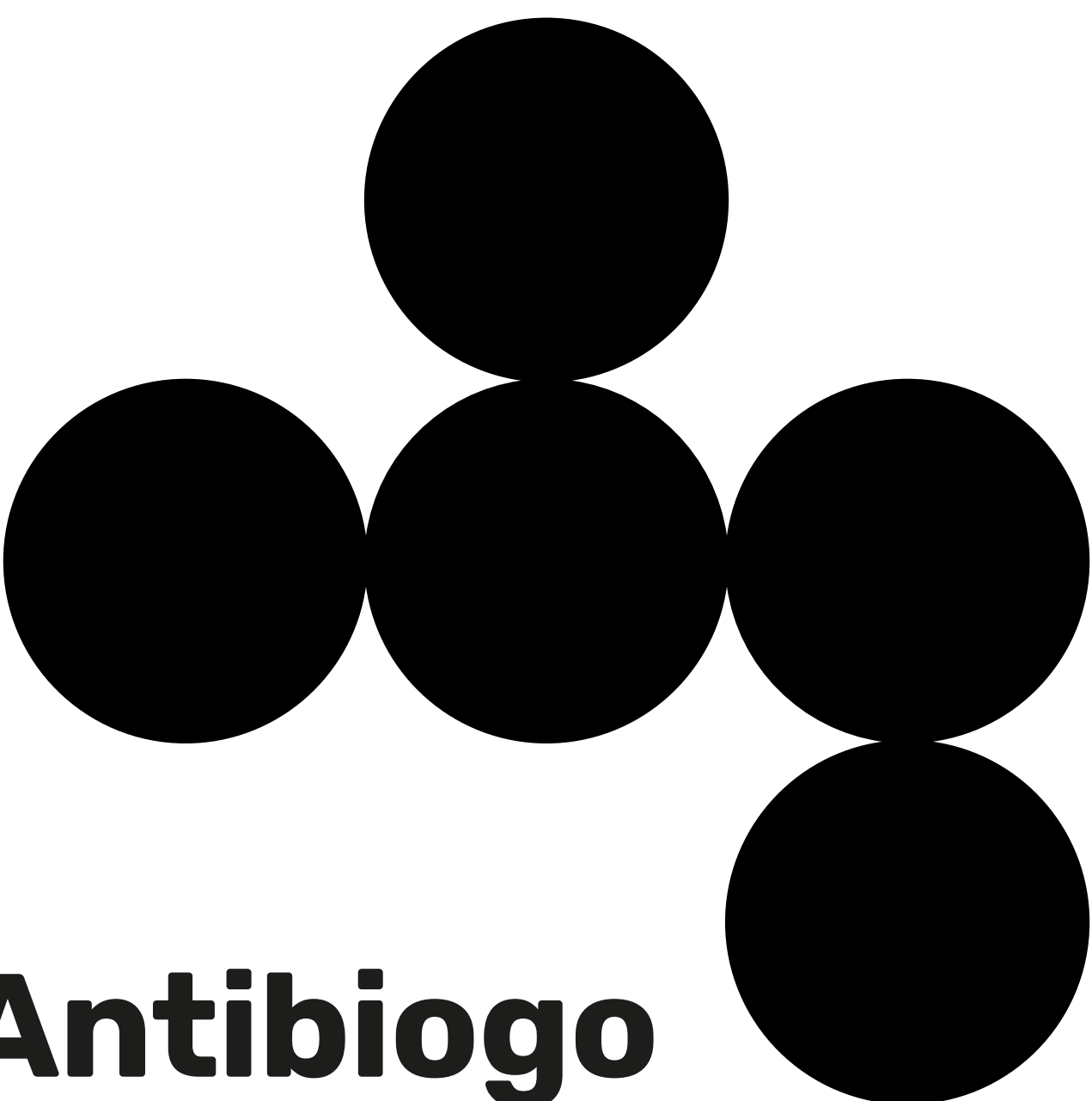



Antibiogo

User manual

In Vitro Diagnostic
Medical Device

IVD

**V10 - 27/07/2026 - Electronic version (no paper version available)
For v2.5 of Antibiogo with Eucast 2026**

History of changes

Page	Description of changes
<u>p3</u>	VERSION - AntibioGo v2.5 with updated 2026 Eucast guidelines
<u>p4-5</u>	INTRODUCTION TO ANTIBIOGO - Additional information about the language of the Intended Users of AntibioGo
<u>p5-7</u>	TEST PRINCIPLE - Eucast SIR definitions updated with MIC request definition
<u>p9-10</u>	WARNING, PRECAUTION AND LIMITATION - Update of the Photo Quality & AST set-up section with additional cleaning instruction regarding the mobile device to optimise photo quality - Update of the Biosafety and Material handling (previously named Biosafety and Specimen handling) section with additional precautions related to mobile device and cardboard photo booth handling
<u>p11-24</u>	OPERATING PROCEDURE / Step by Step guide - First Time Use - Update 'Download the App' section (country selection and metrics sharing consent info) - Step by Step guide - Update the guide with new screenshot according to design changes on the App - Update of the step 7, 8 and 9 to reflect the new user interface navigation - Addition of examples illustrating good and bad practices for IZD adjustment
<u>p29</u>	DATA PRIVACY AND SECURITY - Update Data Privacy section with information on the type of metrics collected
<u>p30</u>	TROUBLESHOOTING & TECHNICAL ASSISTANCE (merging of the 2 old sections) - Addition of troubleshooting guidance related to - camera lens cleaning and image quality - 'Internal App Sharing' setting



Please carefully read this user manual before using Antibiogo.

If you have any questions about Antibiogo, please contact us at support@antibiogo.org or visit: antibiogo.org.

Table of contents

Abbreviations and definitions	3
General information	4
Proprietary Name & Version	4
Introduction to Antibiogo	4
INTENDED USE	4
Type of samples	4
Patient population	4
Intended users	4
VALIDATED BACTERIA	4
ELEARNING TRAINING MODULES	5
Test principle	5
PRESENTATION	5
RESULTS FORMAT	6
SEARCH AND EXPORT RESULTS	7
Requirements	8
MATERIALS REQUIRED BUT NOT PROVIDED	8
AST PREPARATION	8
OPERATION CONDITIONS	8
SHELF LIFE OF ANTIBIOGO	8
SAMPLE COLLECTION, TRANSPORT AND STORAGE	9
Warnings and precautions and limitations	9
INTENDED USE AND USER RESPONSIBILITY	9
DEVICE COMPATIBILITY AND SYSTEM REQUIREMENTS	9
PHOTO QUALITY AND AST SETUP	9
DATA ENTRY AND PATIENT IDENTIFICATION	9
MEASUREMENT AND INTERPRETATION GUIDELINES	10
ANTIBIOTIC DISC AND MEASUREMENT LIMITATION	10
MIC PROCESSING	10
QUALITY CONTROL REQUIREMENTS	10
CLINICAL DECISION-MAKING: ROLES AND RESPONSIBILITIES	10
BIOSAFETY AND MATERIAL HANDLING	10
Operating procedure	11
FIRST TIME USE	11
Set up the photo booth	11
Download the app	12
AST STEP-BY-STEP GUIDE	13
General presentation of Antibiogo's home page	13
Step 1: Create a new AST	13
Step 2: Select the number of Petri dishes and fill in AST information	14
Step 3: Take a photo	15
Step 4: Confirm the photo	15
Step 5: Confirm the number of antibiotic discs	16
Step 6: Add undetected discs	16
Step 7: Confirm the antibiotic name and concentration	17
Step 8: Adjust & Confirm the Inhibition Zone Diameter measurement	18
Step 9: Expert System interpretation	19
Step 10: Review the Summary	20
Step 11a: View Bench sheet	21
Step 11b: View Clinical report	22

Step 12: Save/print/share Bench sheet and Clinical report	23
Optional step : Export logs in case of bug report	24
Final Step : Closing the ANTIBIOGO Application	24
WHONET file upload	25
Quality Controls	25
INITIAL VERIFICATION OF ANTIBIOGO USE	25
INVESTIGATION	25
ROUTINE QUALITY CONTROLS	26
Performance Characteristics	27
ANALYTICAL PERFORMANCE	27
CLINICAL PERFORMANCE	27
Data storage in Antibiogo	29
Uninstallation of the Antibiogo application	29
Data privacy and security	29
DATA PRIVACY	29
DATA SECURITY	29
Troubleshooting & Technical Assistance	30
COMMON ISSUES AND SOLUTIONS	30
CONTACTING SUPPORT	30
REPORTING SERIOUS INCIDENTS	30
References	31

Abbreviations

AMR	Antimicrobial Resistance
App	Antibiogo mobile application
AST	Antimicrobial Susceptibility Testing
EUCAST	European Committee of Antimicrobial Susceptibility Testing
ID	Identifier
IZD	Inhibition Zone Diameter
LMIC	Low and Middle-Income Country
MIC	Minimum Inhibitory Concentration
PDF	Portable Document Format files
SaMD	Software as Medical Device
SOP	Standard Operating Procedure
Caution	Indicates a hazardous situation which, if not avoided, could result in minor or moderate impact
Warning	Indicates a hazardous situation which, if not avoided, could result in serious injury or death

General information

Symbol	Description
	Manufacturer
	<i>In vitro</i> diagnostic medical device
	Consult Instructions for use / User manual https://www.antibiogo.org/support https://www.antibiogo.org/learn
	Fulfil the requirements of Directive 98/79/EC on <i>in vitro</i> diagnostic medical devices
	Caution

Proprietary Name & Version

Antibiogo® - Version 2.5

Introduction to Antibiogo

The development of new antimicrobial agents is currently outpaced by the emergence of new antimicrobial resistance¹ (AMR). The development and diffusion of AMR have become one of the major public health threat² of which the magnitude is not yet fully understood because of the lack of data, especially in areas where access to Antimicrobial Susceptibility Testing is difficult.

In 2019, 1·27 million deaths were attributable to bacterial AMR, high-profile review³ forecasts 10 million deaths worldwide by 2050 if no actions are put in place. These studies underline the critical health burden of AMR and the need for global actions.

Testing the susceptibility of bacteria is important for patient treatment and, if done systematically, gathering data can provide precious epidemiological information. A variety of Antibiotic Susceptibility Tests (AST) are available on the market. However, microbiologists are barely available in resource-limited low- and middle-income countries (LMICs) to interpret the results of ASTs⁴.

Antibiogo, is a qualitative stand-alone mobile device software, supporting the reading and the interpretation of ASTs, aims at providing individual patient treatment benefits and facilitating the collection of epidemiological data on AMR. In doing so, it contributes to the rational use of antibiotics in LMICs, the lack of which is recognized today as a major health danger^{2,5}.

Antibiogo is a CE marked *In Vitro* Diagnostic Software as Medical Device (SaMD) as per the *In Vitro* Diagnostic Directive (IVDD/98/79/CE).

INTENDED USE

Antibiogo is a stand-alone mobile device software application used in conjunction with microbiological culture method intended to aid in the qualitative interpretation of antimicrobial resistance based on EUCAST guideline recommendations.

Antibiogo is an aid to diagnosis performing automated interpretation of Antimicrobial Susceptibility testing using disc diffusion.

Type of samples

Bacteria can be isolated from any clinical sample as listed in Antibiogo software: respiratory aspirate, catheter, central catheter, quality control, swab, wound swab, surveillance swab, cerebrospinal fluid, joint fluid, ascites fluid, pericardial fluid, peritoneal fluid, pleural fluid, bone, pus, blood, tissue, urine, urine catheter, stools, sputum and other.

Patient population

Antibiogo can be used to interpret antimicrobial resistance with samples from any patient presenting with microbiologically confirmed bacterial infection.

Intended users

Antibiogo is intended to be used by laboratory professionals.

