January 22, 2026

Copan WASP S.r.l.
Chiara Congiu
Regulatory Affairs Manager
Via Achille Grandi, 32
Brescia, 25125
Italy

Re: K251511
Trade/Device Name: PhenoMATRIX
Regulation Number: 21 CFR 866.2190
Regulation Name: Automated Image Assessment System For Microbial Colonies On Solid Culture Media
Regulatory Class: Class II
Product Code: PPU, QQY
Dated: December 23, 2025
Received: December 23, 2025

Dear Chiara Congiu:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ribhi Shawar -S

Ribhi Shawar, Ph.D. (ABMM)
Branch Chief, General Bacteriology and Antimicrobial Susceptibility Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251511

Device Name
PhenoMATRIX

Indications for Use *(Describe)*
PhenoMATRIX is a WASPLab optional module intended for the automatic sorting of images of blood-based agar, chocolate agar, MacConkey agar, and CHROMagar Orientation culture media plates according to classification parameters based on Image Analysis Software results and clinical and demographic data.
Image Analysis Software performs semi-quantitative and/or qualitative analysis of culture media plates by detecting microbial growth, estimating colony counts and differentiating isolates based on phenotypic colony characteristics. The system determines how the images should be sorted based on image analysis results in addition to patient data according to expert rules defined by the laboratory.
All images shall be evaluated by trained personnel for final assessment and result definition.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

1. SUBMITTER

Applicant Name:	Copan WASP Srl Via A. Grandi 32 25125 Brescia, Italy +39 030 2687211 copan.regulatory@copangroup.com
Contact Person	Chiara Congiu Copan WASP Srl Via A. Grandi 32 25125 Brescia, Italy +39 338 6904942 copan.regulatory@copangroup.com
Establishment Registration Number:	3009288740
Date Prepared:	May 15, 2025

2. DEVICE NAME

Proprietary Name	PhenoMATRIX
Common/Usual Name	PhenoMATRIX
Classification Name	Automated image assessment system for microbial colonies on solid culture media (21 CFR 866.2190)
Device Class	II
Product Code	PPU, QQY
Panel	Microbiology

3. LEGALLY MARKETED PREDICATE DEVICE

PREDICATE DEVICE

Device Name	APAS Indipendence with Urine Analysis Module
510(K) Number	K183640

PREDICATE/REFERENCE DEVICE

Device Name	APAS Independence with IC Chromogenic MRSA BD Analysis Module; APAS Independence with IC Chromogenic MRSA TFS/S Analysis Module
510(K) Number	K200839

4. DEVICE DESCRIPTION

The PhenoMATRIX is an *in vitro* diagnostic software for automated classification of images of solid culture media plates streaked with microbiological samples derived from the human body.
The PhenoMATRIX comprises software modules intended for image analysis and automatic classification of high-resolution digital images captured by WASPLab device for semi-quantitative and qualitative assessment of microbial growth.
WLPostProcessing, its plugin and the Imaging Product SET perform microbial growth detection, colony counts estimations and isolates differentiation basing on phenotypic colony characteristics.
The image analysis result is combined with LIS data (such as demographic data, clinical data and / or sample data) according to customizable logic rules defined by the laboratory, for image classification. The classification is used for image sorting into dedicated digital folders associated to suggested results.
The PhenoMATRIX requires the WASPLab in order to operate. WASPLab is an *in vitro* diagnostic device for handling, incubation, digital imaging and sorting of agar culture plates.
After PhenoMATRIX processing, the physical plates are left inside the WASPLab and images are available for digital inspection by the trained microbiologist through the WASPLab User Interface.
The trained microbiologist shall assess the plate images in each digital classification folder. To each digital image a suggested result is assigned according to rules previously defined by the laboratory.
The trained microbiologist reviews the plate images, folder by folder, and confirms (or changes) the assigned folder and result. After that, the plates follow the workflow that has been defined by the laboratory according to the assigned result.
The main functionalities of PhenoMATRIX are:

- Assignment of classification parameters to media plate images based on criteria defined by the user (e.g., LIS information, Image Analysis).

- Result assignment according to the classification folder.
- Visualization of media plate images in the WASPLab User Interface for digital inspection.

