Evaluation of the *Ai5 Lab Module* for reading routine *urine cultures* in a public clinical setting

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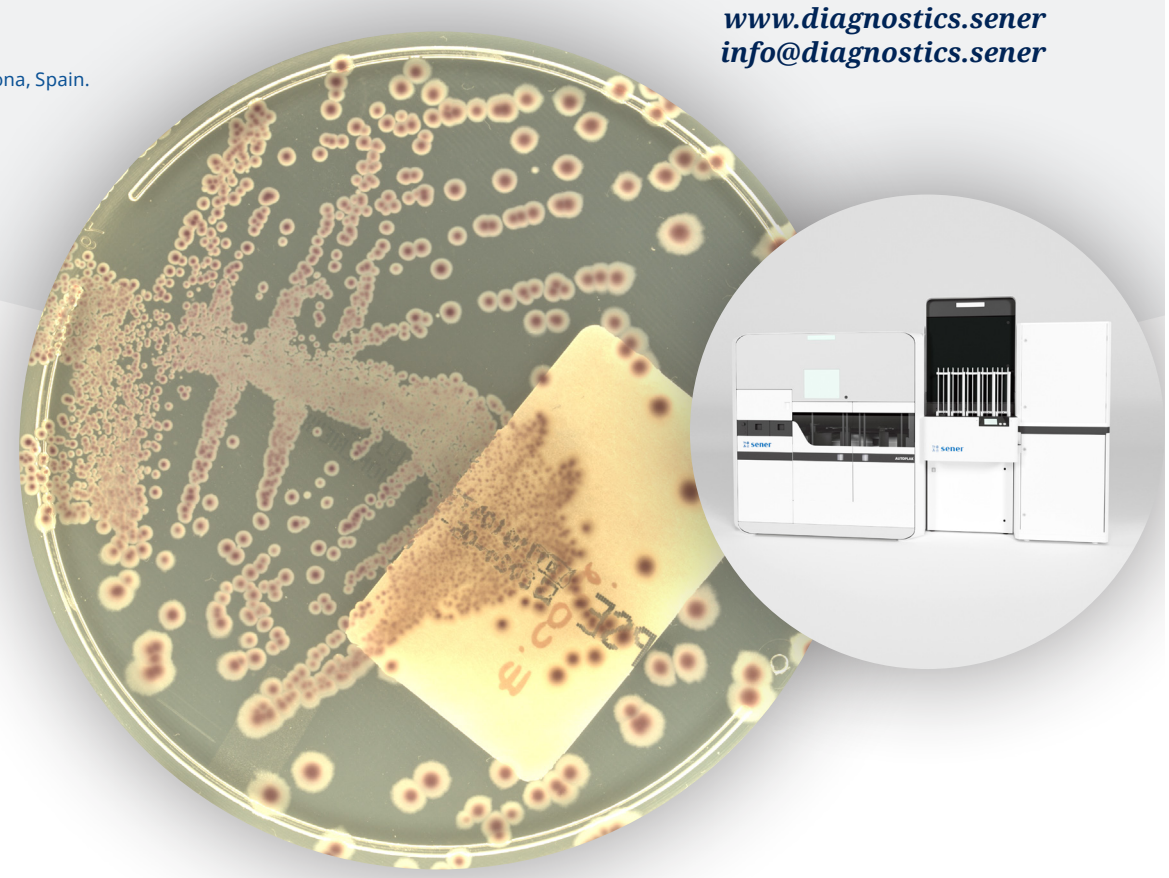

Context

The microbiological analysis of urine samples is essential for diagnosing and treating urinary tract infections (UTIs), which are common globally. Traditionally subjective, this process can affect diagnostic accuracy and treatment initiation. Technological advances, including artificial intelligence (AI), promise to improve analysis efficiency.

This study evaluates an AI algorithm designed to identify bacterial growth and *Escherichia coli (E. coli)* presence in urine samples incubated with the Sener Ai5 Lab system.

Its goal is to improve diagnosis accuracy, providing healthcare professionals with a reliable tool to detect UTIs and reduce the daily workload. It may help to focus efforts on pathological samples and rule out rapidly the negative ones.