The primary intended users are laboratory technicians and any healthcare professionals with experience in preparation and reading of disc diffusion.

Note: AST and standard knowledge of bacteriology good practices as defined in Annex 2 WHO good practices for pharmaceutical microbiology laboratories, N. 961, 2011, 1. Personnel.

Clinicians and general practitioners have access to the Antibiogo results report. The results generated by Antibiogo are intended to provide qualitative Antimicrobial Susceptibility results.

Users must be able to understand at least one of the languages available in the Antibiogo user interface.

VALIDATED BACTERIA

Using **EUCAST** guidelines, Antibiogo is intended to interpret the AST of the following bacteria:

- *Enterococcus Faecalis*
- *Enterococcus spp*
- *Escherichia coli*
- *Klebsiella pneumoniae*
- *Proteus mirabilis*
- *Pseudomonas aeruginosa*
- *Salmonella spp*
- *Staphylococcus aureus*
- *Staphylococcus coagulase negative*
- *Streptococcus pneumoniae*

ELEARNING TRAINING MODULES

Elearning training modules have been developed to support users in the proper use of ANTIBIOGO. While not mandatory, we recommend completing these modules before using AntibioGo to enhance user proficiency and promote consistent use of the software.

The modules are available on the antibiogo.org website, in the 'Learn' section. Don't hesitate to refer to them afterwards, whenever necessary.

These modules cover:

- Introduction to AntibioGo
- Preparing for AST: Photo requirements and photo-booth setup
- Antimicrobial Susceptibility Testing: Getting it right and read it with AntibioGo
- QC for labs
- AntibioGo in depth: Image analysis program and Expert System

Test principle

AntibioGo can be downloaded on an Android mobile device from the Google Play Store app.

AntibioGo can read one AST on one petri dish, or one AST performed with several petri dishes.

PRESENTATION

AntibioGo is a stand-alone mobile device software application and consists of **two major components**:

- **The Image Analysis Program⁶** which is divided into two modules:
 - The first one provided a semi-automatic measurement of Inhibitory Zone Diameters (IZD) around the antibiotic discs from a photo taken with the mobile device camera.
 - The second one identifies antibiotic pellets by reading the printed name and concentration (based on a AI Machine Learning development)

The user **MUST** adjust the proposed diameter measurement, validate name and concentration for each antibiotic disc.

CAUTION: IZD measurement is not automatic. The user MUST always adjust the initial diameter.

To see visual illustrations of measure adjustment, please refer to '**Step 8 - Adjust & Confirm the Inhibition Zone Diameter measurement**' in AST Step by step guide.

- **Expert System:** the Expert System is used for the categorization of pathogens' susceptibility through the application of Disc Diffusion standard EUCAST breakpoints and expert rules compiled in the knowledge base.

The Expert System also:

- applies breakpoints specific to sample type, and provides an interpretation based on the bacteria-antibiotic-sample type combination, when applicable;
- performs coherence checks and flags incoherent interpretations related to uncommon phenotypes;
- identifies non adapted concentration of the tested antibiotics based on guidelines;
- applies expert rules;
- guides the user for identification of resistance mechanisms by asking questions;
- provides warnings when major resistance are identified (ex. carbapenemase);
- suggests the appropriate method of testing when recommended;
- provides informative notes for users (ex. how to manage ATU results as per the guidelines);

The Knowledge base used by our Expert System compiles all EUCAST standard rules and is the same as the one run by the CE-certified SIRxpert® system from i2a Diagnostics, France.

The interpretation results are categorised by comparing the IZD to the breakpoints published by EUCAST as follow (SIR Categorization):

EUCAST Microorganism Categorization		EUCAST Definitions
S	Susceptible, standard dosing regimen	High likelihood of therapeutic success using a standard dosing regimen of the agent.
I	Susceptible, increased exposure	High likelihood of therapeutic success because exposure to the agent is increased by adjusting the dosing regimen and/or by its concentration at the site of infection.
R	Resistant	High likelihood of therapeutic failure even when there is increased exposure.
ABR	Absence of Resistance	Clinical evidence as monotherapy is usually lacking but the agent may still be used for a specific indication or in combination with another active agent or measure.
LLR	Low level Resistant	The strain is a wild type, devoid of any acquired resistance mechanism and low-level intrinsic resistance for an antimicrobial agent. Synergy with penicillin or glycopeptides can be expected if the isolate is susceptible to the penicillin or glycopeptide.
HLR	High level Resistant	The isolate is not a wild type, and with an acquired resistance mechanism for an antimicrobial agent. There will be no synergy with penicillin or glycopeptides.
N/A	No EUCAST breakpoints	Antibiotics do not have breakpoints or the concentration of the Antibiotic is not the one recommended by EUCAST. Please refer to EUCAST guideline.
MIC	MIC Request	Antibiotics tested using the disk diffusion method do not provide a reliable result or require confirmation by minimum inhibitory concentration (MIC) and should be tested using an MIC method to provide accurate interpretation, in accordance with EUCAST recommendations. Please refer to the current EUCAST guidelines for specific indications and interpretation criteria

RESULTS FORMAT

Antibiogo allows the user to generate **two comprehensive results format for printing:**

1 - Bench Sheet



AST ID
SAL-LCM142

Bench sheet v2.4-QC-lab

Technician name: MA
Performed on: 16/08/2025
Generated on 16/08/2025 at 11:34 with Antibio v2.4

Bacteria	Sample ID	Sample type	Sample site	Sample date
Salmonella sp		Stools		

Tested antibiotics

Antibiotics

Amoxicillin + Clavulanic.ac 20-10µg

Ampicillin 10µg

Ceftriaxone 30µg

Imipenem 10µg

Pefloxacin 5µg

Trimethoprim + Sulfamethoxazole 1.25-23.75µg

Azithromycin 15µg

IZD

25

22

28

27

26

27

18

SIR

S

S

S

S

S

S

ABR

Petri dish 1



Petri dish 2



A laboratory document recording all information related to the processed AST used to document and comprehensively summarize the AST processed and the results obtained.

The bench sheet includes:

- AST ID,
- AST and patient information,
- AST picture,
- IZD measurements,
- SIR categorization,
- questions raised by the ES and the answers provided by the user,
- and any lab notes provided by Antibio.

CAUTION: The bench sheet is only for laboratory use and should not be shared with the clinical team.

This bench sheet is only for laboratory use and should not be shared with the clinical team.

End of bench sheet
Generated on 16/08/2025 at 11:34 with Antibio v2.4



2 - Clinical Report

Patient ID
SAL-LBK005

Patient name
Ward
Age
Sex

Bacteria
Salmonella sp

v2.4-QC-lab

AST ID
SAL-LBK005
MA
16/08/2025
Generated on 16/08/2025 at 11:37 with Antibio v2.4

Sample ID

Sample type

Sample site

Date of collection

AST ID

Technician name

Performed on

Access

Watch

Reserve

Amoxicillin + Clavulanic Ac. Iv

Ceftriaxone (meningitis)

Amoxicillin

Ceftriaxone

Amoxicillin Iv

Ciprofloxacin (meningitis)

Ampicillin

Ciprofloxacin (non Meningitis)

Amoxicillin Iv

Ciprofloxacin

Trimethoprim + Sulfamethoxazole

Synergism

Susceptible, standard dosing regimen

A microorganism is categorised as "Susceptible, standard dosing regimen" when there is a high likelihood of therapeutic success using a standard dosing regimen of the agent.

Susceptible, increased exposure

A microorganism is categorised as "Susceptible, increased exposure" when there is a high likelihood of therapeutic success because exposure to the agent is increased by adjusting the dosing regimen and/or by its concentration at the site of infection.

Absence of Resistance

A microorganism is categorised as "Absence of resistance" when the clinical evidence of monotherapy is usually lacking, but the agent may still be used for a specific indication or in combination with another active agent or measure.

Resistant

A microorganism is categorised as "Resistant" when there is a high likelihood of therapeutic failure even when there is increased exposure.

Comments

Amoxicillin Oral in the absence of resistance mechanisms. Amoxicillin must be administered at high exposure in combination with another active therapy.

Azithromycin has been used in the treatment of enteric infections, primarily with Salmonella Typhi and Shigella spp. Isolate without resistance detected will have a disk diffusion zone of >= 12mm.

Chloramphenicol: Recommendations only on meningitis

WHO AWaRe classification

Access

Watch

Reserve

Access antibiotics that have a narrow spectrum of activity and a good safety profile in terms of side-effects.

Watch antibiotics that are broader-spectrum antibiotics and are recommended as first-choice options for patients with more severe clinical presentations or for infections where the causative pathogens are more likely to be resistant to Access antibiotics.

Reserve antibiotics that are last-choice antibiotics used to treat multi drug resistant infections.

End of report

Generated on 16/08/2025 at 11:37 with Antibio v2.4

A report primarily used by clinicians. The clinical report includes:

- AST ID,
- AST and patient information,
- SIR categorization and definition,
- Infection Prevention and Control (IPC) alerts,
- comments added by the technicians,
- and clinically relevant notes and recommendations provided by the Expert System.

In addition to directly tested antibiotics, the clinical report includes inferred results for certain antibiotics: these are interpreted based on the results of tested antibiotics, in accordance with EUCAST guidelines.

It can also provide the interpretation for antibiotics based on the route of administration (**IV or oral**), when applicable as per EUCAST guidelines.

To support appropriate antibiotic selection and antimicrobial stewardship, the clinical report also includes the **WHO AWaRe (Access, Watch, Reserve) classification**⁷ for each antibiotic:

- **Access:** Access antibiotics that have a narrow spectrum of activity and a good safety profile in terms of side effects.
- **Watch:** Watch antibiotics that are broader-spectrum antibiotics and are recommended as first-choice options for patients with more severe clinical presentations or for infections where the causative pathogens are more likely to be resistant to Access antibiotics.
- **Reserve:** Reserve antibiotics that are last-choice antibiotics used to treat multi drug resistant infections.

SEARCH AND EXPORT RESULTS

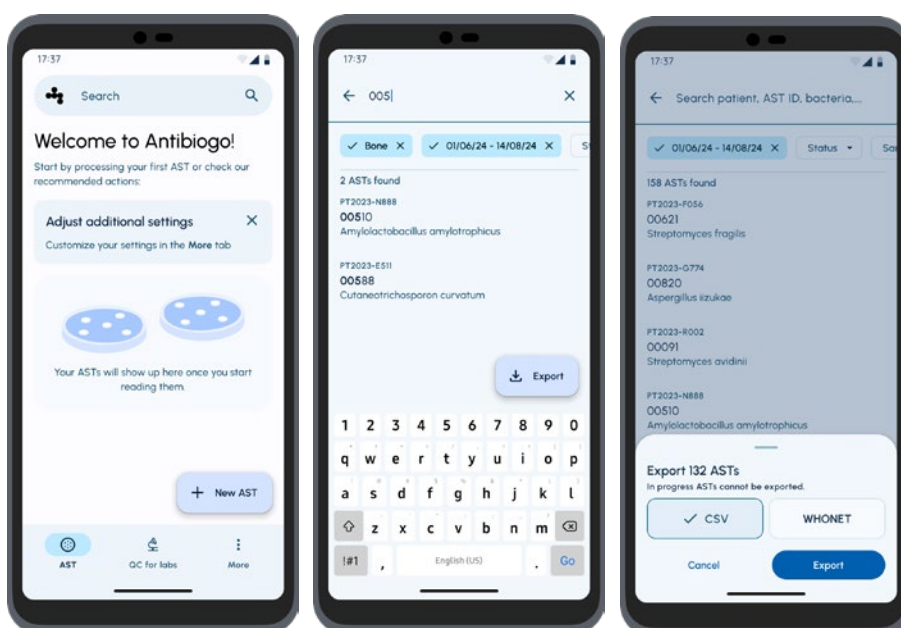
On the Antibio homepage, there is a **'search and export'** function that helps users find and manage and analyze AST results easily.

