National Health and Nutrition Examination Survey 2003-2004

Documentation, Codebook, and Frequencies

MEC Laboratory Component: Trichomonas Vaginalis and Bacterial Vaginosis

Survey Years:
2003 to 2004

SAS Export File:
L34_C.XPT

January 2006

NHANES 2003–2004 Data Documentation

Laboratory Assessment: Lab 34 - Bacterial vaginosis and *Trichomonas vaginalis*

Years of Coverage: 2003–2004 **First Published:** January 2006 **Last Revised:** N/A

Component Description

Bacterial vaginosis (BV) and trichomoniasis are two of the most common vaginal conditions affecting women of childbearing age. In the United States, BV varies depending on the population studied, from 17% in some prenatal and family planning settings to 37% in STD clinics. The same is true for trichomoniasis, with between 3 and 48% of sexually active women diagnosed in various clinical settings. Recent studies have linked BV to adverse pregnancy and gynecologic outcomes, such as preterm labor and delivery, low birth weight, premature rupture of membranes, post-Cesarean endometritis, and post-abortal and post-hysterectomy infections. Also, trichomoniasis has been associated with preterm labor, preterm delivery, and low birth weight. More recently, both BV and trichomoniasis have been linked to an increased risk of HIV acquisition and transmission. However, no national surveillance system exists to measure the full burden of these two diseases, and no reliable national population estimate of BV or trichomoniasis exists. NHANES offers a unique opportunity to assess the prevalence of BV and *Trichomonas vaginalis* infections in the general population, to identify and confirm risk factors, and to monitor trends in prevalence as detection and treatment programs are established and expanded.

Eligible Sample

Female participants aged 14–49 years were tested.

Description of Laboratory Methodology

Bacterial vaginosis

After the slide was gram-stained, the slide was scanned under a microscope using low power objective to locate clusters of epithelial cells. The flora in these areas was noted. The oil immersion lens (×1000) was switched, and between 10 and 20 representative fields were examined to observe cell morphology and gram reaction. The BV score was calculated by Nugent's method. Briefly, the average number of lactobacillary morphotypes per oil immersion field was quantitated. These organisms were usually filamentous, gram-positive rods of varying length that often form chains, but occasionally, they stained

gram-negative. Also, the average number of *Gardnerella* spp. and anaerobic gram-negative rods were quantitated. These may appear as small, gram-variable pleomorphic coccobacilli. Finally, the amount of Mobiluncus morphotypes present was quantitated. They are often thin, wispy, eyelash-like, faintly staining, curved gram-negative rods. Alternatively, they may be much smaller “banana-like” forms with pointed ends. Occasionally, they may stain gram-positive. These bacteria were often absent from gram stain smears of patients with other bacterial morphotypes. The relative amounts of each of the three classes of observed morphotypes were reported. Each morphotype was quantitated from 0 to 4+ with regard to the numbers of organisms present per oil immersion field as described in Table 1.

Table 1. Calculating Individual Scores Based upon Morphotype

	NONE	**<1**	**1-4**	**5-30**	**>30**
Lactobacilli spp	4	3	2	1	0
Gardnerella & anaerobic GNR	0	1	2	3	4
Mobiluncus spp.	0	1	1	2	2

Trichomonas vaginalis

During PCR testing, Taq polymerase and DNA primers complimentary to a unique sequence of target DNA were used to greatly amplify that region if the target was present in the sample. This greatly enhanced the sensitivity of assays used to detect that specific sequence of DNA. After a series of successive cycles of amplification, the presence of double-stranded DNA product was visualized on agarose gels stained with ethidium bromide. Specificity of the product was confirmed with hybridization to a labeled probe. Samples were tested for the presence of amplifiable DNA and absence of inhibitors by performing beta-globin PCR. Beta-globin is common to all mammalian cells, and it is reasonable to expect that some human cells will be present in the sample. If the presence of beta-globin couldn’t be demonstrated, the validity of the sample wasn’t determined.

Trichomonas vaginalis, a sexually transmitted human parasite, was detected by performing PCR with primers from a region of the 18S rRNA gene that produces a 312 base pair product. The specificity of the product was confirmed by hybridization to a digoxigenin-labeled probe according to the method described in Boehringer Mannheim’s Genius System User’s Guide for Filter Hybridization.

