



Evaluating Vaginal pH Detection Kit: A Critical Analysis of the role of Vaginal pH in HPV Identification and Cervical Cancer Prediction

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Abstract

Vaginal pH, a crucial indicator of vaginal health, plays a significant role in the pathogenesis of various gynaecological conditions, including human papillomavirus infection and cervical cancer development.

The vaginal environment, characterized by a delicate balance of microorganisms, serves as a primary defense against pathogens, with an acidic pH being essential for maintaining a healthy microbiome and inhibiting the growth of harmful bacteria. The vaginal pH detection kit is a diagnostic tool designed to measure the acidity or alkalinity of the vaginal environment, providing valuable information about a woman's vaginal health. This paper aims to comprehensively analyse the utility of vaginal pH detection kits in the context of HPV identification and cervical cancer prediction, examining the underlying mechanisms by which vaginal pH influences HPV infection, exploring the association between abnormal vaginal pH and cervical cancer risk, and evaluating the clinical effectiveness of vaginal pH detection kits in screening and managing these conditions. By critically evaluating the scientific literature and available evidence, this analysis seeks to provide insights into the potential of vaginal pH detection kits as a valuable tool in promoting women's health and preventing cervical cancer.

Introduction

The vaginal environment, a complex ecosystem governed by a delicate balance of microorganisms, plays a crucial role in women's health, acting as a first line of defence against pathogens (1). Maintaining an optimal vaginal pH, typically acidic, is essential for inhibiting the growth of harmful bacteria and fostering a healthy microbiome (2). The disruption of this balance, often reflected in changes in vaginal pH, can lead to various gynaecological conditions, including bacterial vaginosis, yeast infections, and increased susceptibility to sexually transmitted infections, including Human Papillomavirus (3). HPV, a common viral infection, is a primary cause of cervical cancer, highlighting the importance of understanding the interplay between vaginal health, HPV infection, and cervical cancer development. Persistent HPV infection is a critical factor in the progression of precancerous cervical intraepithelial neoplasia and invasive cervical carcinoma (4). However, HPV infection alone may not be sufficient to drive full tumorigenesis, suggesting other factors, such as the cervicovaginal bacterial composition, may influence the development of cervical preinvasive disease (5). The vaginal pH detection kit is a diagnostic tool designed to measure the acidity or alkalinity of the vaginal environment, providing valuable information about a woman's vaginal health (6). Understanding the role of vaginal pH in HPV infection and cervical cancer risk is crucial for developing effective prevention and diagnostic strategies (7). Maintaining a healthy vaginal pH is crucial for women's overall well-being, as it plays a vital role in preventing various infections and maintaining the delicate balance of the vaginal microbiome. The vaginal ecosystem is a dynamic and complex environment, heavily influenced by hormonal changes throughout a woman's life. Recent advancements in molecular analysis have expanded the definition of "normal" vaginal microbiota, shifting from a single specific profile to a range of functional microbial equilibria (8). To better understand and manage vaginal health, the development of reliable and accessible pH detection kits has become increasingly important (9).

The Importance of vaginal pH is a critical factor in maintaining the overall health of the vaginal ecosystem. A Normal pH ranges from 4 to 4.5, that creates a condition which helps in the growth of beneficial bacteria, such as Lactobacillus species, which prevents the growth of harmful microorganisms. Various health issues, like bacterial vaginosis, yeast infections, and increased susceptibility to sexually transmitted infections will create disturbance in the balanced pH (8). The hormonal changes is highly responsible for vaginal microbiome, particularly during a women's reproductive life oestrogens are fluctuated (8). By structuring and multiplying the resident microbial communities Oestrogen plays an important role in shaping the vaginal environment. A healthy vaginal pH is maintained during the reproductive years, in which oestrogen level helps in promoting the growth of Lactobacillus species. However, this balance can be disturbed during hormonal transformation such as menopause, oestrogen levels turn down which leads to the changes in the vaginal microbiome and increases the weakness to vaginal atrophy and dryness. Understanding these hormonal changes on the vaginal microbiome is essential for making effective strategies for maintaining vaginal health, including the use of pH detection kits (8)(10).