Search: You can filter results by AST ID, bacteria, sample type, date of sampling or date of AST processing.

Export: Results can be saved one by one or all together in CSV or SQLite format, and used with other systems like WHONET or LIMS (laboratory information management systems).

To upload SQLite file into WHONET, refer to 'WHONET file upload' section, page 25.

This feature supports the surveillance and analysis of antimicrobial resistance data.



Requirements

MATERIALS REQUIRED BUT NOT PROVIDED

Mobile device

- › Minimum requirements:
 - Running Android OS, version 11 or above.
 - Equipped with a 12 megapixels or more camera.
 - At least 400 MB of free storage.
- › Recommended device:
Samsung Galaxy A10 (SM-A105FN/DS)
- › Using a mobile device managed by the laboratory SOPs and dedicated to AST reading by Antibioigo is recommended.
- › An original (non-rooted) mobile device is mandatory for optimal security.
- › The mobile device should be protected by a PIN code or a fingerprint
- › An email address linked to a Google account is required.

Connectivity

- › Downloading and updating the app requires a stable internet connection..
- › Launching the app for the first time requires internet connection
- › The AST measuring and interpreting function can be run offline.
- › A punctual internet access is required to share results.
- › Bluetooth connectivity or USB access can also be used to download results on a computer if no internet network is available.

Material for the photo booth

- › One A3 (42x30 cm) sheet of solid opaque matte-black cardboard,
- › One A4 (21x30 cm) sheet of black felt or any other non-shiny material
- › Four high objects (21 cm) to be used as stands.

Processed AST

- › Round and/or square petri dishes (sizes from 90 mm to 165 mm)
- › Mueller Hinton Agar (MH) and MH agar supplemented with defibrinated horse blood and B-NAD (MH-F) for Fastidious microorganisms
- › Fresh and pure bacterial isolate from the clinical sample
- › Antibiotic discs of about 6 mm diameter.

AST PREPARATION

Antibioigo is designed to read Kirby-Bauer AST prepared according to standard microbiological laboratory procedures defined in guidelines :

- EUCAST:
https://www.eucast.org/ast_of_bacteria/

based on their recommendations including media choice, inoculum preparation, inoculation, positioning of antibiotics, number of antibiotics and incubation conditions.

The AST should be prepared as per the rules and recommendations of EUCAST guidelines.

Antibioigo can only be used to read AST of pathogens cultured and tested on culture media prepared according to EUCAST guidelines.

When using Antibioigo, routine internal quality controls for AST preparation and interpretation must be performed as per EUCAST guidelines. **In case the results of these routine internal quality controls are not compliant, Antibioigo SHOULD NOT be used** for reading and interpretation of the clinical strains.

E-learning training modules are available on the [antibioigo.org](https://www.antibioigo.org) website, in the 'Learn' section. We recommend that you complete them before using Antibioigo. Don't hesitate to refer to them afterwards, whenever necessary.

OPERATION CONDITIONS

The AST reading with Antibioigo must take place in a laboratory only, under controlled temperature, between 18 to 30°C, and 80% relative humidity maximum for temperatures up to 30°C without condensation.

The mobile device used for running Antibioigo must be handled as a critical component of the diagnostic system. To ensure proper function and data integrity, the following environmental conditions must be respected when transporting or storing the device outside of use:

- **Temperature:** 5°C to 40°C
- **Relative Humidity:** 10% to 90%, non-condensing
- **Shock Protection:** The device must be transported in a **protective padded case** to avoid mechanical damage.
- **Electromagnetic Compatibility:** Keep away from sources of strong electromagnetic fields (e.g., transformers, high-power electronics).
- **Security:** When stored, the device must be locked (PIN or biometric), and access restricted as per lab SOP.

The environment in which the phone is used can affect its performance. It is essential to perform AST in environmental conditions that do not present a risk of magnetic or electrical interference. Please refer to the phone manufacturer's data for more detailed and specific information.

SHELF LIFE OF ANTIBIOIGO

The shelf life of the Antibioigo software is estimated at three (3) years from the date of release of a given version, based on the durability of the technology employed, its offline functionality, and the absence of hardware degradation factors.

During this period, and in the absence of software updates (except for critical security or regulatory updates), the performance of the application remains stable when used in accordance with the instructions for use.

The manufacturer commits to notify users of any critical updates that may impact safety, performance, or compliance. Users are responsible for ensuring they are operating the software version that remains within its defined shelf life.

SAMPLE COLLECTION, TRANSPORT AND STORAGE

Refer to your laboratory's standard operating procedures for the collection, transport, and storage of samples used to prepare the AST



Warning, precautions and limitations

INTENDED USE AND USER RESPONSIBILITY

- For professional use only
- The Legal Manufacturer updates the Knowledge Base according to the newly published EUCAST guidelines annual releases. However, it is the user's own responsibility to download the last updated version of AntibioGo.
- Whereas AntibioGo can be used offline, an internet connection is required to complete the download.
- It is the user's own responsibility to check for phone and camera specifications.
- It is the user's own responsibility to ensure the use of a dedicated phone in the laboratory for AST reading and to create a dedicated email address to download and use AntibioGo. This email address should be linked to a Google account.

DEVICE COMPATIBILITY AND SYSTEM REQUIREMENTS

- It is the user's own responsibility to check for the phone updates and compatibility platform: changes to the mobile operating system (e.g. Android version upgrade, security patch, antivirus update, firmware change) can impact the performance or compatibility of AntibioGo.

Users must:

- Verify app behaviour after OS updates by repeating quality control tests as described in the "QC for labs instructions".
- Ensure that Google Play Services are active and updated.

- Do not install AntibioGo on phones with modified Android systems or unofficial security apps, unless they have been approved.
- If an incompatibility is detected, contact support immediately and discontinue use until resolution.

PHOTO QUALITY AND AST SETUP

- The quality of the detection of IZD, antibiotic name and concentration highly depends on the quality of the photo (brightness, contrast, resolution, sharpness, etc.). Ensure that the photo booth setup instructions have been strictly followed.
- To ensure proper image quality and reliable AST analysis, the mobile device camera lens should be regularly inspected and cleaned using a soft dry or lint-free cloth suitable for optical surfaces. After cleaning, users should verify that the image is sharp and free of blur or artefacts before processing an AST.
- When using several Petri dishes for one AST, photos of each Petri dish have to be taken individually. Do not include multiple Petri dishes in the same picture.
- DO NOT use AntibioGo with non-recommended culture media. AntibioGo CANNOT verify if the AST has been prepared in compliance with EUCAST guidelines. It is the user's responsibility to strictly follow the corresponding guidelines. Please refer to 'AST preparation', page 8.

DATA ENTRY AND PATIENT IDENTIFICATION

- Users are responsible for implementing procedures for patient and AST identification management.
- AntibioGo allows the user to enter a Patient Identification Number that does not allow the identification of the patient except by staff with access to the patient's admission file in paper or in the medical information system. The double identification for AST ID and Patient ID helps minimise the risk of misidentification.
- DO NOT share any patient medical condition details or documents containing patient identifiers when contacting the AntibioGo support team.
- The Legal Manufacturer has no access to patient identification data and does not retain any databases.

MEASUREMENT AND INTERPRETATION GUIDELINES

- Antibio performs a semi-automatic measurement of the Inhibition Zone Diameter (IZD). It is the user's responsibility to adjust and confirm the final IZD measurement according to the current version of the reading guides:
 - For EUCAST: '**EUCAST disc diffusion method for Antimicrobial Susceptibility Testing**' available at www.eucast.org

ANTIBIOTIC DISC AND MEASUREMENT LIMITATION

- Antibio DOES NOT manage IZD-specific measurement recommendations for the following bacteria-antibiotic combinations:
 - Enterobacterales with ampicillin
 - Ampicillin-sulbactam and amoxicillin-clavulanic acid
 - Enterobacterales with temocillin
 - Enterobacterales with mecillinam
 - E. coli with fosfomicin
 - Trimethoprim and trimethoprim-sulfamethoxazole
 - Enterococci with vancomycin
 - S. aureus with benzylpenicillin
 - Detection of inducible clindamycin resistance in Staphylococci and Streptococci
- When Antibio requests input from the user, it is their responsibility to ensure the accuracy of the information provided. User errors can affect the results.
- Antibio only works with 6 mm antibiotic discs. Using discs of a different size will affect measurement accuracy.
- Antibiotic discs from any brand may be detected. However, semi-automatic identification is only available for a defined list from Liofilchem, i2a, Oxoid and Bio-Rad. For other brands or non-detected antibiotic names, the user must manually select the antibiotic name and code.
- Manually added antibiotic discs are analysed by the Expert System in the same way as automatically detected ones. All discs are used for the interpretation

MIC PROCESSING

- Antibio does not handle Minimum Inhibitory Concentration (MIC). It can only process Kirby-Bauer disc diffusion results.

QUALITY CONTROL REQUIREMENTS

- Routine internal Quality Control of AST preparation and interpretation must be performed in line with EUCAST guidelines.
- If internal quality control results are not compliant, Antibio SHOULD NOT be used to read or interpret clinical samples. See the 'Quality Control' chapter, page 26 and the 'QC for Labs Instructions' for more information.

CLINICAL DECISION-MAKING : ROLES AND RESPONSIBILITIES

- AST results from Antibio SHOULD NOT be the sole basis for treatment decisions.
- All test results must be interpreted in combination with the patient's clinical history.
- Additional tests should be conducted if results are uncertain.
- A clinical diagnosis SHOULD NOT rely on a single test result.
- The responsibility for patient treatment decisions rests with the clinician.
- Users must define clear roles and access rights between lab technicians, microbiologists, clinicians, and supervisors, in compliance with the health facility's internal policies and applicable local and national regulations.

BIOSAFETY AND MATERIAL HANDLING

- All biological materials, including used ASTs, must be treated as potentially infectious.
- Follow standard laboratory precautions: wear gloves, lab coats, protective eyewear, and other appropriate safety gear.
- To help minimize the risk of contamination, it is recommended to remove gloves before handling the mobile device running Antibio.
- To minimize the risk of contamination and ensure biosafety, the phone used with Antibio should be regularly decontaminated using a disinfectant compatible with electronic devices, in accordance with the laboratory's hygiene protocols.
- The cardboard photo booth setup must be used in accordance with standard laboratory biosafety procedures. As it is not intended for liquid immersion or disinfection, it should be visually inspected regularly and replaced in case of visible soiling, contamination, or physical damage.
- Consult your laboratory's environmental waste personnel on proper disposal of used AST, which may contain infectious material.
- Laboratories are responsible for checking the applicable hazardous waste disposal requirements within their respective countries according to local legislation and regulations.

Operating procedure

Important: Read carefully the user manual before using AntibioGo. It is recommended to print the current version of the user manual to have a paper version available for consultation while performing an AST with AntibioGo.

Note: The user manual is subject to regular updating. It is important to check regularly that the manual used in the laboratory corresponds to the current version.

Note: The installation of ANTIBIOGO and photo booth can be done directly by the user.

FIRST TIME USE

Set up the photo booth

To ensure a good level of image standardisation, a specific setup allowing optimal AST photos is required. The photo booth can be installed with basic materials.

E-learning training modules are available on the antibiogo.org website, in the 'Learn' section. We recommend that you complete them before using AntibioGo. Don't hesitate to refer to them afterwards, whenever necessary.

