

## ORIGINAL ARTICLE

# Implementing 100% quality control in a cervical cytology workflow using whole slide images and artificial intelligence provided by the Techcyte SureView™ System

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**Abstract**

**Background:** Recent advancements in digital pathology have extended into cytopathology. Laboratories screening cervical cytology specimens now choose between limited imaging options and traditional manual microscopy. The Techcyte SureView™ Cervical Cytology System, designed for digital cytopathology, was validated at CorePlus, a pathology laboratory in Puerto Rico, and adopted as a 100% quality control (QC) tool.

**Methods:** The validation study included 1442 whole slide images (WSIs) from 1273 ThinPrep® and 169 SurePath™ cervical cytology slides, digitized with the 3DHIS-TECH Panoramic 1000 DX scanner using dry and water immersion scanning profiles. These WSIs were processed by the Techcyte SureView™ system, with a board-certified cytopathologist reviewing artificial intelligence (AI)-identified objects of interest and comparing them to traditional light microscopy results.

**Results:** Techcyte SureView™ with the water immersion scanning profile outperformed both the dry scanning profile and light microscopy in detecting squamous and glandular abnormalities. It achieved 97% accuracy, 82% sensitivity, 99% specificity, 98% negative predictive value, and 86% positive predictive value. Additionally, the review time was rapid. The system has been operational for several months, enhancing accuracy and workflow efficiency.

**Conclusions:** This study demonstrates that digital cytopathology, particularly through the Techcyte SureView™ system, can improve laboratory workflow and performance. Successful validation led CorePlus to integrate the AI algorithm into their workflow as a 100% QC review tool, resulting in improved accuracy, benefiting both laboratory professionals and patients.

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**KEYWORDS**

artificial intelligence, cervical cytology, cytopathology, digital cytology, digital pathology, quality control

**INTRODUCTION**

The advent of digital pathology (DP) is revolutionizing the practice of pathology. In anatomic pathology (AP), the traditional method of examining tissue samples fixed to glass slides, stained and viewed under a microscope is being replaced by digital whole slide scanning.<sup>1</sup> This process generates high resolution digital whole slide images (WSIs) that can be viewed on large, high resolution computer monitors, often accompanied by tools to help electronically manage workloads and other features. DP offers several advantages over traditional microscopy. It provides better ergonomics, reducing neck, shoulder and back strain associated with fixed posture. Additionally, DP enhances patient safety by minimizing patient and slide misidentification and slide loss errors. It improves the diagnostic workflow with case tracking, archival, retrieval and workload allocations. Service quality is elevated through information sharing, collaboration and clearer diagnostic audit trails. Finally, DP addresses workforce issues by enabling more flexibility and remote work opportunities.<sup>2</sup>

The success of DP has facilitated the adoption of artificial intelligence (AI) algorithms capable of analyzing digital slide images to identify patterns and features indicative of disease, such as cancer.<sup>3</sup> The integration of AI in DP is driving significant advances in precision medicine and personalized treatment plans.<sup>4,5</sup> Studies show AI-assisted diagnoses match or exceed human accuracy and reduce variability among professionals.<sup>5,6</sup> Studies using DP and AI in breast cancer,<sup>7,8</sup> colorectal cancer,<sup>9</sup> prostate<sup>10</sup> and cervical cytology<sup>11</sup> highlight the growing benefits. This is crucial for labs facing workforce shortages<sup>12,13</sup> and variability in examiners' results,<sup>14</sup> especially in cervical cytology, where accurate detection of atypical cells is vital.

The adoption of DP and AI in cytopathology, however, has been slower due to unique challenges such as obtaining suitable full-slide digital scans. For example, gynecological specimens collected for cervical cytology vary in preparation methods, resulting in differing thicknesses and cell distributions.<sup>5,15,16</sup> Whole slide scanners that capture multiple planes of focus, called z-layers, allow pathologists to view different specimen layers, similar to conventional microscopy. However, this increases scanning time and file size.<sup>16</sup> Advances in scanner technology are continuing to reduce scan time and file size while capturing necessary images for accurate specimen review.

Gynecological cytology has not been without some computer assisted user assistance. For nearly 2 decades, cytologists and cytopathologists have employed systems like the ThinPrep® Imaging System and BD FocalPoint GS Imaging System to aid in screening liquid-based Papanicolaou (Pap) tests. Although these systems do not use WSI, they employ AI for location-guided imaging and automated microscope stages to direct users to fields of interest. Despite being

limited to analyzing their own liquid-based preparations, they have significantly increased laboratory productivity.<sup>13</sup>