Vaginal pH detection kits have become a crucial tool for women to monitor their vaginal health and identify potential imbalances. These kits consist of a pH-sensitive strip that can be used to measure the pH level of a vaginal secretion fluid sample. By providing a simple and accessible

way to monitor vaginal pH, these kits empower women to take an active role in managing their reproductive and gynaecological health. Several studies have highlighted the importance of using vaginal pH detection kits, particularly in the context of menopausal women. As the vaginal microbiome have noticeable changes during this transition, pH detection kits can help women and their healthcare providers identify and address any imbalances, leading to improved management of symptoms such as vaginal dryness and atrophy (10). Cervical cancer is a significant health concern, ranking as the fourth most common cancer among women worldwide, with HPV infection being the primary cause (11). However, not all HPV infections lead to cervical cancer; most are cleared by the immune system. The persistence of HPV infection, particularly with high-risk types, is a critical factor in the development of cervical intraepithelial neoplasia and, ultimately, invasive cervical cancer (12). The vaginal microbiome and pH play a significant role in determining the risk and progression of HPV-related cervical cancer.

The importance of vaginal pH as a key indicator of vaginal health is demonstrated in a number of studies, particularly in the context of pregnancy and menopausal women (13). Maintaining an acidic vaginal pH is crucial for preventing the growth of harmful bacteria and protecting against infections (14). Many factors, including hormonal fluctuations, hygiene practices, and underlying health conditions, can influence vaginal pH levels. Salivary pH, flow rate, and taste perception can be affected by hormonal changes that occur throughout a woman's reproductive life (15). Several studies have also explored the connection between race, ethnicity, and vaginal pH, indicating that vaginal pH levels may differ among women of different ethnic backgrounds (16).

Existing research on the vaginal pH detection kits provides valuable insights in maintaining a healthy vaginal environment and the potential applications in diagnostic tools. The studies emphasize the dynamic nature of the vaginal microbiome, particularly in response to hormonal fluctuations, and the significance of understanding these changes for overall gynaecological health. A review article by highlighting the impact of menopause on the vaginal microbiome, noting that an imbalance or dysbiosis in the vaginal microbial community can lead to a range of health issues, including vulvovaginal atrophy and vaginal dryness (10). The authors suggest that the use of pH detection kits can be a valuable tool for monitoring and managing these menopausal-related changes, enabling women and their healthcare providers to take proactive steps in maintaining a healthy vaginal environment.

Another study, titled "Vaginal Microbiome and Epithelial Gene Array in Post-Menopausal Women with Moderate to Severe Dryness," emphasizes the need for non-hormonal interventions in managing vaginal dryness and other symptoms associated with vulvovaginal atrophy. The researchers found that the use of pH detection kits, combined with other diagnostic tools, can provide valuable insights into the vaginal microbiome, and guide the development of personalized treatment strategies. These studies highlight the importance of using vaginal pH detection kits as a crucial component of women's health management, particularly during the menopausal transition.

In this work, a case study is presented on the deployment and efficacy assessment of PrePAPQR (<https://smartqr.co.in/pages/PrePAPQR>), a first of its kind device-free POC Vaginal pH testing kit based on a technology invented at the Indian Institute of Technology (IIT) Kharagpur by the research group and it is licensed and produced by SmartQR technologies (license number MFG/IVD/2024/ 000037). What sets PrePAPQR apart from traditional Vaginal pH meters is its minimalist design, consisting solely of a test strip fabricated indigenously from plant-derived cellulose and a stand-alone mobile app guiding the end-to-end procedure, eliminating the need for any additional device. The strip is having a dimension of 5 mm (width) × 60 mm (length) and the reaction pad in the strip is of 5 mm × 5 mm. The testing process involves a simply collecting vaginal fluid from vagina with the help of cotton swab, which is then applied to a QR-coded paper-microfluidic strip. The user scans the strip using a mobile app, which analyses the colour change to provide instant, real-time vaginal pH results. The algorithm of the application involves device calibration, custom filter application, machine learning based analysis, platform-specific deployment and real time data handing and analysis. A clinical study report with 3189 human subjects was per formed to establish the efficacy of this technology for Vaginal pH using the minimal resources of a paper strip and a smartphone, striking a balanced pH level and the elevated pH level of a user-friendly rapid test.