Steps	Instruction	Figure
Location in the laboratory	The photo booth must be installed in a bright environment. Light should be uniform and diffuse, but not direct (e.g. windows or table lamps should not be directed to the setup).	
List of materials	1. Background: a rectangular piece of matte black felt, A4 size (21x30 cm) 2. Stands: 4 objects to support the upper cardboard. About 21 cm such as a bottle, a tin can or a beaker 3. Upper cardboard: A rigid sheet of matte black cardboard or any other rigid material, A3 size (42x30 cm) or larger	

Installation	Figure
Step 1 - Put the Background (1) on a flat surface (e.g. lab bench). This sheet will improve contrast for the Petri dish, following the EUCAST or CLSI reading guidelines for IZD. - Position the Stands (2) on either side of the Background (1).	
Step 2 - Drill a hole in the middle of the Upper cardboard (3), slightly larger than the camera of the mobile device. - Make sure that the edges of the hole are clear cut.	
Step 3 Put the Upper cardboard (3) on the top of the Stands (2). It must be horizontal and parallel to the Background (1)	

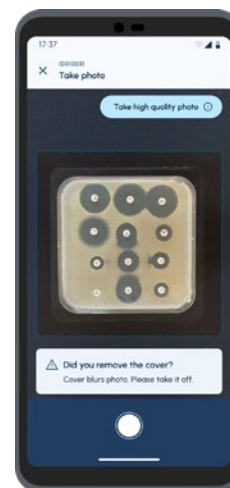
Final adjustment

- › Place the Petri dish in the middle of the **Background** (1), **face up and cover removed**



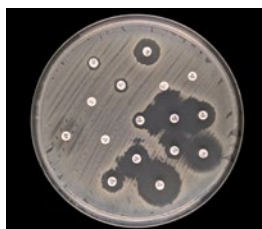
WARNING: whereas the manual reading of the inhibition zone is done with the Petri dish closed and upside down, when using Antibioigo, you should place the Petri dish right side up on the bench with the cover removed.

- › Open your mobile device's camera app
- › Place the mobile device on top of the **upper cardboard** (3), camera facing down and aligned with the hole, in position to take a photo of the Petri dish
- › You might need to adjust the light, the stands' height or to choose other objects to make sure that the full image of the Petri dish is displayed on the screen
- › If you are using Antibioigo to adjust the photo booth, ensure that the Petri dish edges are touching the frame or are within the frame.



Examples of good and bad quality photos:

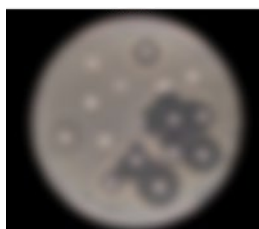
Good picture: round



Good picture: square



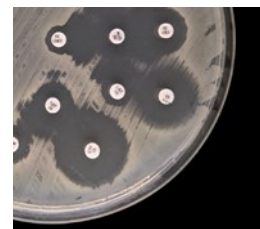
Bad picture: blurry



Bad picture: light reflexion



Bad picture: cropped



Download the app

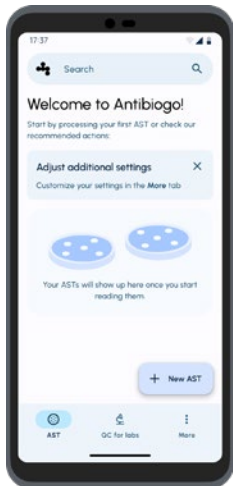
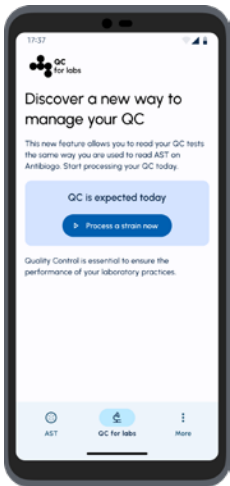
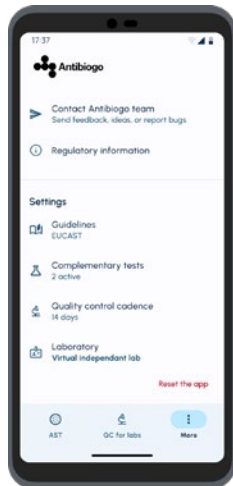
- Antibioigo is available from the Google Play Store app. To download the app, you need a stable internet connection. **Access to Antibioigo is restricted to authorized laboratories.** This access control is based on a predefined list of approved Laboratory IDs. This technical control helps ensure that Antibioigo is used only by laboratories that have been authorized and, where applicable, trained for its intended use.
- From the dedicated phone, open the Google Play Store app: download and install the app and follow the setup steps within the app.
- It is recommended to keep Antibioigo updated and use the most recent version. The knowledge base version used for the Expert System interpretation is displayed on the 'Interpretation' screen. See Step 9 of the Step-by-step guide.
- **The first time you open the app**, multiple checks are done for **security purposes** (see chapter 'Data privacy and security', page 29). You need to enable Screen lock (e.g. PIN code, pattern or fingerprint...) on your device. **You need stable internet connectivity to unlock the main functionalities of the app.** In some cases, some of these checks could appear on further launches.
- You will be asked to select your country. Please edit your country if the default country selected is different from where you operate Antibioigo.
- Additionally, **you are asked if you accept/reject the collection of usage metrics and/or technical and performance metrics.** These metrics will serve to improve Antibioigo. Privacy and transparency are priorities for us (you can refer to the 'Data privacy and security' chapter, page 29).

DO NOT FORGET to perform the Quality Control when using Antibioigo for the first time. Please refer to the 'Quality Control' chapter, page 25.

AST STEP BY STEP GUIDE

General presentation of Antibioigo's home page

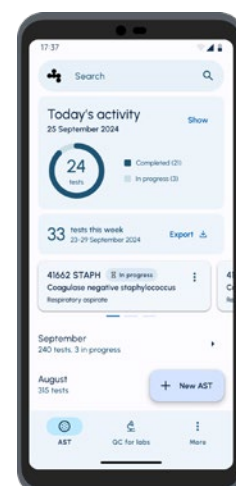
Antibioigo has 3 entries in the main navigation:

AST	QC for labs	More
Everything about AST 	To help you perform your internal QC 	To view settings, contact Antibioigo team and access various information 

E-learning training modules are available on the antibiogo.org website, in the 'Learn' section. We recommend that you complete them before using Antibioigo. Don't hesitate to refer to them afterwards, whenever necessary.

STEP 1: Create a new AST

- Ensure you are on the AST home screen.
- Tap on **New AST** to start creating an AST.
- **NOTE:** While processing an AST, you can pause it and close it. Your progress is always saved.
- Tap on the top-left **X**
- Open it again from the home page or by using the **search toolbar**.



STEP 2: Select the number of Petri dishes and fill in AST information

1 - Enter the **AST ID**

- Be very careful when entering the AST ID, as **this information cannot be modified later on**.
- AST IDs can only be entered once in the app.
No duplicates are allowed.
An error message below the text field **"This AST ID already exists. Use a unique ID."** will be displayed in case of a duplicate.

CAUTION : Do not enter the patient's name.

NOTE: The user should attribute an AST ID to a specific patient to prevent misidentification.

- Confirm your input by using the → button or the **Go/Enter** keyboard key

2 - Enter the **Patient ID**

- Be sure that you enter the Patient ID attributed to the AST ID to prevent misidentification.

CAUTION : Patient identification is a unique identifier per patient. Do not use the patient's name as the unique identifier.

3 - Select the **number of Petri dishes** you want to use for this AST. Antibioigo will create one aggregated result.

4 - Search and select the Sample type from the list.

NOTE: Sample type can impact the interpretation.

5 - Search and select **the Bacteria** from the list.

NOTE: If you are unsure of the specific species, choose the most appropriate group or genus.

6 - Add a new **technician name** or select it from the list.

7 - **Review the information you entered.** Tap on the ✎ icon to edit any of the mandatory fields.

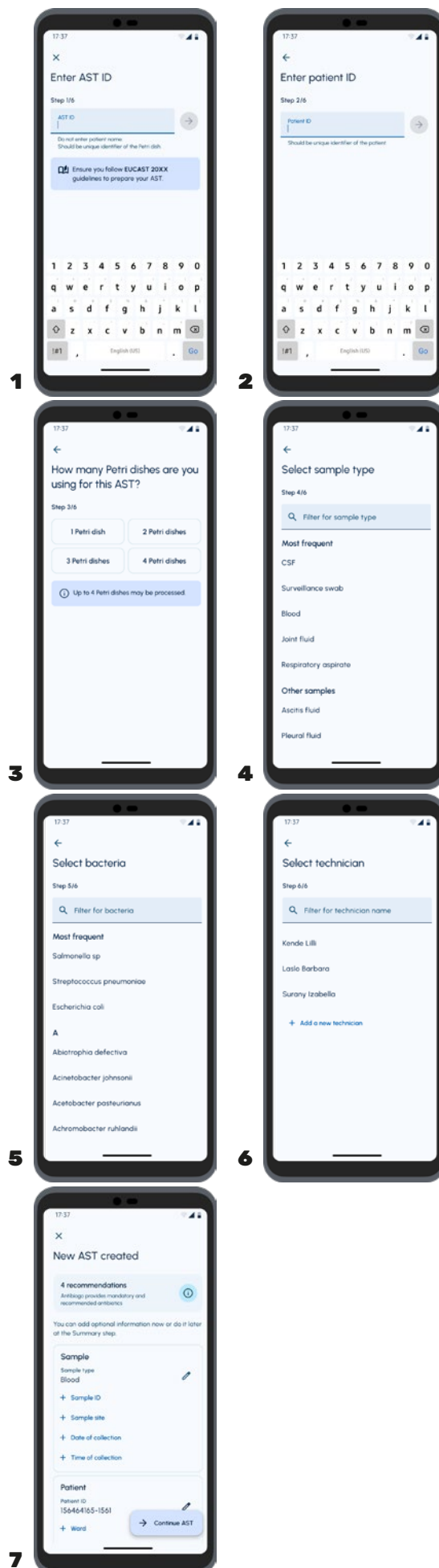
- **Additional sample information** can be entered: **Sample ID, Sample type, Date of collection and Time of collection.** Tap on each item to do so.

- **Additional patient information** can be entered: **Ward, Age and Sex.** Tap on each item to do so.

NOTE: These additional optional information can also be added or modified later at the Summary step.

- By typing on the (i), you can now access the **Antibioigo antibiotics' recommendations** for selecting the relevant antibiotics for AST based on the bacterial species and the sample type. These recommendations are based on EUCAST guidelines, helping identify important resistance mechanisms and allowing for the optimal choice of antibiotics therapy.

- Tap **Continue AST**.



STEP 3: Take a photo

- Place your mobile device on the Upper cardboard of the photo booth.
- Ensure that the mobile device is flat and stationary.



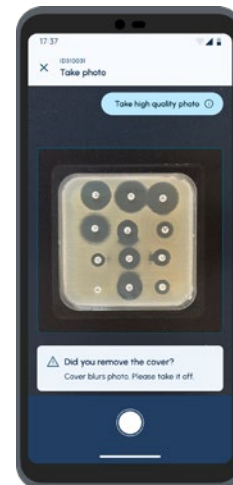
WARNING: Place the Petri dish on the Background of the photo booth, **face up and cover removed.**

NOTE: place only one Petri dish at a time.

When processing multiple Petri dishes, follow steps 3 to 8 for the first one, then repeat the operation for each of them.

- Ensure that the Petri dish edges are touching the frame or are within the frame.
- Tap the **Shutter button** to take the photo.