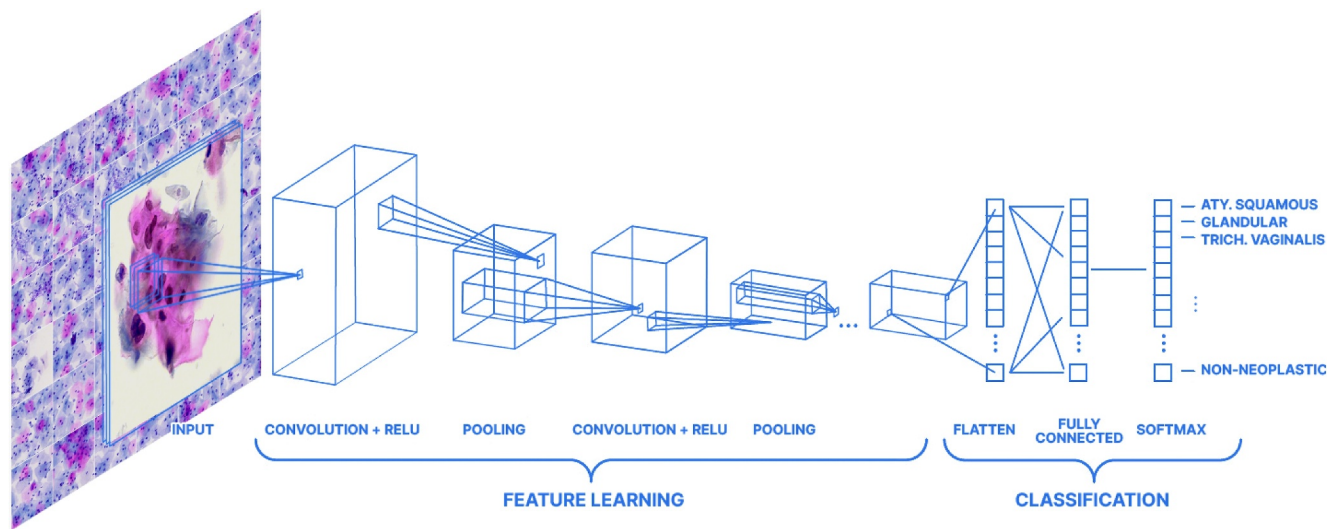
Recent advancements in digital cytopathology have addressed many challenges posed by cytological specimens for whole slide scanners. The Hologic Genius Digital Diagnostics System with the Genius Cervical AI algorithm has become recently available.<sup>17</sup> Improved image quality of cytological specimens has facilitated AI development, with algorithms becoming more accurate as the quality of training images improves.<sup>12,18</sup> Labs can adopt AI-based digital cytopathology for various purposes, such as screening, assistive diagnostics, or quality control, depending on their resources.

In this study, we present the experience of a nonhospital based, independent private pathology laboratory in using the Techcyte SureView™ Cervical Cytology System (Techcyte SureView™) for accurate reading of cervical cytology results from ThinPrep® and SurePath™ preparations. Based on the results of the study, the system was validated as a 100% quality control (QC) tool as a first step in providing DP and AI assistance for cervical cytology. Developments in slide preparation, digital scanning and workflow are presented demonstrating consistently accurate results.

**MATERIALS AND METHODS****AI algorithm and training**

Techcyte SureView™ is a deep learning-based algorithm based on the You Only Look Once (YOLO) architecture. It was trained using the PyTorch deep learning library on digitized BD SurePath™ and Hologic ThinPrep® prepared cervical cytology specimen slides from various reference laboratories and with multiple clinical conditions (Figure 1). These slides were scanned with several whole slide scanners to ensure generalization and compatibility with different scanners. The WSI included single and multilayer images depending on the scanner type. A set of training, validation, holdouts (or test set), plus dry run scans were used in the building and testing of the algorithm. Objects, including those representatives of diagnostic categories referenced in The Bethesda System,<sup>19</sup> were labeled by experts in cytopathology including squamous and glandular cells and organisms to define classification from the WSI (Table 1). The algorithm is then used to identify objects of interest, images of cells and organisms with context, within the WSI for user review and interpretation. The algorithm includes features for squamous cell quantification while also providing a gallery of benign glandular cells for adequacy assessment by the user.

Techcyte SureView™ version 3.0 was trained using these techniques and was used in this study.



**FIGURE 1** A depiction of a neural network, which was used to train the Techcyte SureView™ algorithm and is used to find cells within a whole slide image. Objects are used to teach the algorithm features for identification on the scans. Those features are then learned and applied to predict representative images to the end user.

**TABLE 1** Overview of The Bethesda System labels used in training Techcyte SureView™.

| Atypical squamous | Glandular                           | Organism                     | Nonneoplastic                                  |
|-------------------|-------------------------------------|------------------------------|------------------------------------------------|
| Carcinoma         | Adenocarcinoma-NOS                  | <i>Trichomonas vaginalis</i> | Endometrial                                    |
| HSIL              | Atypical glandular-NOS              | Clue cells                   | Reactive                                       |
| LSIL              | Endocervical adenocarcinoma in situ | <i>Actinomyces Spp.</i>      | Normal squamous                                |
| ASC-H             | Extrauterine adenocarcinoma         | <i>Herpes simplex</i>        | Radiation                                      |
| ASCUS             | Atypical glandular-favor neoplastic | <i>Candida</i>               | Atrophy                                        |
|                   | Endocervical adenocarcinoma         |                              | Repair                                         |
|                   | Endometrial adenocarcinoma          |                              | Chronic follicular cervicitis                  |
|                   | Typical endocervical cells          |                              | Endometrial cells in a woman 45 years or older |
|                   | Reactive endocervical cells         |                              |                                                |

Abbreviations: ASC-H, atypical squamous cells, cannot rule out high-grade squamous intraepithelial lesion; ASCUS, atypical squamous cells of undetermined significance; HSIL, high-grade squamous intraepithelial lesion; LSIL, low-grade squamous intraepithelial lesion; NOS, not otherwise specified.

