

Attachment B.

Protocol for Collection of Oral Human Papillomavirus Specimen (ages 14+)

**National Health and Nutrition Examination Survey (NHANES)
Oral Human Papillomavirus Specimen Collection Pilot Study**

OMB no. 0920-0237

Expires: 11/30/2009

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Oral Human Papillomavirus Specimen Collection Protocol:

Eligibility: Participants aged 14 years or older are eligible for this component.

Informed Consent: Informed consent will be obtained. The purpose of the test will be described to the respondent. As with all of NHANES components, the participant may refuse.

Exclusion Criteria: There are no exclusions for the Oral Human Papillomavirus component.

Study Design:

Specimen Collection

The collection will be accomplished with a 30 second oral rinse and gargle with Scope brand mouthwash. Participants age 14 or more years will alternate a series of three, five second rinse and five second gargles with 10 ml of Scope. The Scope is then expectorated into a sterile collection cup and transported to the MEC laboratory and refrigerated at 4°C.

Laboratory Testing

Testing for 37 types of HPV will be accomplished by means of a multiple polymerase-chain reaction (PCR) assay targeted to the L1 region of the viral genome, using PGMY09/11 L1 primer pools and primers for Beta globulin followed by hybridization to a linear probe array (Roche Molecular Systems).

Report of Findings:

Each participant with a positive test result will receive a letter reporting the results.