After taking the photo, put the cover back on the Petri dish to avoid possible contaminations or biological hazards

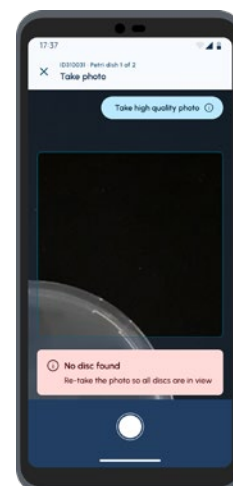


STEP 4: Confirm the photo

- Ensure that the Petri dish is aligned with the dotted lines on all sides, and that no reflections or glare are present. You can adjust the photo position by touching the screen.
- If the photo is of good quality (sharp, no reflections, balanced lightning), tap **Use photo**
- If the photo is not of good quality, blurry, or shows reflections, tap **Re-take photo**. *Go back to Step 3*

Antibiogo analyses the photo.

- If no disc is detected, the message '**No discs found, re-take the photo so all discs are in view**' is displayed
- If all or some discs are detected, *go to Step 5*



STEP 5: Confirm the number of antibiotic discs

Antibiogo automatically detects the number of antibiotic discs on the Petri dish.

You are asked to confirm or change this number based on the actual quantity of discs on the Petri dish.

Two scenarios are possible :

- 1 - The number of antibiotic discs displayed is **equal** to what you see on the Petri dish: Tap **Confirm** and *go to Step 6*.
- 2 - The number of antibiotic discs detected is **less** than what you see on the Petri dish: **correct the number** using the +/- buttons. Antibiogo will compare those values:.

(a) If the difference is low, you will need to help Antibiogo's detection by adding undetected discs in the following step.

(b) Above a certain number of undetected discs* by Antibiogo, you will see the message **"Many discs were not detected"**

There might be an issue with the image quality, caused by a bad photo booth set up.

- After fixing the photo booth, you can tap **Re-take photo** and *go to step 3*.
- Alternatively, you can choose to tap **Ignore and continue**. Be advise that the detection is low and Antibiogo won't be able to suggest antibiotics or diameters correctly.

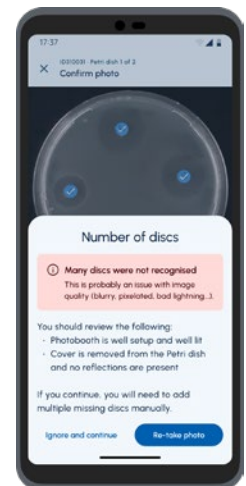
* If Antibiogo fails to confidently detect at least 80% of the antibiotic discs on the Petri dish.



1



2a



2b

STEP 6: Add undetected discs

When Antibiogo fails to detect a disc, you can help it by tapping on the missing discs.

- 1 - Detected discs are highlighted with a blue check. Tap on any undetected disc not highlighted.
- 2 - When Antibiogo detects the disc, you have to confirm the addition. Proceed like this for every undetected disc.

NOTE: Once detected, a disc cannot be discarded here. You will be able to remove a disc during Step 7.

CAUTION: You cannot proceed to the next step until all missing antibiotics have been added.



1



2

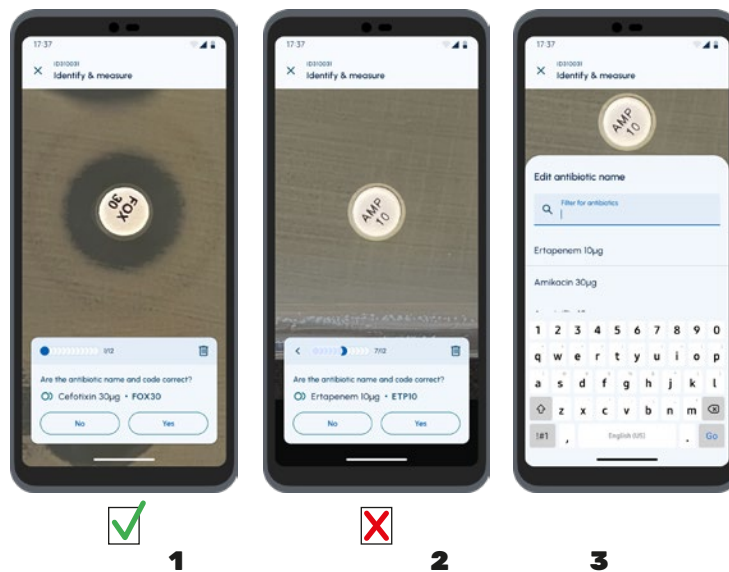
STEP 7: Confirm the antibiotic name and concentration

Each detected disc is displayed one by one on the screen.

Two scenarios are possible:

(a) The antibiotic name has been detected and confirmation is required:

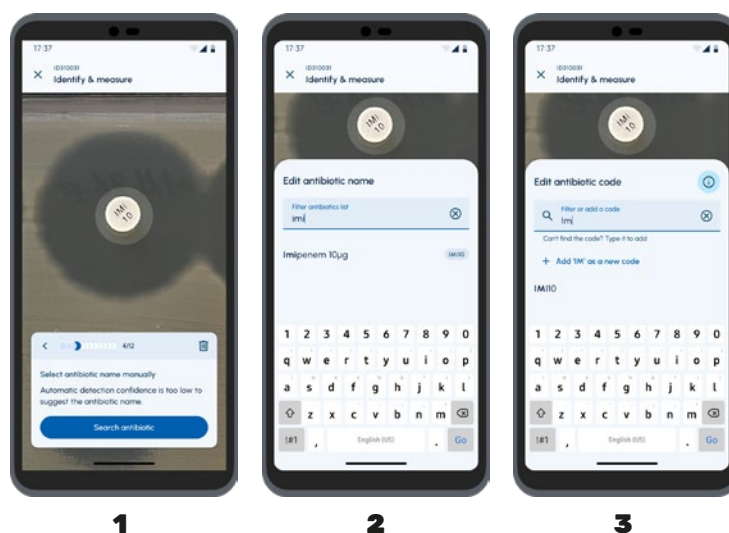
- Check the proposed antibiotic name and concentration by comparison with the Petri dish
 - If the antibiotic name, concentration and code are correct, tap **Yes** (image1).
 - If any of this information is incorrect (image 2), tap **No** then select the correct antibiotic name and concentration in the list (Image 3).
 - Specify the antibiotic code either by selecting an existing one, or entering a new code.
 - Go to Step 8



(b) The antibiotic name has not been detected and no suggestion is provided:

- 1 - Tap **Search antibiotic**
- 2 - Search and select the correct antibiotic name and concentration from the list.
Select an antibiotic name to confirm
- 3 - Specify the antibiotic code either by selecting an existing one, or entering a new code.
Go to Step 8

NOTE: New codes will be remembered by AntibioGo. Double check your spelling before creating one.



STEP 8: Adjust & Confirm the Inhibition Zone Diameter measurement

WARNING: Antibio performs a semi-automatic measurement of the IZD. The user is responsible for adjusting the IZD measurement according to the current version of the EUCAST reading guides. (Please refer to the **'Test Principle'** chapter, page 5)



The proposed border and measurement for the IZD is displayed in a dotted circle line. The IZD value is displayed below.

- Use **+/-** buttons or drag the blue slider left or right to adjust the measurement
- Tap **Confirm** to proceed

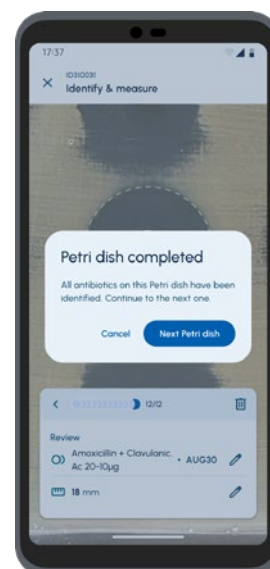
CAUTION: If the IZD dotted circle is not centred to or aligned with the antibiotic disk, you are advised to measure the antibiotic manually and add the measurement value into Antibio.

The next detected disc is displayed. Repeat Step 7 and 8 for each detected disc then continue to Step 9.

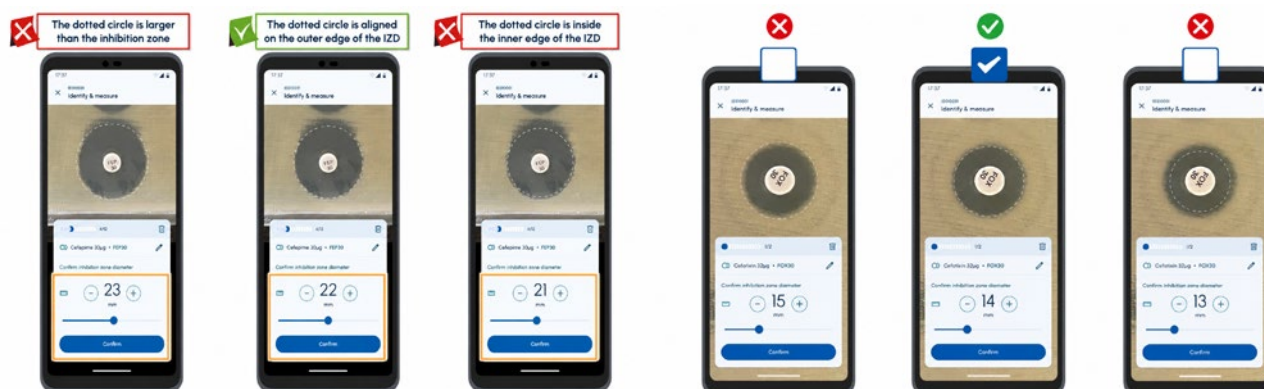
Once the confirmation of the antibiotic name, concentration and code, as well as the measurement of IZD of all detected discs have been completed, Continue to step 9

In **case of multiple Petri dishes**, tap on **Next Petri dish** to continue. Start again from Step 3.

WARNING: As with manual reading, zone edges should be read at the point of complete inhibition. When measuring with Antibio, make sure to **place the inner edge of the dotted circle on the outer edge of the inhibition zone**. Incorrectly placing the dotted circle can result in a difference of 1 to 2 mm in the measurement, potentially leading to false interpretation of results!



The illustrations below provide guidance on correct and incorrect IZD measurement adjustment practices:.



Antibio does not manage certain IZD-specific measurement recommendations.

For more information, refer to the **'Antibiotic disc and measurement limitation'** in the **'Warning, Precautions and Limitations'** chapter, p22. You can also consult the EUCAST website.

STEP 9: Expert System interpretation

Depending on the bacteria, the antibiotic tested, and the AST results, **the Expert System might ask you interpretation questions related to the phenotype detected** (e.g. confirmation of antibiotic name, concentration, inhibition zone) **or a confirmation of specific interactions between antibiotics** (e.g. synergies between antibiotics, addition of a confirmatory test, etc). In some cases, the Expert System won't ask any questions, in that case, continue to Step 10.

WARNING: Be very careful when you answer the complementary tests. Providing an incorrect answer can affect the interpretation of your AST.

Some examples of interpretation questions (not exhaustive):



Staphylococcus aureus AST

QUESTION ABOUT the **Penicillin zone shape** (sharp, fuzzy, not sure)

› **PURPOSE:** Detection of Penicillinase in Staphylococcus aureus

QUESTION ABOUT the **flattening of D-zone**

› **PURPOSE:** Detection of Clindamycin Inducible resistance

QUESTION ABOUT the **aminoglycoside inhibition zones check**

› **PURPOSE:** Discordant interpretation of Aminoglycosides

Enterococcus AST

QUESTION ABOUT **Vancomycin, zone edges and colonies within the zone**

› **PURPOSE:** Detection of Vancomycin resistance.

“ Do you see colonies within the inhibition zone?”

If Yes: Vancomycin is R

If No, a second question is asked: **“Is the edge of the inhibition zone fuzzy or sharp?”**

Enterobacteriales AST

QUESTION ABOUT the **ESBL synergy check**

› **PURPOSE:** Detection of ESBL

IMPORTANT: the absence of visible synergy does not exclude the presence of ESBL. Perform a confirmation test and edit the result.