Slide preparation

ThinPrep® and SurePath™ cytology slides were prepared from physician collected gynecological samples whereby the cervical sampling device is immersed and rinsed in a vial of PreservCyt Solution or BD SurePath™ preservative. The capped vials were sent to CorePlus laboratory. PreservCyt samples were processed on the ThinPrep® 2000 where cells were collected on a specialized filter and deposited on a glass slide in a 20-mm diameter circle in fixative solution according to the manufacturers’ recommendation (ThinPrep® 2000 System manual). ThinPrep® slides were stained with Pap stain on a Leica Spectra automated stainer. BD SurePath™ samples were prepared on the BD Totalys multiprocessor according to manufacturer recommendations including automated preparation

of the slides by removing interferents and allowing cells to settle on the slide surface and staining the slide with a Pap stain.

Slide scanning

The 3DHistech Panoramic 1000 DX instrument was used for WSI employing both traditional dry and water immersion scanning technologies. For dry scanning, the specimens were scanned at 40× magnification in three different focal planes and visualized using extended depth of focus imaging.<sup>20</sup> In this technique, multiple layers are computationally merged into a single composite image to ensure all parts of the specimen are in sharp focus and to provide a comprehensive view of the specimen’s structure. The dry objective

had a numerical aperture (NA) of 0.95, providing image resolution of 0.12  $\mu\text{m}/\text{pixel}$ .

Additionally, the P1000 was equipped with a water immersion objective featuring a 1.2 NA, providing a resolution of 0.12  $\mu\text{m}/\text{pixel}$ , which facilitated enhanced resolution imaging. The enhanced resolution was achieved by altering the refractive index from 1.03 (air) to 1.33 (water), allowing for improved visualization of details in a three-dimensional plane. The water immersion technology was fully automated, incorporating a water syringe to apply water to the sample area and a rubber surface to remove the water post-scanning. For water immersion, specimens were scanned at 40 $\times$  magnification in a single layer.

## Slide review

The software used for slide review validation was Techcyte SureView™ (version 3), a cloud-based software available in the browser. The monitor used for reviewing was the DELL UltraSharp 49 curved Monitor (U4919DW). This monitor has a 99% sRGB color gamut, a 60 MHz refresh rate, and is, as specified by DELL, <2  $\Delta E$  or color difference value.

## Study design

This retrospective study analyzed 1500 gynecological cytology slides from the CorePlus archive, of Hispanic women between the ages of 18–89 and an average age of 45 years. The abnormality rate was 8.3% and HPV positivity rate was 15.7%. Samples were collected between January 1, 2023, and June 30, 2023, and de-identified for the study. Slides with scanning issues, such as breakage or cover slipping problems, were excluded. The selected slides represented a typical sample population seen at CorePlus and were prepared using ThinPrep® (Hologic, Marlborough, Massachusetts) and SurePath™ (BD, Franklin Lakes, New Jersey) methods as described. Scanning was performed with a 3DHitech Panoramic 1000DX (P1000) at 40 $\times$  magnification, using two profiles: the traditional dry scan with three layers and water immersion scanning with a single layer, both as described. These profiles, developed through bench testing, were compared to ensure optimal image quality and processing efficiency.

The clinical performance of Techcyte SureView™ was determined by comparing the original cytopathologist clinical read of cases on glass slides using light microscopy (reference method) to the same cytopathologist reading the same case using the Techcyte SureView™ system following a washout period exceeding 1 month, as depicted in Figure 2. The review time was self-recorded by the cytopathologist. Techcyte SureView™ analysis was performed on each slide scanned using both the traditional dry and water immersion profiles. Scan time was defined as the elapsed time required for scanning to complete after a slide is loaded into the P1000 and the scanning profile is initiated. Adjudication was performed on any discordant results via two pathologist's review of the original slide. Results were reported

as overall accuracy, sensitivity, specificity, and positive and negative predictive value with respect to atypical squamous cells of undetermined significance (ASCUS) or higher diagnosis (ASCUS+).

## Statistical analysis

Analysis of statistical significance between scanning methods and media types was performed using  $\chi^2$  procedure in MedCalc (version 22.014). Significance between performance metrics was determined by hypothesis testing using a Z test for two proportions.