All plate images shall be reviewed by trained microbiologist before any result definition.

5. INTENDED USE

PhenoMATRIX® is a WASPLab® optional module intended for the automatic sorting of images of blood-based agar, chocolate agar, MacConkey agar, and CHROMagar Orientation culture media plates according to classification parameters based on Image Analysis Software results and clinical and demographic data.
Image Analysis Software performs semi-quantitative and/or qualitative analysis of culture media plates by detecting microbial growth, estimating colony counts and differentiating isolates based on phenotypic colony characteristics.
The system determines how the images should be sorted based on image analysis results in addition to patient data according to expert rules defined by the laboratory.
All images shall be evaluated by trained personnel for final assessment and result definition.

6. COMPARISON TO PREDICATE

According to its intended use, PhenoMATRIX is intended to provide semi-quantitative and qualitative analyses of culture media plates images suggesting growth presence and semi-quantification, isolate colors and morphologies. The differences with the predicate device intended uses consist in the specimen type and the review of the assessement by trained microbiologist: while the predicate devices require reviews of physical plate assessed with growth presence, PhenoMATRIX requires reviews of all digital images.
Such differences do not change, expand or limit the intended use of the Predicate Device and does not affect the safety and effectiveness of the predicates. PhenoMATRIX and the Predicate Devices are intended for culture media plates analysis to support diagnosis of microbial infections.
PhenoMATRIX technological characteristics, operational principle, interpretation of results and quality control are similar to the ones of the Predicate Devices.
All products are equipped with an imaging module and an automated incubator for culture media plates processing and images capturing. Image analyses software provides a semi-quantitative and qualitative assessment of microbial colonies on solid culture media plates.

Similarities

Similarities			
Item	**New Device**	**Primary Predicate Device**	**Other**
Device Name (K number)	**PhenoMATRIX®**	**APAS Indipendence with Urine Analysis Module (K183648)**	**APAS Independence with IC Chromogenic MRSA BD Analysis Module; APAS Independence with IC Chromogenic MRSA TFS/S Analysis Module (K200839)**
Device Classification	Class II (special controls)	Class II (special controls)	Class II (special controls)
Regulation Number	21 CFR 866.2190 Automated image assessment system for microbial colonies on solid culture media.	21 CFR 866.2190 Automated image assessment system for microbial colonies on solid culture media.	21 CFR 866.2190 Automated image assessment system for microbial colonies on solid culture media.
Product Code	PPU: Microbial Colony Image Assessment System QQY: Culture Plate Imaging System For Qualitative Assessment Of Resistant Organisms	PPU: Microbial Colony Image Assessment System	QQY: Culture Plate Imaging System For Qualitative Assessment Of Resistant Organisms
Intended Use / Indications for Use	PhenoMATRIX is a WASPLab optional module intended for the automatic sorting of images of blood-based agar, chocolate agar, MacConkey agar, and CHROMagar Orientation culture media plates according to classification parameters based on Image Analysis Software results and clinical and demographic data. Image Analysis Software performs semi-quantitative and/or qualitative analysis of culture media plates by detecting microbial growth, estimating colony counts and differentiating isolates based on phenotypic colony characteristics. The system determines how the images should be sorted based on image analysis results in addition to patient data according to expert rules defined by the laboratory. All images shall be evaluated by trained personnel for final	The APAS Independence is an in vitro diagnostic system comprised of an instrument and software analysis module(s) for specific indications that are used to automate imaging and interpretation of microbial colonies on plates of solid culture media. The APAS Independence is an in vitro diagnostic system comprised of an instrument for automated imaging of agar culture plates and a software analysis module for the following use: The APAS Independence, when using its urine analysis module, automates urine culture plate imaging and interpretation to detect the presence or absence of microbial growth on sheep blood and MacConkey agar	The APAS Independence is an in vitro diagnostic system comprised of an instrument and software analysis module(s) for specific indications that are used to automate imaging and interpretation of microbial colonies on plates of solid culture media. The APAS Independence is an in vitro diagnostic system comprised of an instrument for automated imaging of agar culture plates and a software analysis module for the following use: 1. The APAS Independence, when using its IC MRSA Chromogenic BD analysis module, automates culture plate imaging and interpretation to detect the presence or absence of colonies with colors suggestive of methicillin-