IMPORTANT: For the interpretations of some mechanisms of resistance such as inducible clindamycin resistance and ESBL synergy detection, it is mandatory to apply certain antibiotic discs on the same petri dish, and within a precise proximity. AntibioGo will ask you to confirm the tests reliability and if the guidelines recommendations are followed. If not, AntibioGo will ask you to discard the antibiotic which interpretation may be affected, such as Clindamycin and Amoxicillin-clavulanic acid, respectively.

You can tap on the  icon for more information.

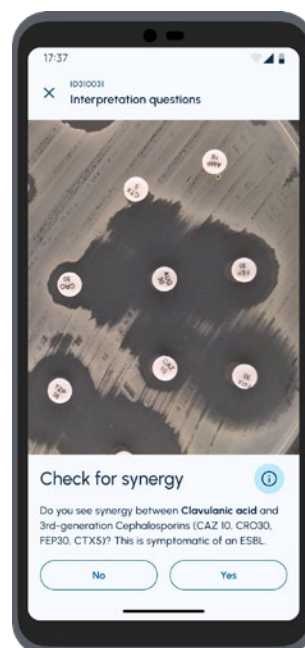
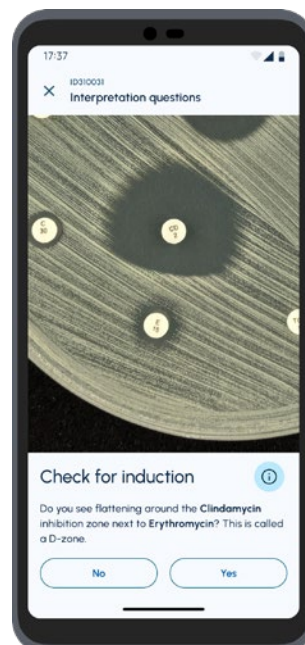
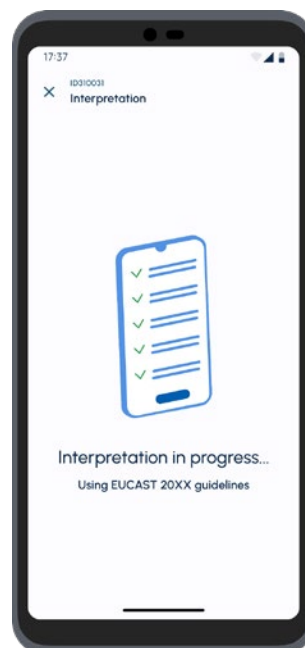
QUESTION ABOUT the **carbapenems resistant confirmation**

› **PURPOSE:** Detection of carbapenemase

All AST

QUESTION ABOUT the **antibiotic name and inhibition zone confirmation**

› **PURPOSE:** Reading of a certain antibiotic is discordant with the natural resistance of the isolate ID entered



STEP 10: Review the Summary



WARNING: this is your last chance to double-check and correct information before the results are generated. **Inaccurate information can have a direct impact on patient management.**

NOTE: After editing any of the following, the Expert System relaunches the interpretation, Step 9.

Petri dish review

In case of multiple Petri dishes, navigate between them by swiping or using the arrow buttons.

- Tap on the picture to view it in full screen. You will be able to zoom in and pan around to review antibiotic names, concentrations, IZD measurements, or any undetected missing antibiotics.
- If needed, tap **Edit** or the  icon to access the Editing mode.
- In Editing mode, tap on any disc to modify the antibiotic name, concentration, code and/or IZD measurement
- Tap **Done editing** once completed.

AST, Patient and Sample information

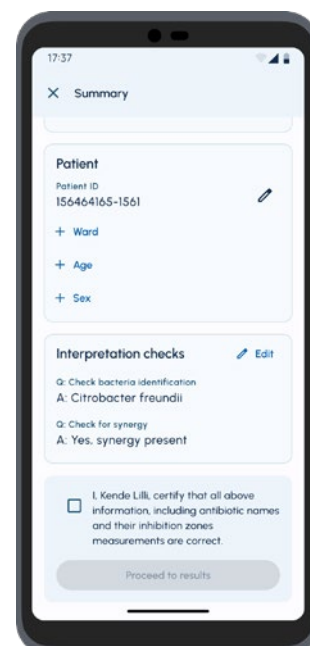
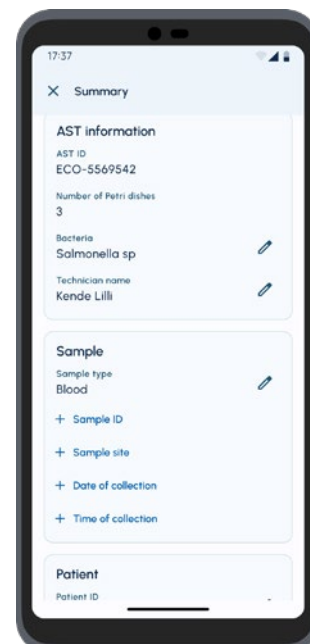
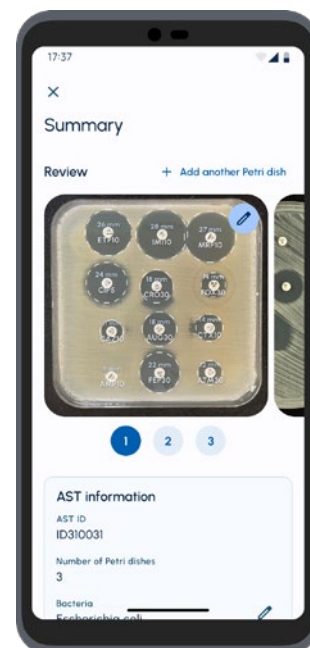
- Review and/or complete the general AST information : AST ID, Patient information, Bacteria, Sample information, Technician Name.
- If needed, tap the  icon to modify or add additional optional information.
- Updated information is saved instantly.

Interpretation checks

- Review the answers you provided to the Expert System
- If needed, tap **Edit** to modify.

Certify the summary before proceeding

- After reviewing all the above information, tap the checkbox to certify - in your name - that all above content is correct.
- Tap **Proceed to results** when done. *Go to Step 11.*



STEP 11a:

View Bench sheet

Antibiogo allows you to save a bench sheet that can be used for documentation practices, verification and validation of results by a microbiologist or a laboratory supervisor.

The Bench sheet is intended to be used only by laboratory staff. It should not be shared with the clinical team.

IPC message

If the Expert System identifies a Multi Drug Resistant bacteria, an Infection Prevention Control alert is displayed in a red banner.

Tested antibiotics

A bench sheet is available with the tested antibiotics names, concentrations, IZDs, and SIR categorization.

Interpretation notes

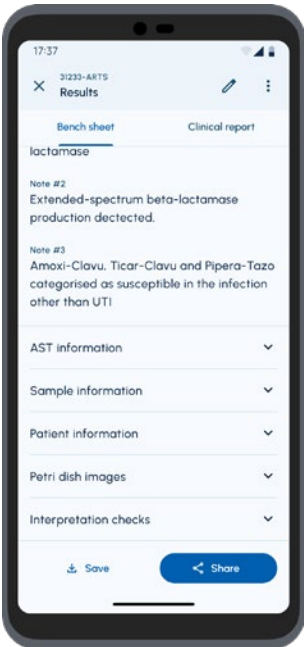
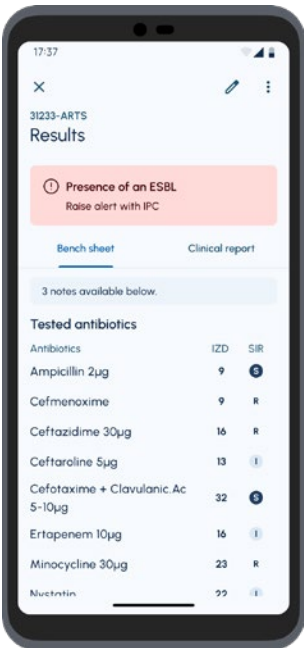
You can find notes that can help you in your interpretation and sometimes recommend additional testings.

IMPORTANT: If you don't read the notes, you can miss important information related to interpretation.

AST, Patient and Sample information

All AST information that you reviewed previously are displayed.

Petri dish images and Interpretation checks are also displayed.



STEP 11b: View Clinical report

The clinical report is available from the result section and is intended for clinicians.

IPC message

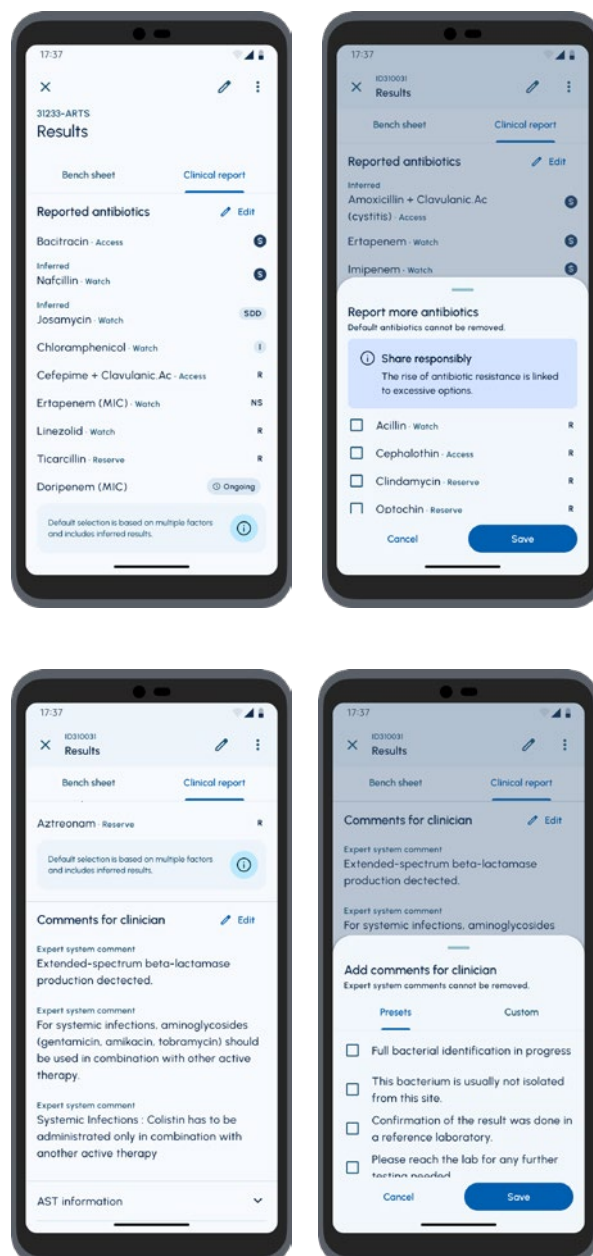
If the Expert System identifies a Multi Drug Resistant bacteria, an Infection Prevention Control alert is displayed in a red banner. (see illustration on Step 11a)

Reported antibiotics

- Reported antibiotics are displayed based on WHO AWaRe classification with only Access and Watch antibiotics available on the results.
 - Reserved antibiotics are hidden but available in case of need or request by the clinician.
 - They can be added using the **Edit** button. Select the antibiotics you want to add, then tap **Save**.
 - These comments are automatically generated by AntibioGo and intended to support clinicians in their understanding of the results, such as resistance mechanisms.
 - You can manually add additional comments by tapping **Edit** besides the title.:
 - Choose between common preset comments in the **Presets** tab or type your comment using the **Custom** tab. These comments will appear on the report as **"Custom comments"**.
- NOTE:** presets comments are 'ready-to-use' comments available in AntibioGo, however you can personalise your comment using the custom comments:
- To remove a comment you added, tap again on the **Edit** button and deselect Presets or delete the custom text.