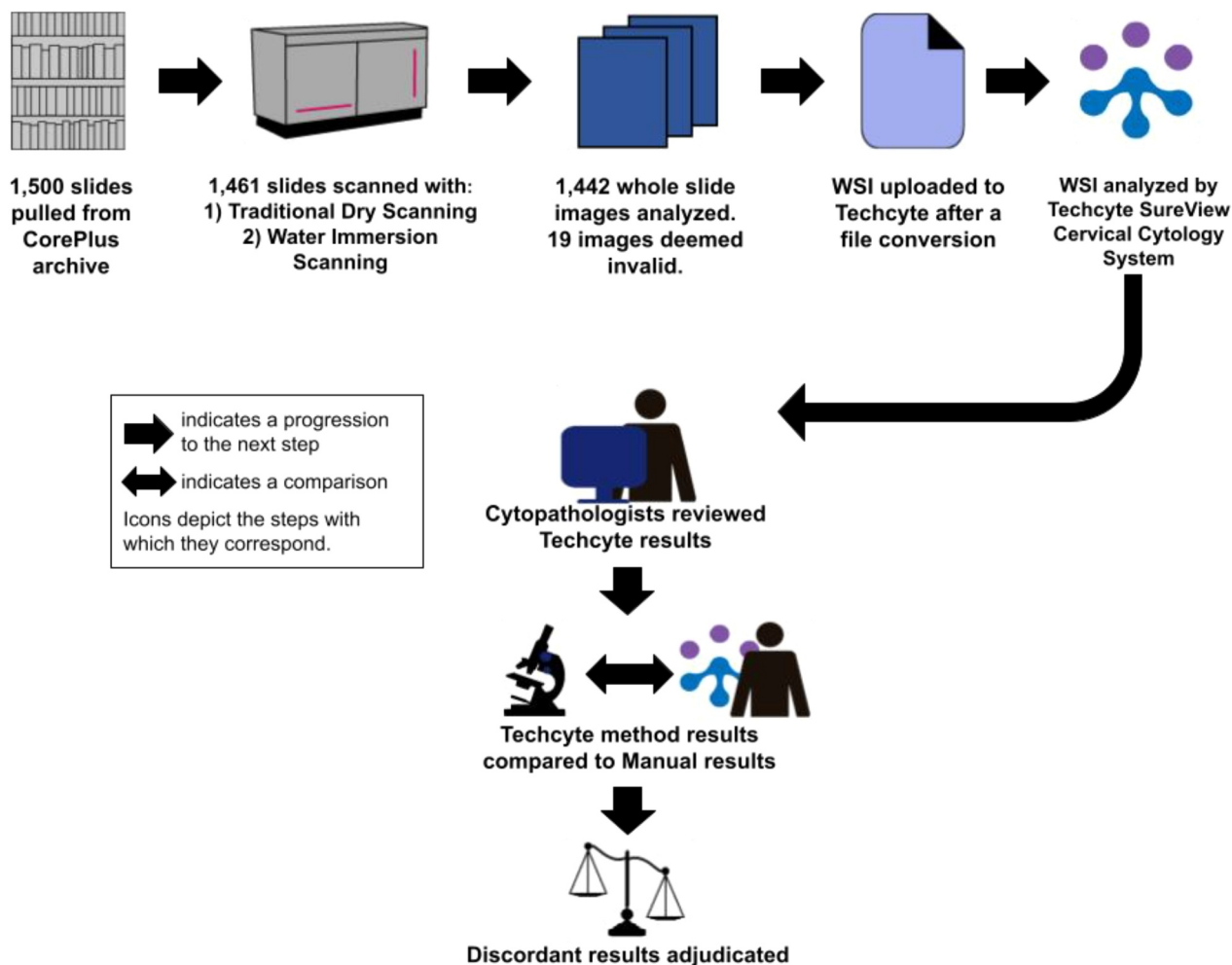
## RESULTS

A total of 1500 WSI were selected from previously reported cases in the CorePlus archive. After an initial quality check, 39 slides were removed due to slides being broken or having coverslip issues, leaving 1461 slides included in the study. Following imaging, an additional 19 slides were excluded due to images invalidated due to focus issues. This resulted in a final analysis of 1442 WSI (Figure 2), comprised of 1273 ThinPrep® and 169 SurePath™ cases.

Scan times varied between slide preparation methods and scanning profiles (Table 2). The scan time using water immersion was one-third of the time required for traditional dry scan for both preparation types. This reduction in time is partly due to the three layers of scanning required to create the composite image using extended depth of focus. SurePath™ file sizes were approximately 50% of ThinPrep® file sizes, with no significant difference between traditional dry and water immersion files sizes for either preparation method. A cytopathologist using Techcyte SureView™ averaged 1 min and 52 s to review the objects of interest per case.

The performance of Techcyte SureView™ was evaluated versus the manual process with the results categorized as normal or abnormal (ASCUS+). Table 3 shows that the water immersion scan with adjudication achieved higher accuracy (97%,  $p < .0001$ ), sensitivity (82%,  $p < .0001$ ), specificity (99%,  $p = .0187$ ), positive predictive value (PPV) (86%,  $p = .0018$ ), and negative predictive value (NPV) (98%,  $p < .0001$ ) compared to the reference method. Further analysis shows the comparison of the algorithm's results and the ground truth has a  $\kappa$  value of 0.82, indicating a high level of agreement.<sup>21</sup> Interestingly, sensitivity, PPV and  $\kappa$  agreement increase dramatically when water immersion is used compared to traditional dry scan. Chi-square analysis indicates that the water immersion with adjudication scan profile is significantly different than the dry scan adjudicated profile (Table 3).