Similarities			
Item	**New Device**	**Primary Predicate Device**	**Other**
Device Name (K number)	**PhenoMATRIX®**	**APAS Indipendence with Urine Analysis Module (K183648)**	**APAS Independence with IC Chromogenic MRSA BD Analysis Module; APAS Independence with IC Chromogenic MRSA TFS/S Analysis Module (K200839)**
	assessment and result definition.	culture plates that are inoculated with a 1µL sample volume. The APAS Independence, when using its urine analysis module, provides a semi-quantitative assessment of colony counts that are used as an aid in the diagnosis of urinary tract infection. All urine culture plates that are identified as positive for growth by the APAS Independence, when using its urine analysis module, must be reviewed by a trained microbiologist	resistant Staphylococcus aureus (MRSA) growth on Beckton Dickson BBL CHROMagar MRSA II agar that has been inoculated with anterior nares swabs and incubated at 36°C ± 1°C for 24 hours. The APAS Independence, when using its IC MRSA Chromogenic BD analysis module, provides an aid in routine screening for colonization with MRSA. It provides one of two screening results: Presumptive MRSA or Negative. All culture plates that are identified as Presumptive MRSA by the APAS Independence, when using the IC MRSA Chromogenic BD analysis module require review by a trained microbiologist. 2. The APAS Independence, when using its IC MRSA Chromogenic TFS/S analysis module, automates culture plate imaging and interpretation to detect the presence or absence of colonies with colors suggestive of methicillin-resistant Staphylococcus aureus (MRSA) growth on Thermo-Fisher Spectra MRSA agar that has been inoculated with anterior nares swabs and incubated at 36°C ± 1°C for 24 hours. The APAS Independence, when using its IC MRSA

Similarities			
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Device Name (K number)	**PhenoMATRIX®**	**APAS Indipendence with Urine Analysis Module (K183648)**	**APAS Independence with IC Chromogenic MRSA BD Analysis Module; APAS Independence with IC Chromogenic MRSA TFS/S Analysis Module (K200839)**
			Chromogenic TFS/S analysis module, provides an aid in routine screening for colonization with MRSA. It provides one of three screening results: Presumptive MRSA, Presumptive nonMRSA, or Negative. All culture plates that are identified as Presumptive MRSA or Presumptive non-MRSA by the APAS Independence, when using the IC MRSA Chromogenic TFS/S analysis module, require review by a trained microbiologist.
IFU target	Microbial growth	Microbial growth	None
Sample type	Urine	Urine	None
Imaging Station	The WASPLab Imaging Station is provided with a LineScan camera that acquires the image of the culture, two Light Emitting Diode (LED) for the illumination of culture plates from the top and from the bottom of the plates, an imaging background that is a motorised white panel used to acquire plate pictures with white background and plate handling mechanisms to manage plates movements, lid opening and lid closings	A fixed Charge Coupled Device (CCD) camera, top and bottom Light Emitting Diode (LED) illumination for the culture plates, and image capture and a plate handling mechanism, all of which are housed in a light-sealed chassis.	A fixed Charge Coupled Device (CCD) camera, top and bottom Light Emitting Diode (LED) illumination for the culture plates, and image capture and a plate handling mechanism, all of which are housed in a light-sealed chassis.
Instrument control and management	WASPLab® device is provided with: - A PANEL PC Touch Screen Monitor on the Imaging Station provided with the user interface to allow the user to manage the	The APAS Controller PC manage image capture, storage and analysis. The Plate Controller PC controls movement of culture plates between the input carriers, imaging	The APAS Controller PC manage image capture, storage and analysis. The Plate Controller PC controls movement of culture plates between the input carriers, imaging

