epithelium cells are considered as promising diagnostic markers of cervical dysplasia. MicroRNA-based diagnostic test-systems can provide a helpful addition to traditional diagnostic techniques.

Methodology NOVAprep-miR-CERVIX is a new test-system based on RT-qPCR analysis of six miRNAs (miR-21-5p; miR-29b-3p; miR-145-5p; miR-451a-5p; miR-1246-5p and miR-1290-3p) in material of cervical smear. Test-system includes quality of material control and control of enzymatic reaction efficacy. Machine learning based of random forest algorithm was applied for RT-qPCR results evaluation. Cervical smear samples were obtained from 226 women: 114 samples of normal epithelium and 112 samples of cervical epithelium with high-grade intraepithelial lesion (HSIL) or carcinoma in situ (CIS) as a result of cytological evaluation. Moreover, any of HSIL/CIS diagnosis was confirmed histologically.

Results The 38 samples from 216 (17.8%) did not pass quality controls and were excluded from analysis. NOVAprep-miR-CERVIX Index (miR-CERVIX-I varied from 0 to 1) was calculated on the base of results of six miRNA analysis for remaining 178 samples. Difference in miR-CERVIX-I was statistically significant in two groups of samples formed on the base of cytological/histological diagnosis (figure 1). Normal condition of cervical epithelium (miR-CERVIX-I < 0.49) was diagnosed with sensitivity 79.2%, specificity 80.46%. HSIL was diagnosed with sensitivity 70.83%, specificity 97.22% (miR-CERVIX-I < 0.49). Moreover, intermediate value of miR-CERVIX-I (between 0.3 and 0.77) is supposed to reflect condition of low-grade intraepithelial dysplasia.

Conclusion NOVAprep-miR-CERVIX can be applied for cervical dysplasia diagnostic and management as a test system complementary to standard methods.