Table 4 displays the distribution of results comparing Techcyte SureView™ with the reference method. Gray boxes represent unity, whereas white boxes with numbers show deviations. In the ASCUS+ analysis, no major discrepancies were found. There were 19 cases where ASCUS was reported using Techcyte SureView™ but were classified as negative for intraepithelial lesion or malignancy (NILM) by the reference method, and the 24 NILM and two



**FIGURE 2** Study workflow and design.

**TABLE 2** Average scan time and file size comparison.

| Preparation | Dry scan time (m:ss) | Water scan time (m:ss) | Dry file size (MB) | Water file size (MB) |
|-------------|----------------------|------------------------|--------------------|----------------------|
| ThinPrep®   | 7:51                 | 2:40                   | 825.92             | 764.30               |
| SurePath™   | 3:28                 | 1:07                   | 443.888            | 412.87               |

**TABLE 3** The results of Techcyte SureView™ using two scan profiles.

| Metric      | Dry scan with adjudication (95% CI) | Water immersion scan with adjudication (95% CI) | Difference between dry and water immersion scan, <i>p</i> -value |
|-------------|-------------------------------------|-------------------------------------------------|------------------------------------------------------------------|
| Accuracy    | 93 (0.92–0.94)                      | 97 (0.96–0.98)                                  | <.0001                                                           |
| Sensitivity | 53 (0.46–0.58)                      | 82 (0.77–0.87)                                  | <.0001                                                           |
| Specificity | 98 (0.97–0.98)                      | 99 (0.98–0.99)                                  | .0187                                                            |
| PPV         | 69 (0.61–0.77)                      | 86 (0.8–0.9)                                    | .0018                                                            |
| NPV         | 95 (0.94–0.96)                      | 98 (0.98–0.99)                                  | <.0001                                                           |
| $\kappa$    | 0.56 (0.48–0.63)                    | 0.82 (0.76–0.87)                                | n.d.                                                             |

Note: Overall  $\chi^2$  statistic = 30.943; *p* value = <.0001; *df* = 3.

Abbreviations: CI, confidence interval; n.d., not done; NPV, negative predictive value; PPV, positive predictive value.

**TABLE 4** Results among the diagnostic groups for the water immersion scan profile after adjudication.

| AI-assisted diagnosis | Ground truth cytologic diagnosis |      |       |     |       |      |      |     |
|-----------------------|----------------------------------|------|-------|-----|-------|------|------|-----|
|                       | UNSAT                            | NILM | ASCUS | AGC | ASC-H | LSIL | HSIL | SCC |
| UNSAT                 | 7                                | 20   | 2     |     |       |      |      |     |
| NILM                  | 1                                | 1257 | 24    |     |       |      |      |     |
| ASCUS                 |                                  | 19   | 65    |     |       | 14   |      |     |
| AGC                   |                                  |      |       | 2   |       |      |      |     |
| ASC-H                 |                                  |      | 1     |     | 2     |      |      |     |
| LSIL                  |                                  |      |       |     |       | 25   |      |     |
| HSIL                  |                                  |      |       |     | 1     |      | 2    |     |
| SCC                   |                                  |      |       |     |       |      |      | 0   |

Note: Shaded cells indicate unity between AI-assisted diagnosis and ground truth cytologic diagnosis.  
Abbreviations: AGC, atypical glandular cells; ASC-H, atypical squamous cells, cannot rule out high-grade squamous intraepithelial lesion; ASCUS, atypical squamous cells of undetermined significance; HSIL, high-grade squamous intraepithelial lesion; LSIL, low-grade squamous intraepithelial lesion; NILM, negative for intraepithelial malignancy; SCC, squamous cell carcinoma; UNSAT, unsatisfactory.

**TABLE 5** Proportion of diagnoses by media type.

| Media     | UNSAT | NILM | ASCUS | AGC | ASC-H <sup>a</sup> | LSIL | HSIL | SCC | Total |
|-----------|-------|------|-------|-----|--------------------|------|------|-----|-------|
| ThinPrep® | 8     | 1138 | 85    | 2   | 3                  | 35   | 2    | 0   | 1273  |
| SurePath™ | 0     | 158  | 7     | 0   | 0                  | 4    | 0    | 0   | 169   |
| Total     | 8     | 1296 | 92    | 2   | 3                  | 39   | 2    | 0   | 1442  |

Abbreviations: AGC, atypical glandular cells; ASC-H, atypical squamous cells, cannot rule out high-grade squamous intraepithelial lesion; ASCUS, atypical squamous cells of undetermined significance; HSIL, high-grade squamous intraepithelial lesion; LSIL, low-grade squamous intraepithelial lesion; NILM, negative for intraepithelial malignancy; SCC, squamous cell carcinoma; UNSAT, unsatisfactory.

<sup>a</sup>Cannot rule out HSIL.

