

Our breakthrough technology can put you at ease.

The LUMA® Cervical Imaging System has been developed to significantly improve the detection of high-grade precancerous cervical abnormalities that have the potential of becoming invasive cancer.

Take care of yourself and take advantage of the most advanced, non-invasive cervical cancer screening analysis available – The LUMA Cervical Screen.

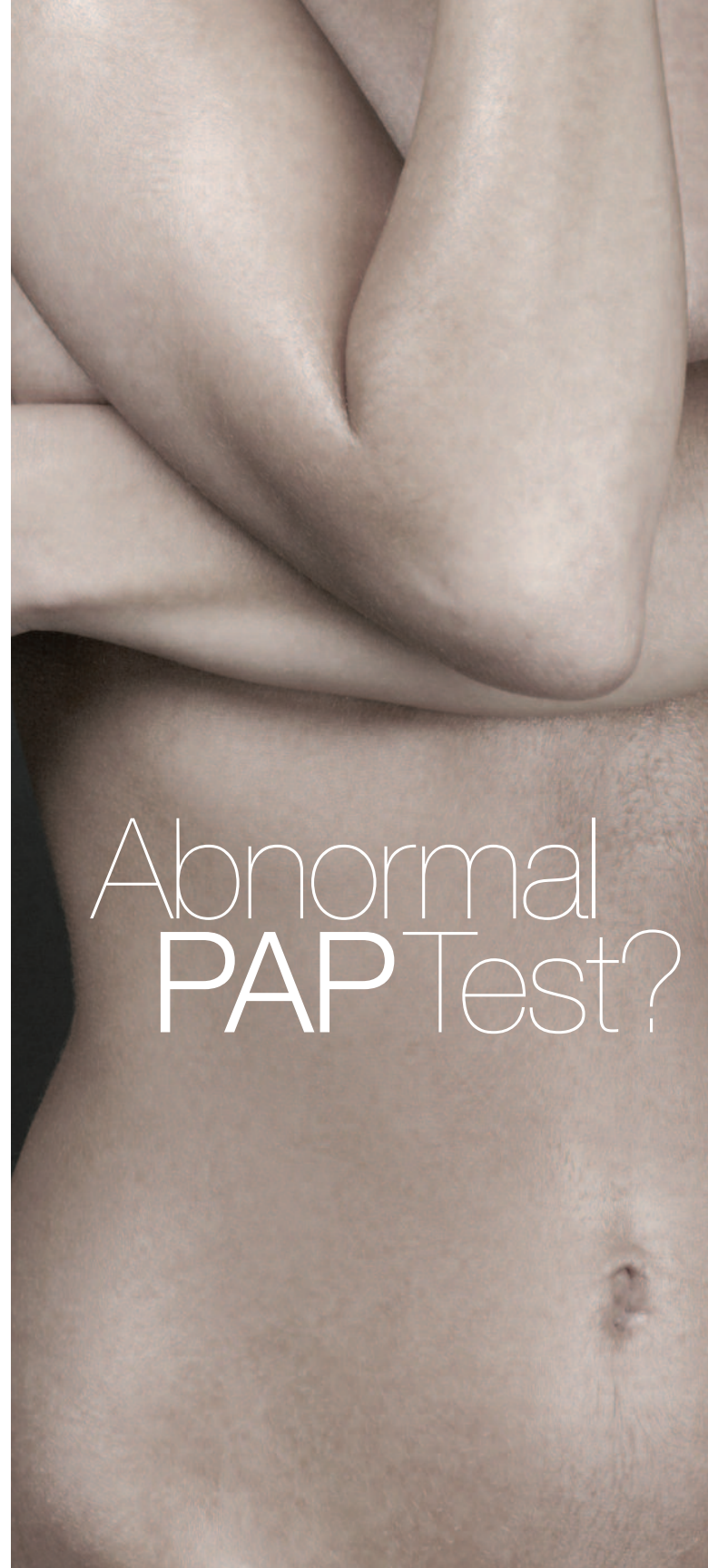
- ▶ FDA Approved
- ▶ Safe, fast and non-invasive
- ▶ Detects at least 26% more cervical abnormalities over traditional Colposcopy
- ▶ A screen display allows the doctor to share the cervical image with the patient



LUMA
CERVICAL IMAGING SYSTEM

800 304-F-001 Rev A

This life-saving screening is exclusively available at the office of:



Abnormal PAP Test?

