Evaluation of the *Ai5 Lab Module* for *continuous reading routine* in a public clinical setting – MRSA case

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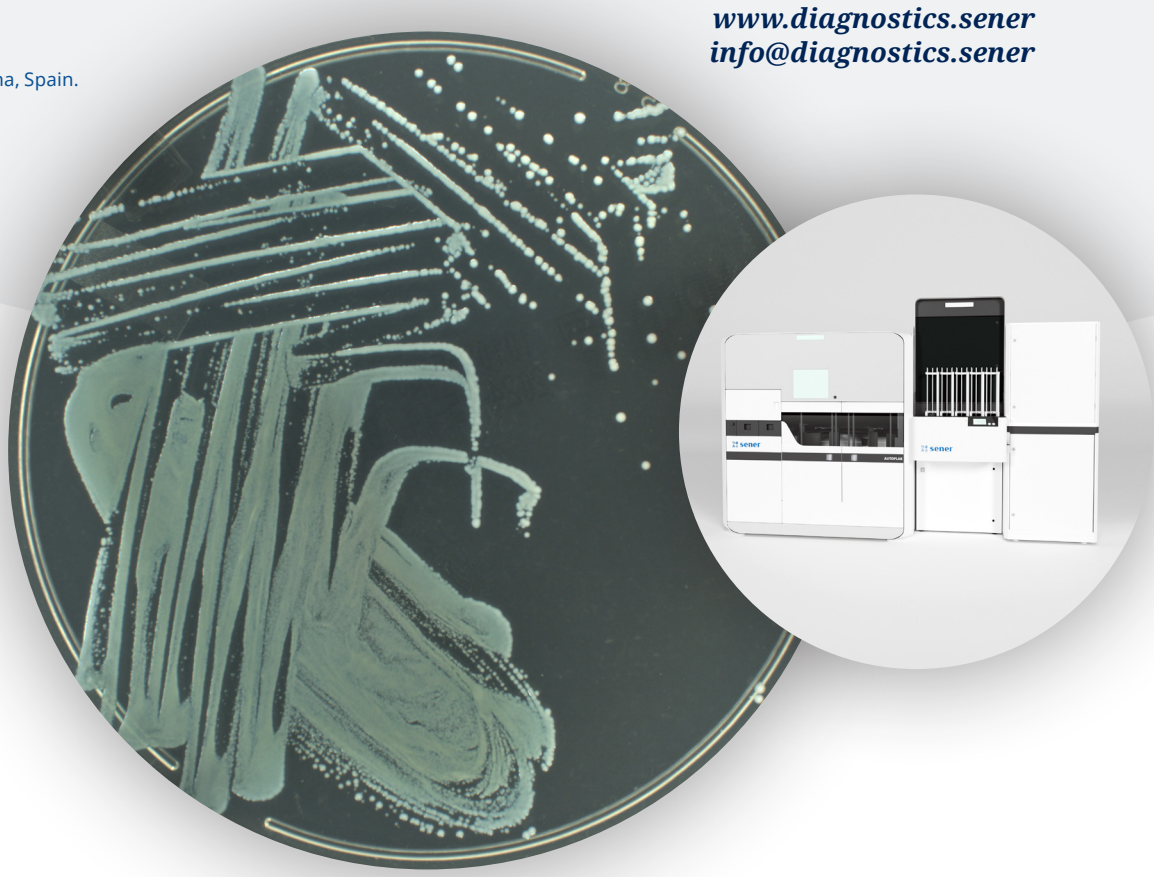


Context

The implementation of an intelligent incubator equipped with a continuous monitoring system for microbiological growth represents a significant advance in the management of clinical microbiology laboratories. This innovative device integrates two imaging systems: one primary and another secondary specifically designed for constant monitoring of sample growth during incubation. This capability for early and automated detection of microbial growth allows for a dual-protocol management based on both time and growth, contrasting with the traditional method focused solely on time.

In this context, **the paper focuses on the evaluation and analysis of an artificial intelligence (AI) algorithm used in the secondary imaging system, highlighting its effectiveness in early detection of microbial growth and the potential to improve efficiency in managing emergencies in clinical laboratories.**

Method

Fifty-seven nasal smears were collected from patients at the hospital and sent to the laboratory for its analysis. Following the nasal smear culturing protocol, the samples were processed to find out if patients were carriers or not of methicillin-resistant *Staphylococcus aureus* (MRSA). It is important to conduct this active search in order to prevent nosocomial outbreaks. Chromogenic media (chromID™ MRSA, manufactured by Biomérieux) was used to facilitate growth and direct identification of MRSA with green colored colonies resulting from alpha-glucosidase activity in the presence of cefoxitin antibiotic.

