Comparison of self-collected vaginal, vulvar and urine samples with physician-collected cervical samples for human papillomavirus testing to detect high-grade squamous intraepithelial lesions

Fig. 1: Flow of 200 women through recruitment and screening. The following values were used as the “gold standard” in calculating sensitivity and specificity: 58 women with high-grade lesions (high-grade squamous intraepithelial lesion [HSIL; cervical intraepithelial neoplasia or CIN grade 2 or 3] or adenocarcinoma), 142 women without high-grade lesions (low-grade squamous intraepithelial lesion [LSIL; cervical intraepithelial neoplasia or CIN grade 1], normal findings, no biopsy performed).

Women approached
\[ n = 300 \]

21 excluded (8 did not speak English, 7 had had a hysterectomy, 1 had been referred for a vulvar lesion, 5 were pregnant)

Eligible to participate
\[ n = 279 \]

34 refused to participate (13 were anxious or uncomfortable about the study, 2 were unable to collect the samples because of arthritis, 1 had no time, 18 gave no reason)

Agreed to participate
\[ n = 245 \]

Complete sample set (vaginal, vulvar, urine, cervical) available
\[ n = 200 \]

45 samples were incomplete

Biopsy or endocervical curettage
\[ n = 161 \]

Results
57 with HSIL (CIN grade 2 or 3)
1 with adenocarcinoma in situ
24 with LSIL (CIN grade 1)
79 with normal findings

No biopsy (cervix normal on colposcopy)
\[ n = 39 \]