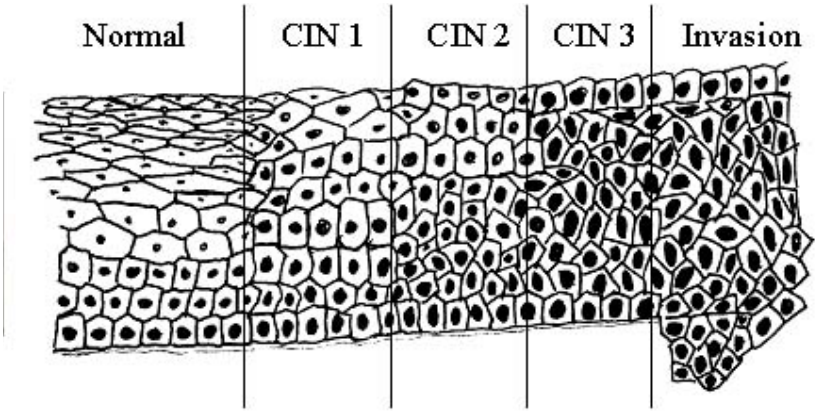
The basis for our confidence that we can detect cervical tissue aberration

In a nutshell: Our confidence stems from the fact that there is biomedical precedent for observing electrometric differences between normal and precancerous (CIN) tissues. CIN stands for Cervical Intraepithelial Neoplasia, and its progressive worsening toward invasive cancer is schematically illustrated in this simple picture:



Schematic representation of the cervical tissue as the electrometric probe "sees" it.
The Pap test analyzing pathologist sees a smear of sample cells scraped from the cervix,
and uses expert judgment to assess whether the cells look normal or abnormal, and how abnormal.

Researchers have found that the differences between electrometric signatures of normal healthy tissues (epithelia) and those of the aberrant tissues (CIN epithelia) are "as significant as those obtained from analyzing Pap smear tests". But the Pap smear analysis is a subjective and tedious visual observation subject to serious errors whereas, in the electrometric examination, the measurement is objective (independent of any pathologist's judgment of the appearance of the tissue sample). The electrometric results are understood to be determined by the same characteristics as those observed visually by the Pap smear analyzing pathologist, namely by changes in the shapes and internal structure of the tissue cells (including the size of their nuclei), and their arrangements (layering) including the changes in the distribution of extracellular space.

At present, an abnormal or suspect Pap smear prompts close observation for disease progression over a long time of many months of anxiety, with the potential for the therapeutic interventions of destruction or excision of cancerous or pre-cancerous tissues. The excisional treatments, as well as the colposcopy with biopsy for definitive diagnosis, are expensive, painfully uncomfortable, and associated with significant failure rates for the more advanced lesions. Early diagnosis is key to success.

Because we optimized our electrometric tissue monitoring so as to track the menstrual cycle (the measurement regime yielding the folliculogenesis cyclic profile), we will have to determine if an aberrant cervical tissue (Pap smear positive) affects the cyclic profile. In any case, to detect tissue aberration we will need to optimize the electrometric procedure so as to be sensitive to the above mentioned tissue characteristics rather than to the effect of folliculogenesis on healthy cervical tissue. The two different measurement regimes are fast and can be applied together in one measurement session.

Vaclav Kirsner PhD, bioZhena Corporation vaclav@biozhena.com