Similarities			
Item	**New Device**	**Primary Predicate Device**	**Other**
Device Name (K number)	**PhenoMATRIX®**	**APAS Indipendence with Urine Analysis Module (K183648)**	**APAS Independence with IC Chromogenic MRSA BD Analysis Module; APAS Independence with IC Chromogenic MRSA TFS/S Analysis Module (K200839)**
	instrument and to check its status; - A Workstation to allow the user to visualize the acquired images; - A Control Unit where all the software managing the instrument are loaded and running to allow plates movements and handling. Moreover, in the Control Unit plates images are stored and can be evaluated by the PhenoMATRIX.	station and output carriers or stacks. The Instrument Controller PC provides the user interface for operation of the APAS Independence and coordinates the functions of the APAS and Plate Controller PCs	station and output carriers or stacks. The Instrument Controller PC provides the user interface for operation of the APAS Independence and coordinates the functions of the APAS and Plate Controller PCs
Image Analysis Module Software	PhenoMATRIX is installed on the WASPLab Control Unit and configurable for plate images assessment.	Analyses modules are installed on the APAS Controller PC to provide the configuration and instructions for image capture and analysis.	Analyses modules are installed on the APAS Controller PC to provide the configuration and instructions for image capture and analysis.
LIS Interface	Analyses results can be sent to the LIS. Data related to the sample are retrieved by LIS.	Analyses results can be sent to the LIS. Data related to the sample are retrieved by LIS.	Analyses results can be sent to the LIS. Data related to the sample are retrieved by LIS.

Differences

Differences			
Item	**New Device**	**Primary Predicate Device**	**Other**
Device Name (K number)	**PhenoMATRIX®**	**APAS Indipendence with Urine Analysis Module (K183648)**	**APAS Independence with IC Chromogenic MRSA BD Analysis Module; APAS Independence with IC Chromogenic MRSA TFS/S Analysis Module (K200839)**
IFU target	Microbial growth	None	Presumptive MRSA colonies
Sample type	Microbiological samples derived from the human body	Urine	Anterior nares specimens

Differences			
Item	**New Device**	**Primary Predicate Device**	**Other**
Device Name (K number)	**PhenoMATRIX®**	**APAS Indipendence with Urine Analysis Module (K183648)**	**APAS Independence with IC Chromogenic MRSA BD Analysis Module; APAS Independence with IC Chromogenic MRSA TFS/S Analysis Module (K200839)**
	in liquid or semi-liquid phase.		
Result management	All digital images shall be reviewed by trained microbiologist for final assessment before result definition and sending to the LIS.	All plates assessed as positive for growth shall be reviewed by trained microbiologist. Negative for growth plates are automatically managed by the device.	All plates assessed as "Presumptive MRSA" or "Presumptive non-MRSA" shall be reviewed by trained microbiologist. Negative for MRSA plates are automatically managed by the device.
Instrumentation	WASPLab	APAS Indipendence	APAS Indipendence
Calibration	No calibration is required for PhenoMATRIX software that is installed on WASPLab device that is calibrated by Copan personnel during setup during manufacturing process.	Daily colour calibration is required prior to use to be performed by the user.	Daily colour calibration is required prior to use to be performed by the user.
QC Control	No quality control procedure is required for PhenoMATRIX product because each single digital image processed by PhenoMATRIX is reviewed by a trained microbiologist who verifies that the classification of the image is accurate according to the set rules. A dedicated quality control procedure shall be carried out on WASPLab device to ensure appropriate system operation. The WASPLab QC protocol is intended to monitor for contamination and to check the entire process starting from primary sample processing to media culture plates' imaging and incubation, to ensure proper performance by the whole system.	Daily performed by the operator by using Positive and Negative for Growth Plates	Daily performed by the operator by using Positive and Negative for Growth Plates

7. NON CLINICAL PERFORMANCE DATA

Digital Image Evaluation:

Blood-based, Chocolate, MacConkey and CHROMagar Orientation culture media plates were streaked with mixed cultures of organisms in different ratios.
After plate incubation, the interpretation of physical plates and digital plates images acquired by 3 WASPLab instruments was performed by three operators with different levels of experience gained in microbiology laboratory. All plates (digital and physical) were interpreted for microbial growth quantification and phenotypical characteristics of isolates as morphology, color, consistency and presence of hemolysis.
The analysis of results showed high and reproducible agreement between plates interpretation on the digital images and the direct interpretation of physical plates, independently from operator experience, plate type, incubation time, WASPLab and test day.
In particular, the inspection of digital image allows for the correct identification of phenotypical characteristics of colonies. The overall percent agreement between the image interpretation and the inspection of physical plates was always >95%.