Materials and Methods

The research for this paper involved a comprehensive literature review of scientific articles and studies related to vaginal pH detection kits and their role in women's health. The review of the literature aimed to synthesize the current understanding of the vaginal microbiome, its relationship with hormonal changes, and the potential benefits of using pH detection kits for managing various gynaecological conditions. "Crosstalk Between Female Gonadal Hormones and Vaginal Microbiota Across Various Phases of Women's Gynaecological" "Menopause and the vaginal microbiome" (10)

Deployment of a fully indigenous method for producing high-quality cellulose from cotton, a plant fibre derived from the seed hairs of plants in the Mallow family. Cotton linters were used specifically, which are short fibres left after cotton processing, due to their high purity and strength. The plant material underwent chemical pulping to break down lignin and extract cellulose fibres. After pulping, the cellulose was thoroughly washed and bleached to eliminate any residual lignin and impurities, resulting in clean, white pulp. The pulp was carefully beaten to balance fibre length and fibrillation, refining the fibres to a controlled, uniform length. This allowed for the formation of a porous structure with consistent pore size (around 10 µ 180 µ m) and thickness (about m). This step was crucial for regulating the permeability and mechanical characteristics of the cellulose material. A novel strategy was employed to prepare samples of isolated cellulose fibers, which involved immobilizing isolated fibers onto chemically pretreated glass slides to promote cellulose adhesion (17).

The subsequent step involved using peroxyformic acid for mild delignification, achieving higher performance compared to cotton from commercial menstrual pads and characterizing physical and chemical properties to understand structure-function relationships across multiple length scales (18). The sustainability of hygiene products can be enhanced by using fluid cellulose-based hydrogels instead of synthetic superabsorbent polymers. Cellulose-based hydrogels are biocompatible materials with diverse biomedical applications, including drug delivery, tissue engineering, and wound healing. They are also used in agriculture, textiles, and industrial applications as smart materials (19). Due to their biodegradability, biocompatibility, and renewability, nanocellulose has attracted considerable attention in academia and industry, and cellulosic materials are sustainable, green, and environmentally friendly.

In the PrePAPQR Test, the procedure begins with the sample collection in which firstly Register the patient in the application and then initiate with the further process. Where we have wear hand gloves before taking sample. Then Open the Package and remove cotton swab. Separate the labia of Vagina with the other hand So that vaginal wall is expose/Visible. Then we have to carefully insert the Cotton swab tip into the Vagina upto 2 Inch (5cm) so that it reaches the Cervix area and rotate the swab for 15 Seconds. By making sure that cotton swab is well moist with the Vaginal fluid. Remove the swab from the Vagina for the testing. Then without touching to the tip of the vaginal swab containing vaginal fluid. Take the strip, by gently rotating the swab on the reaction pad of the testing strip and allow it to cover whole reaction pad then

show the colour change on reaction pad and as the camera popups on the screen align the portion of the strip as describe on the screen and then capture the photo of the strip. The results can be seen instantly which can be downloaded from there.

Results

The research paper provides a comprehensive overview of the importance of vaginal pH detection kits in women's health, particularly in the context of hormonal changes associated with menopause.

The studies reviewed emphasize the dynamic nature of the vaginal microbiome and its sensitivity to hormonal fluctuations, with a focus on the impact of menopause on the vaginal microbial community. The use of pH detection kits is presented as a valuable tool for monitoring and managing menopausal-related changes, enabling women and their healthcare providers to take proactive steps in maintaining a healthy vaginal environment.

The key findings from the literature review include:

1. The vaginal microbiome is highly responsive to hormonal fluctuations, and an imbalance or dysbiosis in the vaginal microbial community can lead to various health issues, such as vulvovaginal atrophy and vaginal dryness.
2. Vaginal pH detection kits are a valuable tool for women to monitor their vaginal health and identify potential imbalances, empowering them to take a more active role in managing their reproductive and gynaecological well-being.
3. The use of pH detection kits, combined with other diagnostic tools, can provide valuable insights into the vaginal microbiome, and guide the development of personalized treatment strategies, particularly for managing menopausal-related symptoms.
4. Maintaining a healthy vaginal pH is crucial for promoting overall reproductive and gynaecological health, and the use of pH detection kits can be an essential component of a comprehensive approach to women's healthcare.