AST, Patient and Sample information

All AST information that you reviewed previously are displayed.



STEP 12:

Save/print/share Bench sheet and Clinical report

Save the report

- On the Bench Sheet or Clinical Report screen, tap **Save**.
- Choose the file format:
 - **Bench sheet:** PDF or CSV
 - **Clinical report:** PDF only
- A message will appear: «Bench sheet saved».
- Tap **Open**, or use your phone's **file manager** to find the saved file.

Share the report

You can send the report using another app. This feature requires **internet** 📶 or **Bluetooth** 📶

- Tap **Share**.
- Choose the file format (PDF or CSV).
- Select how you want to share it:
 - 📧 Messaging app (e.g., WhatsApp, Signal)
 - 📧 Email app (e.g., Gmail, Outlook)
 - 📁 Storage app (e.g., Google Drive, Dropbox)
 - 🖨 Connected printer (see next section)

The available options depend on the apps installed on your device. You can add more via the Google Play or Samsung Galaxy Store.

Print the report

You can print saved reports in two ways from:

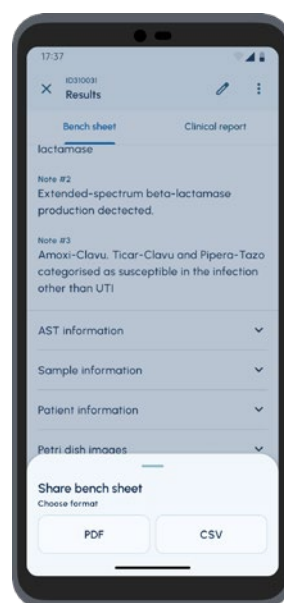
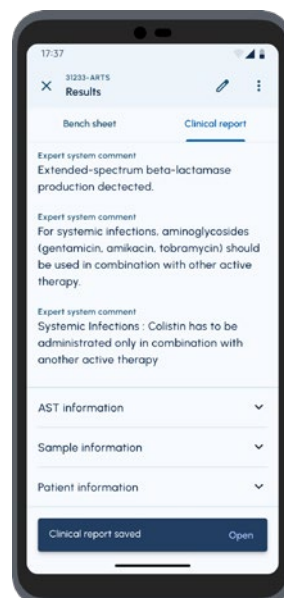
a) A computer (*recommended as the most reliable method*)

- Connect your phone to a **computer** using a **USB cable** or **Bluetooth**.
- Copy the saved file (PDF or CSV) to the computer.
- Open and print it normally.

b) Your phone

- Tap **Share** and choose **PDF**.
- Select a **printer app** (e.g., Print, HP Smart, Canon Print).
- Follow the app's steps to print.

Your phone must be connected to the **internet** or the same **Wi-Fi network** as the printer.



Patient ID		Patient name	Ward	Age	Sex
SPN-LBMI98					

Bacteria		AST ID		Technician name		Performed on	
Streptococcus pneumoniae		SPN-LBMI98		MA		25/03/2025	
Sample ID		Sample type		Sample site		Date of collection	
		Blood					

Generated on 25/03/2025 at 23:07 with Antibio v2.3

Antibiotics result

Susceptible, standard dosing regimen

A microorganism is categorised as "Susceptible, standard dosing regimen", when there is a high likelihood of therapeutic success using a standard dosing regimen of the agent.

Access	Watch
R Amikacin	R Azithromycin
R Aztreonam	R Ceftazidime
R Gentamicin	R Clarithromycin
R Netilmicin	R Erythromycin
R Penicillin V	R Kanamycin
R Tetracycline	
R Tobramycin	
R Trimethoprim + Sulfamethoxazole	

Comments

Chloramphenicol: Recommendations only on meningitis

WHO AWaRe classification

Access	Watch	Reserve
Access antibiotics that have a narrow spectrum of activity and a good safety profile in terms of side-effects.	Watch antibiotics that are broader-spectrum antibiotics and are recommended as first-choice.	Reserve antibiotics that are last-choice antibiotics used to treat multi drug resistant infections.

OPTIONAL STEP

Export logs in case of bug report

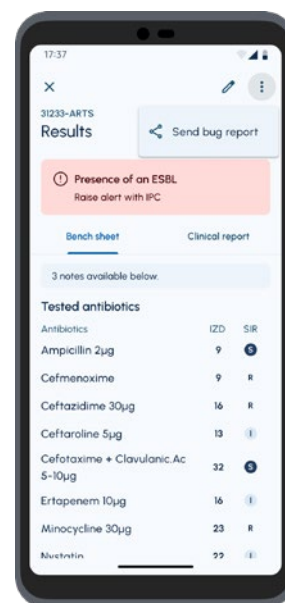
This feature allows you to export AST results generated by AntibioGo for bug report purposes using a third party email app.

This feature requires an **internet**  connection and an **email app** .

On the Results page:

- Tap the **three dots** icon on the upper right
- Select **Send bug report**
- Select an app installed on your device:
 - ☐ Client email app (Gmail, Outlook...)

The support email address will be entered automatically in the recipient field.



FINAL STEP

Closing the ANTIBIOGO Application

To ensure safe and complete closure of the application:

- Complete and save any ongoing AST.
- Export or backup data if required by your local procedure.
- Use the standard system action to close AntibioGo. You can refer to the **Android FAQ***.

CAUTION: Do not power off the device while ANTIBIOGO is processing data.

If the application becomes unresponsive, follow your laboratory's IT protocol or restart the device.

* <https://support.google.com/android/answer/9079646>

WHONET file upload

If you want to transfer your AST database from AntibioGo to WHONET, ensure to extract the data in SQLite format as described in '**Search and export**' section, page 7.

These separate SQLite files are generated by AntibioGo for individual time periods.

To simplify cross-period analysis, we've introduced **AST Merge** – a desktop application that consolidates multiple SQLite exports into a single, WHONET-compatible SQLite database ready for upload.

Step-by-step instructions are available in a dedicated instruction manual **on the antibiogo.org website**, in the '**learn**' page at the '**download**' section.

Quality Controls

INITIAL VERIFICATION OF ANTIBIOGO USE

Prior to the first use of AntibioGo, the laboratory must perform a parallel QC using manual method and AntibioGo using standard ATCC control strains, in accordance with EUCAST guidelines, and compare the results. This verification step ensures proper installation, configuration, and use of the application under the local laboratory conditions.

In case of discrepancies between the manual and AntibioGo results (e.g. IZD out of expected range or significant differences between the two methods), the laboratory must investigate the root cause.

INVESTIGATION

- The investigation includes, but is not limited to, reviewing the following:
- Proper incubation conditions (temperature, atmosphere, incubation time)
- Accurate preparation and quality of culture media and antibiotic discs
- Correct measurement of inhibition zones (IZD)
- Use of appropriate reading distance, lighting, and camera positioning
- Proper handling of the reference strains.

If the cause of the discrepancy cannot be identified, the laboratory **must contact our support team** for further assistance. (see Technical assistance section)

E-learning training modules are available on the antibiogo.org website, in the 'Learn' section. We recommend that you complete them before using AntibioGo. Don't hesitate to refer to them afterwards, whenever necessary.

ROUTINE QUALITY CONTROLS

- External quality controls should be performed in accordance with laboratory accrediting organisations requirements as applicable.
- Internal quality control used in the laboratory for routine media preparation and antibiotic discs validation (using ATCC bacteria) are performed under the responsibility of the laboratory to ensure that the AST are prepared and read in accordance with EUCAST guidelines and that the equipment is properly installed and operational.

The following strains should be used for internal quality control with AntibioGo:

Bacteria to select from the list in AntibioGo	Recommended ATCC reference strains for routine quality control - EUCAST
Escherichia coli Klebsiella pneumoniae Proteus mirabilis	Escherichia coli ATCC 25922
Salmonella sp	Escherichia coli ATCC 25922
Shigella sp	Escherichia coli ATCC 25922
Enterococcus faecalis Enterococcus sp	Enterococcus faecalis ATCC 29212
Pseudomonas aeruginosa	Pseudomonas aeruginosa ATCC 27853
Acinetobacter baumannii	Pseudomonas aeruginosa ATCC 27853
Staphylococcus aureus Coagulase negative Staphylococcus	Staphylococcus aureus ATCC 29213
Streptococcus pneumoniae	Streptococcus pneumoniae ATCC 49616

For the non-validated bacteria (*Haemophilus influenzae*, *Helicobacter pylori*, *Campylobacter* spp, *Neisseria gonorrhoeae*) follow EUCAST guidelines for Quality Control.

- If the results of the IZD measured for internal quality control using AntibioGo ARE NOT in the expected range established in the EUCAST guidelines (**Eucast recommended strains for Quality Control**)* SHOULD NOT be used,
- The routine internal quality control should be performed every week or more frequently according to the laboratory routine practices and their results must be recorded and archived.
- In addition to the routine internal quality control, the internal quality control should be performed before the first use of AntibioGo and after each update of AntibioGo.

* https://www.eucast.org/fileadmin/src/media/PDFs/EUCAST_files/QC/v_12.0_EUCAST_QC_tables_routine_and_extended_QC.pdf

Performance Characteristics

ANALYTICAL PERFORMANCE

Analytical sensitivity and specificity were evaluated by comparing AST interpretations performed with Antibioغو versus AST interpretation performed by two clinical microbiologists, on a panel of 5 reference strains with

known/defined IZD for various antimicrobials across 3 different sites. The category agreement for the interpretation of the 5 reference strains are presented in Table 1^a.

TABLE 1: Category Agreement of AST interpretation when using Antibioغو compared to the reference method, i.e. interpretation by a clinical microbiologist, by pathogen and by combined/overall site.

	Antibioغو vs Clinical Microbiologist Category Agreement
	% Agreement, S*, R** and I*** (95% CI)
Enterococcus faecalis ATCC 29212	90% (0.91-0.93)
Escherichia coli ATCC 25922	92% (0.91-0.93)
Pseudomonas aeruginosa ATCC 27853	75% (0.74-0.76)
Staphylococcus aureus ATCC 25923	92% (0.88-0.97)
Staphylococcus aureus ATCC 29213	92% (0.88-0.97)
Overall Category Agreement	91% (0.90-0.92)

*S for Susceptible, **R for Resistant, ***I for Susceptible, Increased exposure

CLINICAL PERFORMANCE

The clinical performance of Antibioغو for the interpretation of AST of *E.coli*, *Klebsiella pneumoniae*, *Proteus mirabilis*, *Salmonella sp*, *Staphylococcus aureus*, *coagulase negative Staphylococcus*, *Enterococcus sp*, *Enterococcus faecalis*, *Streptococcus pneumoniae*, *Pseudomonas aeruginosa* was evaluated across 3 different sites.

ASTs were prepared and incubated following the EUCAST recommendations.

The interpretation by the Antibioغو Expert System and the identification of resistance mechanisms was compared to the interpretation by two clinical microbiologists considered as the gold standard. Kappa testing^b was used to assess the overall concordance of the results provided by Antibioغو and the microbiologist. The results expressed in terms of category agreement and discrepancies were classified as 'minor', 'major' and 'very major'.

For each susceptibility category (S for 'Susceptible', I for 'Susceptible, Increased exposure' and R for 'Resistant'), the category agreement (%) was calculated in line with the principles set in ISO 20776-2:

- Identical interpretation in both methods was defined as agreement^c
- Categorization of I in one method and R or S with another method was defined as minor discrepancy^d
- Categorization of S in the manual reading and R in Antibioغو was defined as major discrepancy^e
- Categorization of R in the manual reading and S in Antibioغو was defined as a very major discrepancy^f.

A total of 355 clinical isolates were included in the analysis across the 3 sites (Table 2).