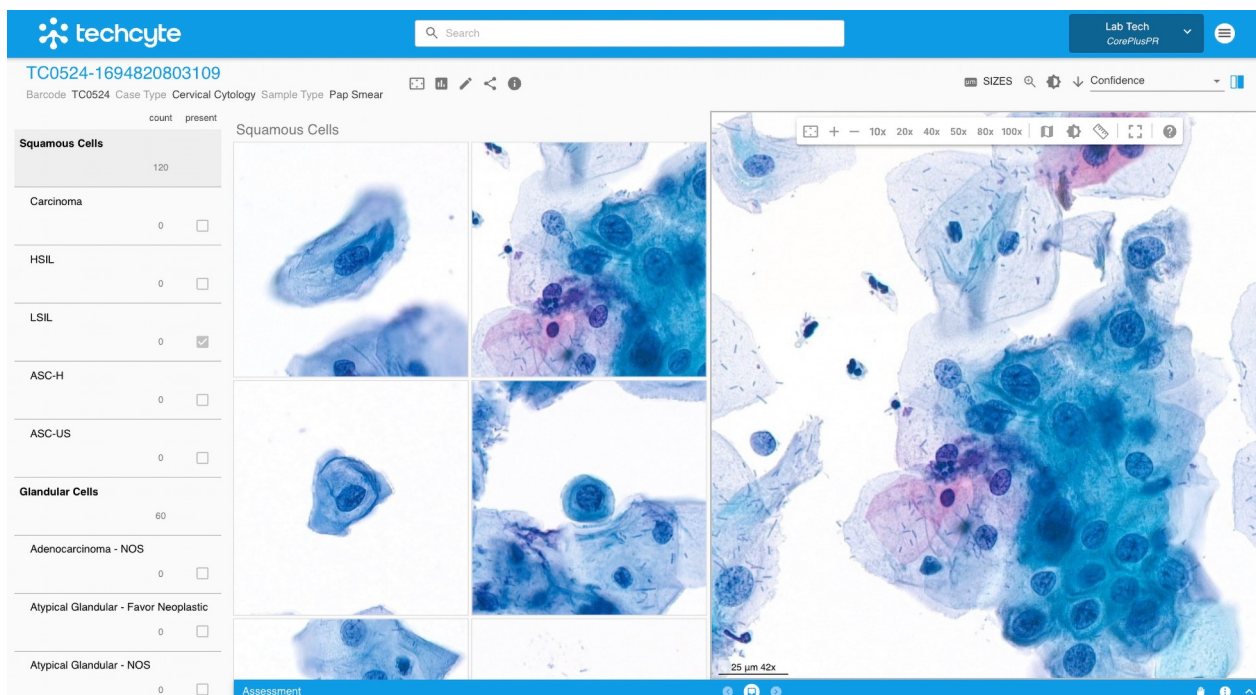
unsatisfactory reported using Techcyte SureView™ that were classified as ASCUS by the reference method. The proportion of each diagnosis between SurePath™ and ThinPrep® and SurePath™ is shown in Table 5. Although there were only 169 samples tested with SurePath™ whereas 1273 were tested by ThinPrep®, a  $\chi^2$  test between results of each compared to the reference method showed no statistical difference ( $\chi^2 = 2.680$ ,  $df = 3$ ,  $p = .446$ ) indicating that the performance with the two media were similar. Data not shown.

DISCUSSION

DP and AI are revolutionizing surgical pathology by enhancing diagnostic accuracy through identification of subtle patterns and features that might be missed by human eyes. These technologies also improve efficiency by automating routine tasks, ensure consistency by reducing human subjectivity, and assist pathologists with diagnostic, predictive and prognostic analysis. However, the adoption of DP and AI in cytopathology has been slower. According to a recent survey by the American Society of Cytopathology (ASC) Digital Cytology Task force, although 61% of respondents scan surgical pathology slides, only 41% scan cytology slides.<sup>22</sup> This slower uptake is partly due to variability of pre-analytical steps such as handmade

smears, cytospin, or liquid- based cytology techniques, which produce differences in the size, density, and thickness of cellular material.<sup>20</sup> These differences challenge digital scanning, often resulting in poor image quality. Although Z-stacking, which captures images across multiple layers, can address thickness variability, it significantly impacts scan time and increases file size. Additionally, some digital scanners lack Z-stacking capabilities. From this survey the largest number of requested improvements in digital cytology was in scanning technology (72.5% of respondents) and digital slide image quality (63.3% of respondents). Other barriers include interoperability with existing equipment and workflows, as well as the need for training and expertise.

Techcyte SureView™ is an AI platform designed to assist cytologists and cytopathologists in reviewing cervical cytology slides. It identifies and presents diagnostically relevant objects within WSI of cervical cytology slides prepared using BD SurePath™ or Hologic ThinPrep® methods (Figure 3). The platform is scanner agnostic compatible with both multilayer composite images and single layer images from many scanners including the 3DHitech Panoramic 1000DX scanner (this publication). The algorithm was trained using a deep learning, convolutional neural network model with diagnostically relevant objects identified and labeled by expert cytologists and cytopathologists. Within the Techcyte SureView™ user interface,



**FIGURE 3** Techcyte SureView™ user interface from a previous version (V3) of the system that was used within this study. The user interface shows the categories of objects for user classification on the left. Objects in each category are shown in the center as a gallery and a view of the entire whole slide image is shown in the larger image on the right.

users classify objects into diagnostic categories, according to The Bethesda System for Reporting Cervical Cytology, supporting workflows for primary, secondary (including rescreening), and pathologist reviews. Additionally, microorganisms including yeast such as *Candida spp.* and bacteria such as *Actinomyces spp.* and *Lactobacillus* are readily apparent for comment.

