

Guidance Healthcare Provider's Guide to the epiCervix Test

Introduction

The epiCervix test represents a significant advancement in cervical cancer screening, combining cutting-edge epigenetic analysis with rigorous clinical validation to detect early signs of cervical precancer and cancer. This guide provides healthcare providers with essential information on the epiCervix test, enabling effective integration into patient care practices.

Laboratory Standards and Compliance

Our CAP-accredited and CLIA-certified laboratory adheres to the highest standards of quality, reliability, and privacy, in strict compliance with HIPAA regulations. This commitment ensures the epiCervix test is both trustworthy and secure, offering peace of mind to both providers and patients.



The Science Behind the epiCervix Test



Developed from pioneering research by Professor Moshe Szyf and his team, the epiCervix test utilizes DNA methylation analysis to identify changes indicative of cervical cancer. This epigenetic approach offers a nuanced understanding of cancer development, providing a powerful tool for early detection.

Key Features:

- **Early Detection:** Targets DNA methylation changes associated with cervical cancer.
- **High Accuracy:** Uses next-generation sequencing and proprietary algorithms for precise analysis.
- **Non-Invasive:** Requires only a routine cervical sample.

The Role of Professor Moshe Szyf

A leader in the field of epigenetics, Professor Moshe Szyf's groundbreaking work forms the scientific foundation of the epiCervix test. His research at McGill University has revolutionized our understanding of how environmental factors influence DNA methylation patterns, with significant implications for cancer detection and prevention.



Key Publications

El-Zein, M., et al., International Journal of Cancer, 2024.
Validation of novel DNA methylation markers for cervical precancer and cancer.

El-Zein, M., et al., International Journal of Cancer, 2020.
Genome-wide DNA methylation profiling identifies novel genes in cervical neoplasia.

Implementing the epiCervix Test

Patient Eligibility

Recommended for women as part of routine screening and those with inconclusive Pap tests or at high risk for cervical cancer.

Sample Collection and Submission

After collecting the specimen and while still in the presence of the patient, ensure to legibly note or affix a pre-printed label on the primary specimen container. This label must include the patient's Date of Birth (DD/MM/YYYY), the Clinic/Medical Number, the collection date (DD/MM/YYYY), and the initials of the person who collected the specimen. Use indelible ink for handwritten information to guarantee durability and legibility. This process ensures accurate identification and traceability of the specimen from collection to analysis, aligning with best practices for specimen handling and patient privacy.

Interpreting and Discussing Results

Positive Results: Indicate the need for further diagnostic testing.

Negative Results: Suggest no detectable cancer in our assay which has a certain rate of false negatives (5%), but regular screening should continue.

Discuss results with patients transparently, providing reassurance and clear guidance on next steps.

FAQs

Understanding the epiCervix Test

- Q: What is the M-Score?
A: The M-Score is a proprietary metric used in the epiCervix test to quantify the methylation status of specific genes that are ubiquitously methylated in cervical cancer. It provides a standardized measure to assess the presence of DNA with a cancer methylation profile in the sample, helping guide clinical decision-making.
- Q: What are the sensitivity and specificity of the epiCervix test?
A: The epiCervix test demonstrates high sensitivity and specificity for detecting cervical precancer and cancer. Sensitivity refers to the test's ability to correctly identify those with the disease, while specificity refers to the test's ability to correctly identify those without the disease. Clinical validation studies have shown the epiCervix test to achieve a sensitivity of 84.3% and a specificity of 95%, making it a reliable tool for early detection.

Test Implementation

- Q: What kits are recommended for Pap smear collection?
A: For the collection of cervical samples for the epiCervix test, we recommend using a spatula, brush, or broom method, which are standard tools for collecting cervical cells. The collected sample should then be placed in a ThinPrep® Pap Test PreservCyt® solution container. This method ensures that the sample is preserved correctly for analysis.

Complementing Existing Screening Methods

- Q: How does the epiCervix Test complement existing screening methods?
A: The epiCervix test provides additional insights beyond traditional screening methods such as the Pap smear and HPV tests by detecting cancer DNA in the sample.

After a Positive Test Result

- Q: What are the next steps after a positive epiCervix test?
A: A positive result strongly suggest the presence of cancer DNA in the sample. Further diagnostics, such as colposcopy or biopsy, are recommended to confirm findings and determine appropriate treatment.

Conclusion

Incorporating the epiCervix test into your practice offers an advanced tool for early cervical cancer detection. By leveraging the latest in epigenetic research and analysis, you can significantly enhance patient care and outcomes.



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Harnessing the epigenome



Contact Information

For further information or to discuss specific cases, please contact our professional support team:

Email: professionalsupport@epicervix.com
Website: epicervix.com/healthcare-professionals

We are committed to supporting healthcare providers in the critical work of early cancer detection and prevention.