TABLE 2: Distribution of clinical isolates per site

List of Pathogens/Genera	# isolates enrolled	# isolates per site (isolate-antibiotic combinations)			Total isolate-antibiotic combinations for analysis
		site 1	site 2	site 3	
<i>Staphylococcus aureus</i>	52	33 (460)	13 (169)	6 (79)	
<i>Coagulase negative staphylococcus</i>	27	27 (351)	-	-	351
<i>Escherichia coli</i>	109	6 (96)	51 (763)	52 (1098)	1957
<i>Klebsiella pneumoniae</i>	31	7 (111)	7 (104)	17 (287)	502
<i>Proteus mirabilis</i>	12	9 (143)	-	3 (51)	194
<i>Salmonella sp</i>	19	-	19 (302)	-	302
<i>Pseudomonas aeruginosa</i>	48	32 (411)	5 (60)	11 (136)	607
<i>Enterococcus faecalis</i>	11	-	10 (39)	1 (7)	46
<i>Enterococcus species</i>	28	2 (8)	23 (92)	3 (16)	116
<i>Streptococcus pneumoniae</i>	18	-	18 (106)	-	106
Total isolates (isolate-antibiotic combinations) enrolled	355	116 (1580)	146 (1635)	93 (1674)	4889

The category agreement per clinical isolates was determined (Table 3).

TABLE 3: Category agreement per clinical isolates

Concordance and category agreement (S, R, I) per clinical isolates			
Species	# pathogen-antibiotic combinations	% agreement	Kappa (95% CI)
<i>Staphylococcus aureus</i>	708	96.19	0.92 (0.88 – 0.95)
<i>Proteus mirabilis</i>	194	87.63	0.79 (0.71–0.86)
<i>Klebsiella pneumoniae</i>	502	88.65	0.80 (0.76 – 0.85)
<i>Coagulase negative staphylococcus</i>	351	96.58	0.93 (0.90–0.97)
<i>Escherichia coli</i>	1957	90.04	0.84 (0.81–0.86)
<i>Enterococcus sp</i>	116	93.10	0.86 (0.77–0.95)
<i>Pseudomonas aeruginosa*</i>	607	67.05	0.50 (0.45 – 0.56)
<i>Streptococcus pneumoniae</i>	106	93.40	0.88 (0.79 – 0.96)
<i>Salmonella sp</i>	302	91.72	0.79 (0.71 – 0.87)
<i>Enterococcus faecalis</i>	46	89.13	0.76 (0.57 – 0.95)

*For *Pseudomonas aeruginosa*, the majority of discrepancies (33%) are related to the introduction of the Susceptible High Exposure susceptibility category by EUCAST in 2019.

The classification of discrepancies per clinical isolates is summarised in Table 4.

TABLE 4: Classification of discrepancies per clinical isolates

Species	# overall	% agreement	Total R	Total S	# mD*	% mD	# MD**	% MD	# VMD***	% VMD
<i>Coagulase negative Staphylococcus</i>	351	96.58	140	204	9	3%	3	1%	0	0%
<i>Enterococcus faecalis</i>	46	89.13	13	33	0	0%	5	15%	0	0%
<i>Enterococcus sp</i>	116	93.10	60	56	0	0%	8	14%	0	0%
<i>Escherichia coli</i>	1957	90.04	908	1049	182	9%	11	1%	2	0%
<i>Klebsiella pneumoniae</i>	502	88.65	275	174	54	11%	2	1%	1	0%
<i>Proteus mirabilis</i>	194	87.63	78	98	23	12%	1	1%	0	0%
<i>Pseudomonas aeruginosa</i>	607	67.05	190	204	198	33%	2	1%	0	0%
<i>Salmonella sp</i>	302	91.72	27	242	24	8%	1	0%	0	0%
<i>Staphylococcus aureus</i>	708	96.19	192	500	23	3%	4	1%	0	0%
<i>Streptococcus pneumoniae</i>	106	93.40	43	57	3	3%	2	4%	2	5%

*mD: minor discrepancy, **MD: major discrepancy, ***VMD: very major discrepancy

a. It is represented by $(NCA \times 100) / N$ and expressed as a percentage, where NCA is the number of pathogen-antibiotic pairs with the same SIR category for both methods, and N is the total number of pathogen-antibiotic pairs tested

b. Cohen's kappa coefficient, a statistic that is used to measure inter-rater reliability for qualitative (categorical) items, with a lower confidence interval greater than 0.81 – the general cut-off for “almost perfect” agreement as described in table 1 below.

Table 1. Recommended interpretation of Cohen's kappa Coefficient

c. It is represented by $(NCA \times 100) / N$ and expressed as a percentage, where NCA is the number of bacterial isolates with the same SIR category for both methods, and N is the total number of bacterial isolates tested.

d. It will be represented as $NmD \times 100 / N$ and expressed as a percentage, where NmD is the number of tests that result in a mD, and N is the total number of bacterial isolates tested.

e. It will be represented as: $NMD \times 100 / NSREF$ and expressed as a percentage, where NMD is the number of tests that result in an MD, and NSREF is the number of susceptible bacterial isolates as determined by the reference method.

f. It will be represented as $NVDM \times 100 / NRREF$ and expressed as a percentage, where NVDM is the number of tests that result in a VMD and NRREF is the number of resistant bacterial isolates as determined by the reference method.

Data storage in Antibioigo

In progress and completed AST, including photos and results, are stored on the device for a duration of 1 year. After this period, all AST data is permanently deleted. Completed ASTs cannot be manually deleted before the automatic deletion, 1 year after completion.

ASTs in progress can be deleted at any time by tapping on the 3-dots on the upper right of each AST, and tapping **Delete AST**.

It is the user's own responsibility to ensure that AST results are saved on a computer or any other type of backup solution depending on laboratory archiving procedures.

Uninstallation of the Antibioigo application

If you plan to stop using the mobile device running Antibioigo, or you decide to uninstall the app, please make sure that all medical data stored on the device—such as AST results or patient IDs—is securely deleted in compliance with internal laboratory procedures and applicable data protection regulations.

Since all health-related information is stored **only on your device**, it is your responsibility to protect and safely erase this data when the app is removed or the device is no longer in use.

We recommend the following best practices:

- **Delete any saved AST** results using the Antibioigo app interface or your device's storage settings.
- If the device is being permanently retired, **fully erase its data using a secure deletion method that complies with your local data privacy laws** (e.g., certified data erasure tools, if required).

Fondation Médecins Sans Frontières, as the app's manufacturer, **has no access to any user or patient data** and does **not** store any data on external servers.

Data privacy and security

DATA PRIVACY

Access to those data are under the sole laboratories and national authorities responsibilities. We are committed to maintaining your privacy and ensuring transparency in our data collection practices. When using Antibioigo, all medical related data (AST content, results, or patient data) are saved locally in your device. Access to those data are under laboratories and national authorities responsibilities.

The manufacturer has no access to those data and does not keep any databases.

Your privacy and data protection are the top priorities of La Fondation MSF. When using the Antibioigo

app, you have the option to consent to the collection of navigation analytics and anonymized usage metrics during the first installation. These analytics help us improve the app's functionality and user experience.

Metrics are broadly classified into two categories:

Usage metrics: Usage metrics refers to anonymized information about how you interact with the app. For example:

- **Navigation events** (e.g., tapping buttons, moving between screens)
- **Input actions** (e.g., selecting a checkbox or choosing an item from a list)

Technical and performance metrics: These metrics help us identify issues such as app crashes, loading times, and error logs. The data collected includes:

- **Anonymous device identifiers** (used only to distinguish devices)
- An **approximate device location** (city-level precision only)
- **Device characteristics and settings** (model, language, operating system version, time zone)
- **Antibioigo app information** (installed version, installation source)

For both usage and technical and performance metrics, **no antibiotic names, inhibition diameters, patient information, or any other medical or personal data are collected.**

We work to comply with European standards. In regard to the General Data Protection Regulation (GDPR), Antibioigo is a controller. We apply its regulation to our data use and organisation.

As a non profit organisation, we do not make business out of any data collected in this app's use.

DATA SECURITY

Antibioigo is designed to protect your results and data. If basic security conditions are not met, the app will not work. This helps prevent any risky or unreliable use.

When you open the app for the first time, it checks whether your phone is properly secured (for example, with a PIN code, pattern, or fingerprint). If no screen lock is set, the app will ask you to activate one before continuing.

Antibioigo also checks that your phone is running in a safe environment. If the phone has been modified (e.g., rooted) or doesn't meet security standards, the app will display an error message and stop working. This ensures results stay reliable and patient safety is not compromised.

The app also checks its own encrypted internal files—like the knowledge base and key calculation systems—are safe and complete. If something is wrong or missing, the app will stop to avoid giving incorrect or incomplete results.

If you're having trouble using Antibioigo, please refer to the "Troubleshooting & Technical Assistance" section or contact our support team at:

support@antibioigo.org

Troubleshooting & Technical Assistance

If you experience problems using Antibio, check the common issues below. If the problem continues, follow the steps at the end of this section to contact our support team.

COMMON ISSUES AND SOLUTIONS

Issue description	Solution
App crashes after installation	Got to Settings->Apps->Google Play Services->Storage . Tap on Clear cache then reopen the app.
App crashes during opening	Long-press the Antibio app icon . Then tap on (i) App info -> -> go to storage -> tap Clear cache at the bottom right. Then reopen the app.
App crashes during use	Close and reopen the app. Your data is saved as you work, but you may need to re-enter the last few fields. If you are not able to complete the full AST flow in the app, you have to read the AST manually according to the laboratory practices.
Poor image quality / blurry image	Clean the mobile device camera lens and verify that the photo booth setup and lighting conditions are appropriate.
Cannot open previously created AST	Restart the device and open the app again. If it still doesn't work, contact support.
Screen or buttons look cut off / cropped	Antibio is optimized for Samsung A10 . Display issues may happen on other devices. Use the recommended model if possible.
Cannot export locally a file using a custom file manager	Always use the built-in "Save locally as..." option. Other file manager apps may not be fully compatible.
Can't find your file	Look in the Downloads folder with your File Manager.
No printer option	Check your internet connection or install a printer app (available from an app play store).
Internal app sharing is turned off	1. Open Google Play Store on your device. 2. Tap your profile icon -> Settings -> About. 3. Tap "Play Store version" 7 times until you see: "Developer options enabled". 4. Go to: Settings -> System -> Developer options 5. Toggle on: "Internal app sharing" 6. Open the Antibio link and install the app. Note: Once the app installation is completed, it is recommended to disable Internal app sharing again: Settings -> System -> Developer options -> Toggle off "Internal app sharing".

CONTACTING SUPPORT

If the app is not functioning as expected or you have any questions, you can contact the Antibio Support Team using one of these options:

Option 1: Use the app to send feedback

Use this if the app opens and you have internet access.

- Open  Antibio.
- Tap the More tab (bottom of screen).
- Tap **Send Feedback**.
- Select an installed email app (e.g., Gmail, Outlook depending on your device)
- Describe your issue and send the email.

CAUTION: DO NOT share any results or documents showing Patient Identifiers.

Option 2: Send us an email directly

If you cannot use the app or access the feedback feature, send an email to: support@antibio.org. Our trained support team will respond as soon as possible.

REPORTING SERIOUS INCIDENTS

If you encounter a **serious incident** involving this software, report it immediately to:

- **Fondation Médecins Sans Frontières**, and
- The **competent authority** in your country.

This is required under **Article L.5212-17** of the French Public Health Code.

According to European regulation, a **serious incident** is defined as one that:

- Caused or may cause the **death** of a patient, user, or another person
- Led or may lead to a **serious, temporary or permanent deterioration** in someone's health
- Represents a **serious public health threat**.

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Manufactured by



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Device Name
Antibiogo