PhenoMATRIX Analytical Performance:

Reproducibility study
The study aimed to evaluate the reproducibility with which PhenoMATRIX interprets digital images. Different culture media (blood-based, Chocolate, MacConkey and CHROMagar Orientation) were streaked with mixed cultures of organisms in different ratios. Plate images were captured by three different WASPLab instruments for the analysis by PhenoMATRIX imaging software modules, including detection of microbial growth, quantification of microbial growth and/or the detection of colony morphology/color and assessment of growth purity. All the IPs products were included in this evaluation to challenge all the capabilities. Test runs were conducted in three distinct days. The reference result was given by the visual inspection of plate images by an experienced technician.

Accuracy of microbial growth detection
This study was conducted using plates images captured by WASPLab, exhibiting presence or absence of microbial growth from various species. Blood-based agars, differential agar and selective agar from multiple manufacturers were included as culture media.
The detection of microbial growth by PhenoMATRIX image analysis modules was compared with the visual reading by one operator performed on the same plate image. Growth detection accuracy was calculated as agreement between software output and human interpretation.
All the image analysis modules achieved >99% positive percent agreement for growth detection. Negative percentage agreement was >85% based on the specificity of the culture medium.

Accuracy of microbial growth quantitation
This study was conducted using plates images captured by WASPLab, exhibiting microbial growth of different species at increasing microbial load. Blood-based agars, differential agar and selective agar from multiple manufacturers were included as culture media.
Semiquantitative analysis by PhenoMATRIX image analysis modules was compared with the visual reading performed on the same plate image by one operator.
All the image analysis modules obtained >80% agreement on the logarithmic classes of microbial load up to $\geq 10^6$ CFU/mL.

Analytical Specificity

Morphological detection on blood-based and MacConkey agar

The PhenoMATRIX ability to detect colony morphology associated to different clinically relevant organisms was evaluated by testing images of blood-based and MacConkey agar culture plates captured by WASPLab, selected with different pathogens at various microbial loads in pure and mixed cultures.

The morphologies detected by PhenoMATRIX were compared with the visual reading of the plate image performed by a trained operator.

For most species (and groups of species), the positive percent agreement of detecting the colony morphology for the species is >80%. Performance may vary on some species that have less specific morphology on the tested culture media.

Tables below report the list of morphologies that can be detected by PhenoMATRIX.

Colony morphologies reported on blood-based agar plate. (*) The detection of swarming morphologies aims to prevent the assessment of the microbial growth for the impossibility to accurately determine which species grow under the swarming colonies

Morphology	Description
Coliform morphologies	Coliform like colonies, grey circular colonies with large dimension
Swarming morphologies(*)	Presence of swarming phenomenon related to *Proteus* spp.
Pseudomonas-like morphologies	Flat colonies with irregular shape and metallic reflection, with different shapes and dimensions as Pseudomonas species like
Staphylococcus aureus-like morphologies	Yellowish circular colonies with medium size with different hemolytic patterns
Staphylococcus saprophyticus-like morphologies	White creamy circular colonies with medium size without β-hemolysis
Other *Staphylococcus* spp.-like morphologies	White/greyish circular colonies with small to medium size without β-hemolysis
Enterococcus spp.-like morphologies	Greyish circular colonies with small/medium size with γ-hemolysis
Streptococcus pyogenes-like morphologies	Greyish-white round colonies with small medium size associated with presence of bright β-hemolysis
Streptococcus agalactiae-like morphologies	Greyish-white round colonies with small/medium size associated with presence of β-hemolysis
Viridans morphologies	Grey round colonies with small/medium size with halo indicative of α-hemolysis (it may include *Aerococcus* spp.)

Morphology	Description
Candida spp. like morphologies	Cream round colonies that may display "feet" and small size
Other gram-positive morphologies	Colonies with large dimensions
Other gram-negative morphologies	Colonies with small to medium size with different hemolytic pattern

Colony morphologies reported on MacConkey agar plate

Morphology	Description
Non-mucoid lactose fermenter morphologies	Pink/violet flat colonies
Pseudomonas morphologies	Transparent/ beige flat colonies with irregular shape. May display green pigment
Non-fermenters	Transparent/beige colonies

Morphological detection and semi-quantification on CHROMagar Orientation medium

The PhenoMATRIX ability to detect colony morphology associated to different clinically relevant organisms associated with urinary tract infections was evaluated by testing images of CHROMagar Orientation plates captured by WASPLab, selected with different pathogens at various microbial loads in pure and mixed cultures.