To transition our cytology laboratory workflow to incorporate DP and AI similar to our surgical pathology processes, we considered a modified cytology workflow. Assessing slide preparation methods, optimizing digital scanning time and digital scanning profiles to create a WSI, determining file sizes, evaluating image quality, and measuring review efficiency for cytologist and cytopathologist were evaluated. In particular, it was important to include both primary slide preparation methods, ThinPrep® and SurePath™ because the techniques differ substantially.<sup>15,23,24</sup> Compared to the reference method of a standard manual microscope review workflow, the modified approach maintained diagnostic performance and increased productivity.

Importantly, this study addressed a fundamental challenge in digital cytopathology: obtaining an adequate scan image. The digital scanning workflow used the 3DHistech Panoramic 1000 DX scanner, known for its high throughput and high resolution, capable of producing WSIs in various formats. A key feature is its water immersion scanning, which enhances image clarity by matching the refractive index of water (1.33) with cellular structures, reducing light scattering. Using water as a medium requires the water immersion scan objective to have a higher numerical aperture for high resolution and detailed imaging capable of minimizing spherical aberrations and optical distortions, making it ideal for thick tissue sections and cell clusters.

Because of these advantages, water immersion scan images achieve higher resolving power compared to dry objectives. Although both water immersion and dry objectives share the same micrometer-per-pixel resolution, the higher NA of the water immersion objective produces a crisper image, resulting in superior performance in this study.

Water immersion scanning demonstrated significant improvements in workflow efficiency and output quality compared to the multilayer dry scanning method used. Specifically, scan times were reduced by 66% for ThinPrep® and 68% for SurePath™ slides, with an 8% reduction in file size for each. Despite these faster scans and smaller file sizes, performance was superior in each slide preparation method, as evidenced by higher clinical sensitivity, PPV, and overall accuracy. Both scanning profiles facilitated the high-volume scanning of Pap test slides throughout the day, enhancing laboratory workflow without additional steps.

In addition to these benefits, another notable improvement observed in this study was the average review time. For Techcyte SureView™, the review time was 62% shorter than the reference method, indicating significant time savings for laboratories and potentially increasing the number of cervical cytology samples examined within a single workday. This efficiency is partly due to Techcyte SureView™ enabling cytologists and cytopathologists to examine hundreds of selected images daily through a viewer, rather than manually reviewing tens of thousands of individual cells through a microscope.

Furthermore, Techcyte SureView™ with the water immersion scan profile demonstrated results consistent with the reference method, with most discrepancies occurring in the NILM and ASCUS

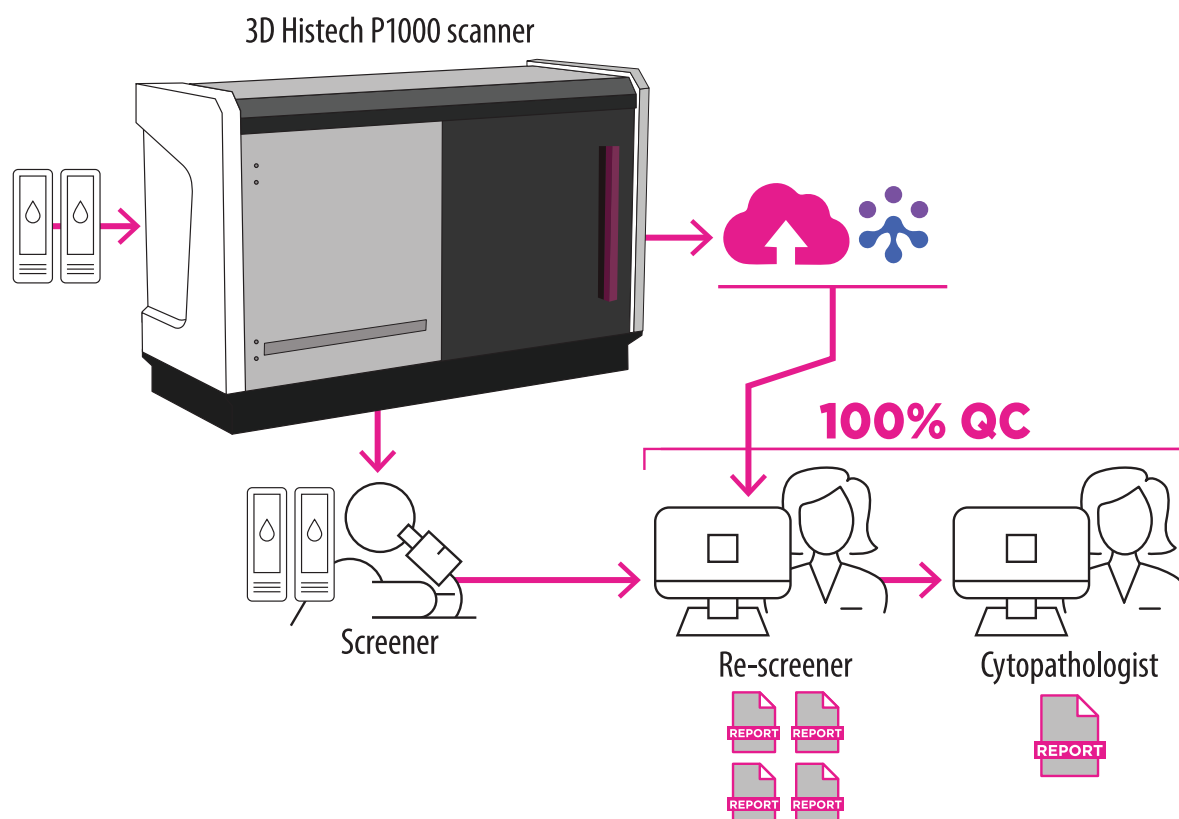
categories. Differentiating between ASCUS and NILM in cytology is challenging due to the subjective nature and inconsistent application of the ASC category, as well as low interobserver and intraobserver reproducibility.<sup>25</sup> Importantly, no significant diagnoses were misclassified into a lower category using Techcyte SureView™. In cervical cytopathology, the primary objective is detecting potential cancerous and pre-cancerous cells, making clinical sensitivity and NPV crucial to avoid false negatives. In this study Techcyte SureView™ achieved an NPV of 98% with a clinical sensitivity in the context of water immersion scanning at 82% (95% CI, 0.77–0.87). This performance suggests the new method effectively avoids false negatives, with the calculated  $\kappa$  statistic indicating almost perfect agreement with the reference method.<sup>21</sup>