No of Samples 3000	Normal pH Value detected (4 to 4.5)	Borderline pH Value detected (4.6 to 5.0)	Higher pH value detected (5.1 to 7.0)	No of Borderline and higher pH value having risk of developing (BV & Trichomonas's)
Age 18 to 30 years	169	737	348	1085
Age 31 to 65	426	956	364	1320
Total	595	1693	712	2405

Table 1: The Number of Patients Sample with Normal, Borderline, Abnormal pH Count

The results were analysed in a determined way. The pH is Normal, Borderline, Abnormal were determined in the study tested with 3000 vaginal specimen's samples of age group ranging from 18 years to 65 years. The table and determined data are given in the annexure. The pH is Normal, Borderline, Abnormal were determined in the study tested with 3000 vaginal specimen's samples of age group ranging from 18 years to 65 years.

The results of PrePAPQR showed more than 19.83% Normal, 56.43% Borderline, 23.73% Abnormal, with the results obtained from the device. As we can see in the below Fig.1 having pie chart with sequence of below 30 and above 30 of normal first and followed by borderline and abnormal. And in Fig.2 the line graph is represented in the same sequence of groups as in Fig.1 with normal, borderline, abnormal patient's data. The pie chart mentioning number and the similarly numbers shown in line graph represents as below:

- 1) 6% of pie chart represents below 30 Normal which has 169 patients as shown in line Graph.
- 2) 14% of pie chart represents above 30 Normal which has 426 patients as shown in line Graph.
- 3) 24% of pie chart represents below 30 Borderline which has 737 patients as shown in line Graph.
- 4) 32% of pie chart represents above 30 Borderline which has 956 patients as shown in line Graph.
- 5) 12% of pie chart represents below 30 Abnormal which has 348 patients as shown in line Graph.
- 6) 12% of pie chart represents above 30 Abnormal which has 364 patients as shown in line Graph.

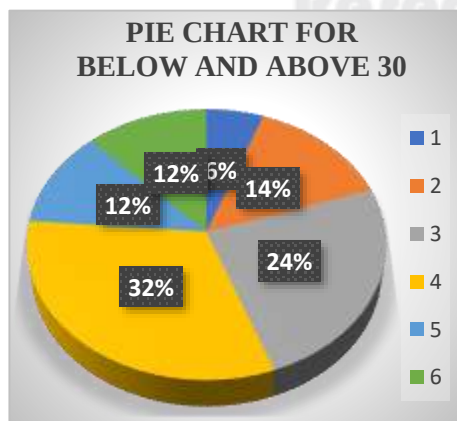


Fig.1 Pie Chart for normal, borderline, Abnormal pH

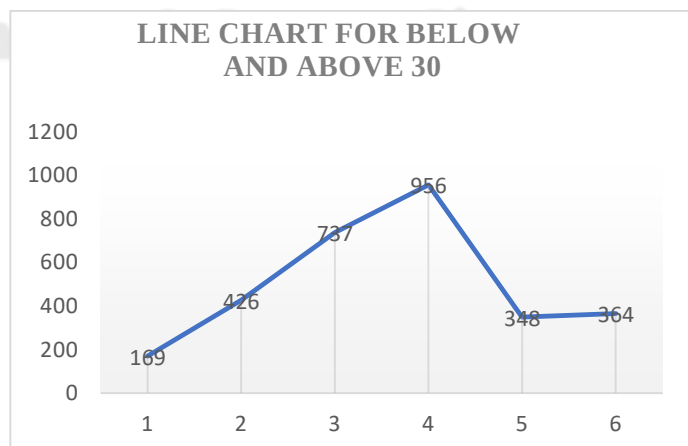


Fig.2 Line Chart for normal, borderline, abnormal pH

From these 3000 tests we got around 712 abnormal, 1693 borderline, and 595 normal from which a random 238 patients sample were send for the VIA testing which is around 8% in which we randomly selected patients from all group with different age groups in which we got 14 positive VIA test from 238 which is about 5.88% of total VIA test and 0.47% of total number of patients whose pH test was done. But we found that the patients who were positive had elevated pH value more than 5.6 which is usually abnormal. We further refereed them to doctors for further investigation. From this we can say that generally the VIA positive can be seen at the abnormal pH which can leads to many RTI, STI which can increase the possibility of HPV and cervical cancer if ignored.

Discussion

The findings from this research paper highlight the importance of vaginal pH detection kits in the context of women's health, particularly during the menopausal transition. The studies reviewed emphasize the dynamic nature of the vaginal microbiome and the significant impact of hormonal fluctuations, such as those experienced during menopause (10)(20).

