

Evaluation of KWIK-STIK™ for Streamlined Quality Control on the ASStar® System

Natalie Brown¹, Kali Sorum RM(NRCM)², Jenny Göransson¹, Michelle Myers¹, Anna Karman¹, Eva Hell¹

¹Q-linea, Uppsala, Sweden. ²Microbiologics, St Cloud, Minnesota, US.

Background

ASStar® (Q-linea) is a fully automated, rapid phenotypic Antimicrobial Susceptibility Testing (AST) system that delivers Minimum Inhibitory Concentrations (MICs) and categorical interpretation in ~6 hours, directly from positive blood cultures (1). To ensure consistent performance, ASStar requires routine quality control (QC) testing using either four (FDA panel) or five (IVDR panel) American Type Culture Collection (ATCC) strains (2, 3).

Traditional QC workflows require preparation and maintenance of cryopreserved stock cultures, as well as specialized equipment and storage conditions. KWIK-STIK™ (Microbiologics) is a ready-to-use QC reference material designed to streamline QC workflows (4).

This study evaluated whether a KWIK-STIK-based workflow provides consistent QC performance with the ASStar System.

Conclusions

QC testing of the ASStar System using KWIK-STIK demonstrated excellent agreement with the standard protocol.

Benefits of the KWIK-STIK approach include:

- Eliminating the need for freezer storage of stock cultures
- Reducing hands-on preparation time and specialized equipment requirements
- Stable performance during immediate culture plate usage or short-term storage
- Consistent reproducibility across reagent lots, instruments, and lab testing sessions

KWIK-STIK is a reliable and fully compatible source for the ASStar QC method, offering labs a simplified alternative for generating MIC results compared to the standard protocol, while preserving accuracy and reducing operational burden.

Materials and methods

QC was performed using:

- Four ATCC strains covering all antimicrobials in the ASStar BC G- Kit (FDA panel)
- Five ATCC strains for the ASStar BC G- Kit (IVDR panel)

Each strain was cultured on non-selective agar, prepared from KWIK-STIK lyophilized pellets and from traditional frozen stock cultures. The primary plates were either directly tested in the ASStar System using the QC protocol documented in the ASStar BC G- Kit *Instruction for Use* (5), or were stored at 2–8°C for up to two weeks for later subculturing. (Figure 1.)

- The number of data points was calculated as the number of antimicrobials multiplied by the number of tests
- Performance percentages were calculated as the number of data points passed out of the total number of data points

Strains from ATCC/CCUG

The QC strains were tested in duplicates in each run, from the first or second subculture.

Strains from KWIK-STIK

Each test was performed repeatedly, with each condition evaluated on at least three separate occasions. QC strains were tested in duplicate in each run using the second subculture. These second subcultures were prepared from either one-day-old or seven-day-old master plates.

Testing period: May to December 2024 across multiple ASStar BC G- Kit reagent lots, three KWIK-STIK lots, and different ASStar instruments and testing days.

MIC results from the KWIK-STIK workflow were compared to the standard protocol (ISO 20776-1:2019 and CLSI M07 Edition 12) (6, 7), with agreement defined as ± 1 MIC dilution step.

References

- Göransson, J et al. "Performance of a System for Rapid Phenotypic Antimicrobial Susceptibility Testing of Gram Negative Bacteria Directly from Positive Blood Culture Bottles." *Journal of clinical microbiology* vol. 61.3 (2023): e0152522. doi:10.1128/jcm.01525-22
- American Type Culture Collection (ATCC). <https://www.atcc.org/>
- Culture Collection, University of Gothenburg (CCUG). <https://www.ccug.se/>
- English LYFO DISK, KWIK-STIK, KWIK-STIK Plus Instructions for Use: <https://www.microbiologics.com/English-IVDR-Instructions-for-Use-LYFO-DISK-and-KWIK-STIK>
- ASStar BC G- Kit Instructions for Use: <https://qlinea.com/support-zone/>
- ISO 20776-1:2019 Susceptibility testing of infectious agents and evaluation of performance of antimicrobial susceptibility test devices - Part 1: Broth microdilution reference method for testing the in vitro activity of antimicrobial agents against rapidly growing aerobic bacteria involved in infectious diseases. <https://www.iso.org/standard/70464.html>
- CLSI, Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically, 12th ed. CLSI standard M07 Clinical and Laboratory Standards Institute; 2024. <https://clsi.org/shop/standards/m07/>

Results

The MIC results for each bug-drug combination were evaluated according to the standard procedure. Results were classified as *passed* if MIC values were within the acceptable ranges, and as *failed* if no result was obtained or when MIC values fell outside the acceptable ranges.

