3q26 Amplification is rarely present in women whose LSIL cytology does not represent CIN 2+ disease

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Background

Current Percent Distribution of Abnormal Cytology Results in US

Projected Distribution of Cytologic Abnormalities with HPV Vaccination

Study Objectives

The primary aim: to determine the sensitivity, specificity and negative predictive value of the 3q26 gain test for women with LSIL index cytology.

The secondary aim: to determine the negative predictive value of the 3q26 gain test one year after the LSIL cytology

The exploratory aim: to describe the 3q26 gain test characteristics in the follow up cytology six months after treatment for CIN 2/3

Study Design

Retrospective study
All women with LSIL cytology from May 2007-Jan 2009 who came for colposcopy at Truman Medical Center
Archival SurePath LSIL samples
• No other sampling from vial
• Refrigerated at 35-38°F
3q26 gain evaluated in index Pap
Mean of 621 days after collection
(range: 314-923)
Gain definition:
≥2 nuclei with 5 or more copies of 3q26
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Results

Population Description

Conclusions

• The absence of 3q26 gain shows promise as a biomarker for reassurance that CIN 2/3 is not present in women with LSIL cytology, with a high NPV

• The absence of 3q26 gain shows potential as a biomarker for reassurance that CIN 2/3 will not be developing within one year from the woman’s LSIL cytology

• The absence of 3q26 gain should be studied as a biomarker for prediction of screening interval after LEEP treatment for CIN 2/3