

Optimization and validation of a new cytology stain – CytoPath line®

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Cytology plays an important role in the screening and diagnosis of cervical cancer. The correct staining of cervical smear allows the recognition of essential characteristics for the diagnosis of some pathologies. However, given the existence of flaws in the current staining procedures, the development of new staining techniques as well as the optimization of the existing ones is important. Recently, a new staining line - the CytoPath line® is being developed by DiaPath S.p.A. The objective of this work is to evaluate its performance in the staining of gynecological cytology samples.

For this purpose, 60 gynecological liquid-based samples were used, were observed microscopically and evaluated by 3 independent evaluators. At the end, the staining under test was compared with the traditional technique.

The evaluation was performed taking into account parameters for both nuclear and cytoplasmic staining. The microscopic evaluation allowed to identify differences in the two stains at the level of color intensity of nuclei and cytoplasm. The statistical analysis performed on nuclear staining evaluation reveals significant differences on parameters of "differentiation" and "hematoxylin color". Concerning cytoplasmic staining evaluation, statistically significant differences were only found on "cyanophilia intensity" parameter. In addition, the overall evaluation of both staining techniques showed statistically significant differences, being superior the performance of the staining under test, with a reduction of 10% of the total time of the technical procedure.

In conclusion, the new CytoPath line® staining line proved to be superior to the traditional Papanicolaou staining in some of the evaluated parameters, so its utilization is recommended for diagnostic purposes in gynecological cytology.

Keywords: Cervical cytology, Papanicolaou staining, CytoPath line®, screening