NHANES 2001-2002 Data Release
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Documentation for Laboratory Results

Laboratory 5 – Urinary Chlamydia and Urinary Gonorrhea

(1) Documentation File Date – August 28, 2003

(2) Documentation File Name - Laboratory 5 – Urinary Chlamydia and Urinary Gonorrhea

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

(4) Component Description

Urinary chlamydia and Urinary gonorrhea

Sexually transmitted infections caused by *Chlamydia trachomatis* and *Neisseria gonorrhoeae* may lead to pelvic inflammatory disease, ectopic pregnancy, infertility, and chronic pelvic pain in women. They are associated with increased risk of HIV transmission. Pregnant women may transmit infection to their newborn causing serious medical complications. At present there are no reliable estimates on the prevalence of chlamydial and gonococcal infection in the general population of the United States.

NHANES offers an opportunity to assess the prevalence of chlamydia and gonococcal infection in the general population and to monitor trends in prevalence as prevention programs are established and expanded.

(5) Sample Description:

5.1 Eligible Sample

Participants aged 14 to 39 years were tested. Public data file includes data for persons 18-39 years of age. Please see Analytic Notes for Data Users about the release of data for adolescents 14-17 years of age.

(6) Description of the Laboratory Methodology

6.1 Urinary chlamydia

The *Chlamydia trachomatis* assay uses LCR TM (ligase chain reaction) amplification technology in the LCx Probe System for the direct, qualitative detection of plasmid DNA of Chlamydia trachomatis.

The LCx *Chlamydia trachomatis* assay uses the nucleic acid amplication method LCR to detect the presence of *C. trachomatis* plasmid DNA directly in clinical specimens.

The four oligonucleotide probes in the LCx assay recognize and hybridize to a specific target sequence within the C. trachomatis plasmid DNA. The oligonuleotides are designed to be complementary to the target sequence so that in the presence of target, the probes will bind adjacent to one another. They can then be enzymatically joined to form the amplification product, which subsequently serves as an additional target sequence during further rounds of amplication. The product of the LCR reaction is detected on the Abbott LCx analyzer.

6.2 Urinary gonorrhea

The *Neisseria gonorrhoeae* assay uses LCR TM (ligase chain reaction) amplification technology in the LCx Probe System for the direct, qualitative detection of a specific target nucleic acid sequence in the Opa gene of *Neisseria gonorrhoeae*.

The LCx *Neisseria gonorrhoeae* assay uses the nucleic acid amplication method LCR to detect the presence of *Neisseria gonorrhoeae*. The four oligonucleotide probes in the LCx assay recognize and hybridize to a specific target sequence within the Opa gene of *Neisseria gonorrhoeae* DNA. The oligonuleotides are designed to be complementary to the target sequence so that in the presence of target, the probes will bind adjacent to one another. They can then be enzymatically joined to form the amplification product which subsequently serves as an additional target sequence during further rounds of amplication. The product of the LCR reaction is detected on the Abbott LCx analyzer.

(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

Blood specimens were processed, stored and shipped to the Division of AIDS, STD, and TB Laboratory Research, National Center for Infectious Diseases, National Centers for Disease Control and Prevention for analysis. 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:

Public data file includes data for persons 20-39 years of age. Urinary chlamydia and gonorrhea data for youth 14-17 years of age will be in the Research Data Center (RDC) or through special agreement.

(10) Analytic Notes for Data Users:

Collaborators may obtain the 2001-2002 NHANES Adolescent STD Special Use Datafile through a special agreement. The data set is a SAS file containing 3 variables for examined participants aged 14-17 years. Other interested researchers may use this file in the NCHS Research Data Center (RDC). The variable descriptors and variable names are as follows:

Sequence number-Seqn
Chlamydia result-URXUCL
Gonorrhea result-URXUGC