Overall, >95% of the results obtained using KWIK-STIK were within ± 1 MIC dilution step of the results generated using the standard frozen stock protocol, meeting criteria defined in ISO 20776-1:2019 and CLSI M07 Edition 12. This was true for all tested antimicrobials in both the FDA and IVDR panels.

Results were consistent and reproducible across ASStar reagent lots, KWIK-STIK lots, instruments, and testing days.

Table 1. Performance of QC strains from ATCC/CCUG (Customer QC panels (EU + US study panel))

ID of reference strain	Source of reference strains	Number of tests	Number of antimicrobials	Number of data points	Passed (n/N)	Failed (n/N)	Performance (%)
<i>E. coli</i> ATCC25922	CCUG	108	13	1,404	1390/1404	14/1404	99.0%
<i>K. pneumoniae</i> ATCC70603	CCUG	105	8	840	837/1404	3/1404	99.6%
<i>P. aeruginosa</i> ATCC27853	CCUG	62	13*	806	804/1404	2/1404	99.8%
<i>S. pneumoniae</i> ATCC49619	CCUG	59	6	354	351/1404	3/1404	99.2%
<i>K. pneumoniae</i> ATCCBAA2814	ATCC	53	1	53	53/1404	0/1404	100%
<i>E. coli</i> ATCC25922	CCUG	108	13	1,404	1390/1404	14/1404	99.0%

*ERT US, COL EU (total 13 antimicrobials)
CCUG: Culture Collection, University of Gothenburg
ATCC: American Type Culture Collection

Table 2. Performance of QC strains from KWIK-STIK (Customer QC panels (EU + US study Panel))

ID of reference strain	Number of KWIK-STIK lots tested	Number of tests	Number of antimicrobials	Number of data points	Passed (n/N)	Failed (n/N)	Performance (%)
<i>E. coli</i> ATCC25922	3	25	13	325	321/325	4/325	98.8%
<i>K. pneumoniae</i> ATCC70603	4	19	8	152	151/325	1/325	99.3%
<i>P. aeruginosa</i> ATCC27853	4	14	13*	182	181/325	1/325	99.5%
<i>S. pneumoniae</i> ATCC49619	4	17	6	102	102/325	0/325	100%
<i>K. pneumoniae</i> ATCCBAA2814	2	14	1	14	14/325	0/325	100%

*ERT US, COL EU (total 13 antimicrobials)

Experimental design

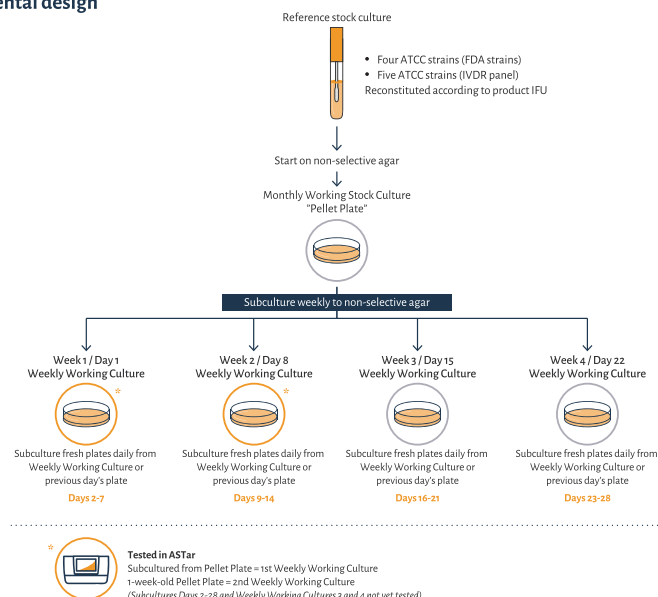


Fig 1. Experimental design.