The morphologies detected by PhenoMATRIX and their semi-quantification were compared with the visual reading of the plate image performed by a trained operator.

For most species (and groups of species), the positive percent agreement of detecting the colony morphology for the species is >80%. Performance may vary on some species that have less specific morphology on the tested culture media. The agreement between the software's and the operator's morphology semi-quantification was generally >80%, except when colonies exhibited gradient-like features in both color intensity and morphology.

Tables below report the list of morphologies that can be detected by PhenoMATRIX.

Colony morphologies reported on CHROMagar™ Orientation medium

Morphology	Description
Enterococcus spp.	Blue-green small colonies
Staphylococcus saprophyticus	Light pink to rose, small opaque colonies with or without halos
Streptococcus agalactiae	Light blue-green to light blue, pinpoint to small colonies, with or without halos.
Escherichia coli	Dark rose to pink, transparent colonies, medium to large size, with or without halos in the surrounding medium

Morphology	Description
Klebsiella, *Enterobacter, Serratia* and *Citrobacter* group	Medium-blue to dark blue colonies
Proteus spp., *Morganella, Providencia* group	Pale to beige colonies surrounded by brown halos.
Pseudomonas spp.	Cream to blue translucent colonies
Naturally-pigmented colonies	White or transparent colonies

β-hemolysis detection
The PhenoMATRIX ability to detect β-hemolysis was evaluated by testing images of blood-based agar plates captured by WASPLab, exhibiting presence or absence of β-hemolytic reaction.
The detection of the β-hemolysis by PhenoMATRIX was compared with the visual reading by one operator performed on the same plate image. β-hemolysis detection accuracy was calculated as agreement between software output and human interpretation.
>95% plates showing β-hemolysis were correctly detected.

8. CLINICAL PERFOMANCE DATA

The study was designed to demonstrate that PhenoMATRIX is able to classify plate images according to custom interpretation rules which should reproduce, totally or partially, the culture interpretation procedures of the microbiology laboratory. The classification rules combine proper analysis of microbial growth on culture plate images with patient data through predefined logic functions and are built to sort plate images into folders according to similarities in microbial growth pattens, facilitating image review and routing toward the appropriate microbial workups.
A simulator was provided to three U.S. clinical laboratories. Each PhenoMATRIX simulator was configured according to specific classification criteria agreed with the respective laboratories and was loaded with images of culture plates, associated with demographic data when needed. Images were classified by PhenoMATRIX and displayed to the laboratory microbiologist on the WASPLab interface for classification result confirmation or modification.

Number of plate images and Types of samples analyzed at each clinical site

Site	Number of plate images	Sample Type
A	3856	Body Fluids
B	418	Clean-catch urine specimens
C	1571	Clean-catch urines and urines collected with catheter and pediatric bag,
Total	5845	

Per each site, according to sample types and classification rules, different agar media plates and image analyses outcomes were analyzed

Type of agar plate and image analyses outcomes analyzed

Site	Agar Media Plate	Image analyses outcomes
A	- TSA+5% Sheep Blood - Columbia CNA + 5% Sheep Blood - Chocolate agar - MacConkey agar	• Microbial growth detection • Microbial growth quantitation • Growth purity assessment • Morphological detection
B	TSA with 5% Sheep Blood // MacConkey Agar Plate (biplate)	• Growth detection • Growth semi-quantification
C	CHROMagar Orientation//Trypticase Soy Agar +5% Sheep Blood (biplate)	• Growth detection • Growth semi-quantification • Growth purity • Morphological detection • Beta-hemolysis detection

Each PhenoMATRIX configuration demonstrated high classification agreement with the culture plate classification performed by the laboratory microbiologist through the digital review of plate images.

Summary of classification agreement at each clinical

Site	Number of Samples in agreement	% Agreement per sample classification
A	415/420	98.8%
B	406/418	97.1%
C	1474/1571	93.8%