The described workflow has enabled CorePlus to integrate Techcyte SureView™ into its digital cytopathology process, ensuring 100% quality control (QC) of all cytology slides (Figure 4). Initially, a cytologist screener reviews the slides using microscopy. These slides are then scanned using water immersion scanning to produce WSIs. All WSIs are subsequently reviewed by a cytologist supervisor or a cytopathologist using Techcyte SureView™. Atypical results are forwarded to a cytopathologist, who examines the WSI with Techcyte SureView™. This process as described ensures that 100% of the slides undergo QC. Techcyte SureView™ helps identify false

negatives and reduces variability between cytologists and cytopathologists, streamlining the workflow for the cytopathologist. This level of QC far exceeds the 10% random review requirement of negative and high-risk cases required by the Clinical Laboratory Improvement Amendments in the United States.

Finally, Techcyte SureView™, combined with digital pathology and WSI, provides educational opportunities that traditional pathology cannot. By minimizing result variability, the algorithm highlights objects of interest and their context needing further review by laboratory professionals. AI integration into educational settings allows professionals to present AI-assisted results and perform various administrative and educational tasks, such as creating personalized educational materials. These tools are beneficial for training new cytologists and cytopathologists and for continuous process improvement.

In conclusion, this study highlights the transformative potential of digital cytopathology and AI in enhancing laboratory workflows and performance. Given the anticipated disparity between the demand for pathologists and the available supply,<sup>26</sup> enhancing productivity per pathologist through the implementation of technologies such as DP and AI may be essential in mitigating this shortfall. The integration of digital cytopathology and AI algorithms significantly improves diagnostic accuracy and operational efficiency. Although achieving QC of



**FIGURE 4** Digital cytology workflow for 100% quality control. Cytology slides prepared by ThinPrep® or SurePath™ are first digitized with a custom water immersion profile and uploaded to the Techcyte SureView™ system. Glass slides are first screened under a microscope by a screener. A re-screener reviews the results of all scans in the Techcyte SureView™ and compares the results to that of the screener. Any atypical results are reviewed by a cytopathologist in the Techcyte SureView™ system and final results are rendered.

even 10% of cases is a challenging benchmark in cytopathology for many laboratories, this study demonstrates that the implementation of Techcyte SureView™ has enabled an unprecedented 100% QC of cases. This integration promises immediate benefits for both laboratory professionals and patients alike by ensuring high accuracy and reliability of test results, facilitation of early error detection and enhancement of patient safety and laboratory reputation. As the field progresses, further advancements in performance and productivity are expected, motivating more laboratories to adopt DP and AI into their workflows. Continued evolution in this field is anticipated to drive further improvements in laboratory workflows.

## AUTHOR CONTRIBUTIONS

**Maria del Mar Rivera Rolon:** Conceptualization, validation, investigation, methodology, and writing—review and editing. **Erik Gustafson:** Formal analysis, writing—original draft, and writing—review and editing. **Riley Cole:** Writing—original draft and writing—review and editing. **Jaylene Matos:** Validation, investigation, data curation, and methodology. **Kellie Hicken:** Writing—review and editing. **Jacob Hicks:** Writing—review and editing. **Brian Cahoon:** Writing—review and editing and resources. **Mariano de Socarraz:** Conceptualization, writing—review and editing, and resources. **Juan Carlos Santa-Rosario:** Conceptualization, investigation, methodology, writing—review and editing, and supervision.

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## CONFLICT OF INTEREST STATEMENT

Juan Carlos Santa-Rosario discloses travel, speaking, and lecture fees paid by Eprexia and a financial relationship with Techcyte that may include equity or stocks. Mariano de Socarraz discloses a financial relationship with IBEX and Techcyte that may include equity and stocks. Brian Cahoon reports equity and stocks with Techcyte. Jacob Hicks reports equity and stocks with Techcyte. Riley Cole reports equity and stocks with Techcyte. Kellie Hicken reports equity and stocks with Techcyte and travel reimbursement from Techcyte. The other authors declare no conflicts of interest.

## DATA AVAILABILITY STATEMENT

All data generated or analyzed during this study are included in this published article and its supplementary information files.

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