There were no changes to the equipment, lab method, or lab site from the previous 2 years.

A detailed description of the laboratory method used can be found on the NHANES website.

Laboratory Quality Control and Monitoring

The NHANES quality assurance and quality control (QA/QC) protocols meet the 1988 Clinical Laboratory Improvement Act mandates.

Detailed QA/QC instructions are discussed in the NHANES Laboratory/Medical Technologists Procedures Manual (LPM). Read the LABDOC file for detailed QA/QC protocols.

A detailed description of the QA/QC procedures can be found on the NHANES website.

Data Processing and Editing

Vaginal swabs were processed, stored, and shipped to Magee Women's Hospital, Pittsburgh, PA. Detailed specimen collection and processing instructions are discussed in the NHANES 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.

There are no derived variables, top coding, fill values, or minimal detectable limits in this data file.

Detailed instructions on specimen collection and processing can be found on the NHANES website.

Analytic Notes

The analysis of NHANES 2003–2004 laboratory data must be conducted with the key survey design and basic demographic variables. The NHANES 2003–2004 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.

Final BV score and interpretative reporting:

BV score	Interpretation
0–3	Normal vaginal flora
4–6	Intermediate
7–10	Indicative of bacterial vaginosis

The results of the *Trichomonas* PCR test will be finalized as follows:

A sample will be considered positive if it yields a 102 base pair fragment after PCR amplification that is recognized by the *Trichomonas*-specific DNA probe upon Southern blot hybridization.

A sample will be considered negative if it does not yield the 102 base pair fragment after PCR amplification, or when the PCR product's identity cannot be confirmed by Southern blot hybridization.

A sample will be considered uninterpretable if the specimen was found to be both *Trichomonas* and beta-globulin negative by PCR. This can be due to the presence of inhibitors, or the lack of DNA, or both.

References

1. N/A

Locator Fields

Title: Bacterial vaginosis (BV) and *Trichomonas vaginalis*

Contact Number: 1-866-441-NCHS

Years of Content: 2003–2004

First Published: January 2006

Revised: N/A

Access Constraints: None

Use Constraints: None

Geographic Coverage: National

Subject: Bacterial vaginosis (BV) and *Trichomonas vaginalis*

Record Source: NHANES 2003–2004

Survey Methodology: NHANES 2003–2004 is a stratified multistage probability sample of the civilian non-institutionalized population of the U.S.

Medium: NHANES Web site; SAS transport files

National Health and Nutrition Examination Survey
Codebook for Data Production (2003-2004)

Trichomonas Vaginalis and Bacterial Vaginosis (L34_C)
Person Level Data

April 2006

SEQN	Target
	F(14 Yrs. to 49 Yrs.)
Hard Edits	**SAS Label**
	Respondent sequence number
English Text: Respondent sequence number.	
English Instructions:	

LBXBVPH	Target
	F(14 Yrs. to 49 Yrs.)
Hard Edits	**SAS Label**
	PH of Bacterial Vaginosis Specimen
English Text: PH of Bacterial Vaginosis Specimen	
English Instructions:	

Code or Value	Description	Count	Cumulative	Skip to Item
PH of Bacterial Vaginosis Specimen	Value was recorded	1741	1741	
< blank >	Missing	350	2091	

LBXTV	Target
	F(14 Yrs. to 49 Yrs.)
Hard Edits	**SAS Label**
	Trichomonas Vaginalis
English Text: Trichomonas Vaginalis	
English Instructions:	

Code or Value	Description	Count	Cumulative	Skip to Item
1	Positive	78	78	
2	Negative	1632	1710	
3	Uninterpretable	45	1755	
.	Missing	336	2091	

LBXBV	Target
	F(14 Yrs. to 49 Yrs.)
Hard Edits	**SAS Label**
	Bacterial Vaginosis
English Text: Bacterial Vaginosis	
English Instructions:	

Code or Value	Description	Count	Cumulative	Skip to Item
1	Positive	586	586	
2	Negative	709	1295	
3	Indeterminate	445	1740	
4	Lack of lactobacillis/abnormal epithelial cells	0	1740	
5	Lack of lactobacillis/abnormal epithelial cells and abnormal bacteria	0	1740	
.	Missing	351	2091	