What does an abnormal Pap result mean?

An abnormal Pap result is the first indication that changes in your cervical tissue might be occurring. The Pap test or Pap smear is a common screening test given to all women at the time of their annual exam. Although the Pap test can identify cervical abnormalities, it does not pinpoint a specific location of concern. This is why further testing is required.

The purpose of further diagnostic testing after an abnormal Pap test is to locate transitioning tissue before it evolves into cancer. Tissue in this state of transition is called dysplasia.

Cervical dysplasia itself does not cause health problems. However, because dysplasia could become cervical cancer, it must be accurately identified as early as possible.

How does my doctor find dysplasia?

There are two methods currently available for identifying dysplasia. The most commonly used method is Colposcopy. This technique is performed with a special lighted magnifying device to look at the vulva, vagina and cervix. If an area of concern is visible during this examination, a small sampling of tissue will be taken. This technique is decades old and limited in accuracy since dysplasia may not always be visible to the physician at the time of your exam. A newer technique, cervical imaging via the LUMA Cervical Imaging System is now used as an adjunct to Colposcopy. This technique uses a low intensity laser to illuminate the cervix to identify exact locations of suspect tissue not visible to the human eye.

Why should I consider a LUMA Cervical Imaging Scan in addition to Colposcopy?

A recent large scale clinical trial sponsored by the National Cancer Institute found that Colposcopy failed to detect 33% of high-grade precancerous lesions in women referred with questionable abnormal Pap results. This often led to repeat examinations to arrive at a definitive diagnosis. By adding the LUMA Cervical Imaging scan as an adjunct to colposcopy, doctors can now reliably identify exact locations of

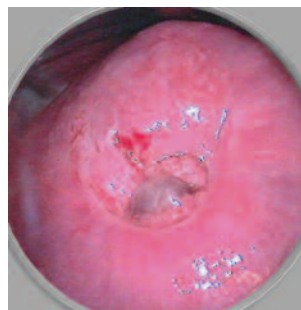


Image of cervix. Healthcare provider could not visualize any areas of concern.

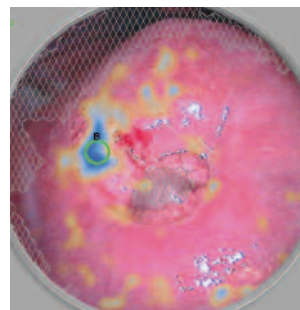


Image of same cervix utilizing the LUMA Cervical Imaging System, identifying High Grade Dysplasia. (Blue). The Green circle indicates LUMA directed biopsy site.

suspect tissue for biopsy, thus avoiding repeat visits for further examination. Recent studies have shown that using the LUMA System in conjunction with Colposcopy identified at least 26% more cases of dysplasia than Colposcopy alone.

How does the LUMA Cervical Imaging System work?

The LUMA System uses a low intensity laser light to illuminate the surface of the cervix, scanning it to identify the exact locations of suspect tissue. An image is produced that color codes these areas for physicians to target tissue collection sites. The LUMA System is highly effective because it operates

via a wavelength of light beyond what the human eye can see. The LUMA System is able to differentiate healthy tissue from diseased tissue more precisely because it recognizes and differentiates critical cellular information.

What are the benefits of having the LUMA System scan performed?

Combining the expertise of your physician with the power of the LUMA System will identify dysplasia sooner. In addition, the LUMA System can help differentiate between low grade dysplasia and high grade dysplasia. This results in improved diagnosis, superior biopsy selection and earlier and more effective treatments.

Is the LUMA System FDA approved?

Yes. The LUMA System was approved by the FDA as a safe and effective tool when combined with Colposcopy to improve diagnosis.

What can I expect after my exam?

Your doctor will follow up with you to discuss the test results obtained and to recommend any additional care that might be required. These results usually fall into three categories:

Normal Tissue: *No further follow-up is required. Return to routine Pap screening.*

Low Grade Dysplasia: *Can resolve back to a normal state, warranting "watchful waiting" as the immune system attempts to repair changing cells.*

High Grade Dysplasia: *Is more likely to become cancerous than to return to a normal state, warranting interventional and often surgical therapy.*