Method

A thousand urine samples were collected from patients across various hospital units and sent to the laboratory for analysis. Following a strict urine culturing protocol, these samples underwent meticulous processing. Microscopic examinations, including urine sediment analysis and Gram staining, were conducted to ensure proper collection, ascertain their quality, and determine if they met the criteria for further culturing, specifically assessing for pyuria and the presence of microorganisms.

Upon completion of these preliminary steps, the samples were then inoculated with 10 µL of urine onto chromogenic media (CHROMID® CPS® Elite, manufactured by Biomérieux). Subsequently, they were incubated overnight at a temperature range of 35 to 37ºC. This media facilitated swift and dependable isolation, as well as direct identification of *E. coli*, streamlining the diagnostic process.

Afterwards, three separate but interconnected assessments were conducted:

1. The clinical growth significance was evaluated by an experienced microbiologist as part of their routine laboratory duties. In instances of uncertainty, supplementary tests such as MALDI-TOF were conducted. Additionally, antibiotic susceptibility testing was carried out. Subsequently, the clinical report was compiled and submitted.
2. Upon validation of the samples, a secondary control check was conducted. Another microbiologist examined the plates to determine the presence or absence of growth and whether the observed colonies were *E. coli* or not. All pertinent data was meticulously recorded in a spreadsheet.
3. Photographs of the CPS® agar were captured utilizing the Main Image technology, and the algorithm's maturity was evaluated by running it. Furthermore, the algorithm underwent assessment against the routine results obtained from the double control check performed in the laboratory.

Performance evaluation

The results were categorized into either microorganism-positive or negative growth. Upon detecting positive growth, the presence of *E. coli* was assessed. In cases of uncertainty, the IA algorithm produced a "not sure" result.

Both the algorithm and microbiologists identified true positive growth in 847 samples, demonstrating a **sensitivity of 100%**. Furthermore, true negative growth was observed in 68 samples, while 12 false positive results were noted, resulting in a **specificity of 85%** (Table 1).

In terms of *E. coli* evaluation, there was a true positive result in 355 samples, with 9 false negative results, showing a **sensitivity of 97.53%**. Moreover, true negative results were observed in 609 samples, whereas 11 false positives were noted, resulting in a **specificity of 98.23%**. Sensitivity and specificity values are shown in Table 1.

Sensitivity/Specificity values:

	Sensitivity (%)	Specificity (%)	Number of Samples
Microorganism growth	100%	85%	927*
E. coli presence	97.53%	98.23%	984*

Table 1: Sensitivity/Specificity rates
****" Not sure" results delivered by the IA algorithm were excluded.***

Moreover, the algorithm delivered 89 "not sure" results: 10 (11.23%) of these were identified as true colony growth by both microbiologists, while the remaining 63 (70.78%) were determined by both experts to be true absence of growth. In terms of *E. coli*, 9 (10.11%) were confirmed and identified as true *E. coli* colonies, whereas 7 (7.86%) resulted in colonies different from *E. coli* according to the experts.

Predictive values:

	NPV (%)	PPV (%)	Number of Samples
Microorganism growth	100%	98.60%	927*
E. coli presence	98.54%	96.99%	984*

Table 2: Predictive values
****" Not sure" results delivered by the IA algorithm were excluded.***

Regarding the predictive values (Table 2), it can be inferred that if the algorithm fails to detect microorganism growth, the CPS plate could be discarded, thereby reducing the workload. Moreover, when the IA algorithm identifies the presence of *E. coli*, the sample should be treated as a potential urinary tract infection (UTI).

Conclusion

The technology demonstrates a remarkable level of agreement, reliability, and consistency in detecting both microorganism growth and the presence of *E. coli*.

It exhibits an excellent ability to discern non-significant urine cultures without the need for an experienced microbiologist. Furthermore, it achieves a perfect level of *E. coli* identification when present in urine cultures.

In conclusion, the technology and algorithm prove to be exceptionally easy to operate and represent valuable tools for consideration in the microbiologist's daily workflow. Their accuracy suggest potential for streamlining processes and enhancing efficiency in laboratory procedures.

This study has been approved by the Clinical Research Ethics Committee of the Institut de Recerca de l'Hospital de la Santa Creu i Sant Pau – IIB Sant Pau (expedient number: IIBSP-SEN-2023-137).