The research underscores the need for comprehensive and personalized approaches to managing vaginal health, as an imbalance or dysbiosis in the vaginal microbial community can lead to a range of health issues. Vaginal pH detection kits have emerged as a valuable tool for women to actively monitor their vaginal health and identify potential imbalances, enabling them to take proactive steps in maintaining a healthy vaginal environment.

The use of pH detection kits, combined with other diagnostic tools, can provide valuable insights into the vaginal microbiome, and guide the development of personalized treatment strategies. This is particularly important in the context of menopausal-related symptoms, where the use of these detection kits can help women and their healthcare providers identify and manage issues such as vulvovaginal atrophy and vaginal dryness.

Maintaining a healthy vaginal pH is crucial for promoting overall reproductive and gynaecological health, and the use of pH detection kits can be an essential component of a comprehensive approach to women's healthcare.

By empowering women to actively monitor their vaginal health, these detection kits can play a crucial role in the early identification and management of various health conditions, ultimately improving the quality of life for women across all stages of their reproductive journey. Greater understanding of the vagina will give women confidence to engage in more open communication, which will increase their knowledge and empower them to take control of their sexual and reproductive health (21).

Vaginal Microbiome and Menopause

During menopause, the decline in estrogen levels can lead to significant changes in the vaginal microbiome, resulting in a reduction in the population of *Lactobacillus* species (22). This shift can increase the risk of vaginal infections and other health issues, as the protective effects of *Lactobacillus* are diminished. An elevated vaginal pH and depletion of vaginal lactobacilli in the estrogen-deficient postmenopausal state can complicate the use of traditional BV diagnostics, as these methods were originally developed in premenopausal women. For instance, postmenopausal women receiving estrogen replacement therapy who are sexually active continue to be at risk for bacterial vaginosis (23). The research paper highlights the use of vaginal pH detection kits as a tool for women to monitor their vaginal health during the menopausal transition, enabling them to detect potential imbalances and seek timely medical intervention.

Probiotics and Vaginal Health

The administration of probiotics may not be an effective means of modulating the vaginal microbiome for clinical purposes in an infertile population (24). However, the introduction of probiotic organisms has been explored as a potential strategy to restore and maintain vaginal health, particularly in the context of bacterial vaginosis prevention and treatment (25). The impact of probiotics on female reproductive tract health remains a subject of ongoing investigation, despite their widespread use in treating intestinal diseases (26). The literature also suggests the potential of probiotics, particularly *Lactobacillus* species, in maintaining a healthy vaginal microflora and preventing urogenital infections (27). Studies have shown that lactobacilli can acidify the vaginal microenvironment, inhibit the proliferation of pathogenic microorganisms, and promote the maintenance of a healthy vaginal microbiome (28), (29). Maintaining a low vaginal pH, largely due to the presence of lactic acid-producing bacteria such as **Lactobacillus**, is crucial for preventing the overgrowth of pathogens and maintaining overall vaginal health (30).

Clinical Significance and Personalized Treatment Strategies

Vaginal pH detection kits can be used as part of a comprehensive approach to women's healthcare, allowing for the identification of potential imbalances and the implementation of personalized treatment strategies. These kits can be particularly useful in managing menopausal-related symptoms, where hormonal changes can significantly impact the vaginal microbiome and pH levels. The analysis of the urogenital and intestinal microbiota in perimenopausal women reveals significant changes in the microbiota in patients with recurrent vaginitis, which may aid in the development of diagnostic and therapeutic strategies (31).

Conclusion

In conclusion, vaginal pH detection kits have emerged as a valuable tool for women to monitor their vaginal health and identify potential imbalances. The research reviewed in this paper underscores the dynamic nature of the vaginal microbiome and the significant impact of hormonal fluctuations, such as those experienced during menopause (8)(10)(20).

The use of pH detection kits, combined with other diagnostic tools, can provide valuable insights into the vaginal microbiome, and guide the development of personalized treatment strategies, particularly for managing menopausal-related symptoms. Maintaining a healthy vaginal pH is crucial for promoting overall gynaecological health, and the use of pH detection kits can be an essential component of a comprehensive approach to women's healthcare.

By empowering women to actively monitor their vaginal health, these detection kits can play a crucial role in the early identification and management of various health conditions, ultimately improving the quality of life for women across all stages of their reproductive journey.

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