N/A