Afterwards, the following assessments were conducted:

1. The samples were inoculated in duplicate by seeding the swab on the agar. Firstly, the plate was incubated in a conventional heater for 18 to 24 h at a temperature range of 35 to 37ºC (*gold standard*). Secondly, another plate was incubated for the same number of hours and temperature but inside of the intelligent incubator equipped with a continuous monitoring system.
2. The plate inside the conventional heater had readings every 2 h by a microbiologist, whereas the one inside the continuous monitoring system, pictures were taken every 15 minutes
3. As part of the routine laboratory duties, the growth significance was further evaluated in terms of:
   a. Time-based protocol: after the incubation protocol, morphology and color were analyzed. Every single photo was evaluated by the microbiologist to detect inoculum or colony-forming unit (CFU) growth. In case of uncertainty, supplementary tests such as MALDI-TOF were conducted.
   b. Growth-based protocol: Time saved by using continuous monitoring was calculated by the experts. In addition, the AI algorithm prediction was evaluated against the microbiologist criteria.
4. All data from the duplicate but parallel study was recorded and analyzed in a spreadsheet. Furthermore, the report was performed.

Performance evaluation

Time-based protocol

The sample growth results were obtained by comparison between the microbiologist criteria versus the AI algorithm prediction (Table 1). Both of them identified as true positive growth 31 nasal smears, demonstrating a **100% sensitivity**. Furthermore, 24 of the 31 positive nasal smears had MRSA presence, whereas the remaining 7 had other growth different from MRSA.

In addition, true negative growth was observed in 12 nasal smears, while 14 false positive results were noted, resulting in a **specificity of 46.15%**. These false positive results could be explained due to artifacts in the culture plates such as bubbles in the agar or condensation droplets which could lead to reasonable confusion. Zero false negatives were observed.

Microorganism growth								
	AI algorithm prediction		Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Samples	Accuracy
Micro-biologist criteria	Growth	No growth	100%	46.15%	68.88%	100%	57	75.43%
Growth	31	0						
No growth	14	12						

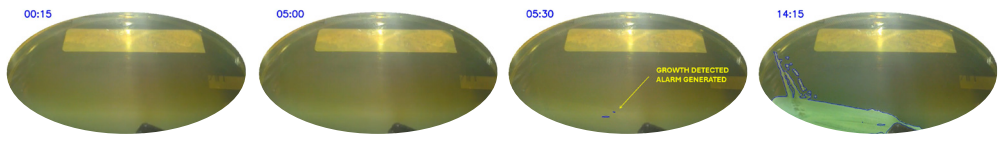
Table 1. Contingency table comparing microorganism growth between the AI algorithm versus the microbiologist criteria. PPV: Positive predictive value. NPV: negative predictive value.

Regarding the sensitivity and negative predictive value, it can be inferred that the algorithm is able to detect 100% of microorganism growths with none false negatives, helping to early detection of microbial growth and improving the management in clinical laboratories. The total accuracy of the study was 75.43%. Cohen's kappa coefficient was 0.482 showing a moderate strength of agreement.

Growth-based protocol: Continuous monitoring

The continuous monitoring technology needed an average of **8.3 h** to detect sample growth in contrast to the 10.7 h needed with the protocol based on readings every two hours. Additionally, the continuous monitoring protocol represented a significant time saving versus the *gold standard* based solely on time with incubation periods from 18 to 24 h.

So, it can be concluded that the continuous monitoring system allowed a shortening time of diagnosis between 9 and 15 h.



Images from the continuous monitoring system since the start of incubation until growth detection.

Conclusion

The technology based on both time and growth demonstrates an excellent ability to detect microorganism growth significantly earlier than the microbiologist thanks to its continuous monitoring system. This allows the microbiologist to optimize the diagnosis time, stablish rapid isolation measures when MRSA is present and also prevent from nosocomial infections.

This new dual protocol - continuous monitoring technology could suppose a before and an after in the clinical laboratory sector because it is so easy to operate and a really valuable tool to take into consideration in the daily workflow.

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).