510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY

I Background Information:

A 510(k) Number

K232756

B Applicant

Copan WASP S.r.l.

C Proprietary and Established Names

Colibrí

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
LON	Class II	21 CFR 866.1645 - Fully automated short-term incubation cycle antimicrobial susceptibility system	MI - Microbiology
QQV	Class II	21 CFR 866.3378 - Clinical mass spectrometry microorganism identification and differentiation system	MI - Microbiology
QBN	Class II	21 CFR 866.3378 - Clinical mass spectrometry microorganism identification and differentiation system	MI - Microbiology

II Submission/Device Overview:

A Purpose for Submission:

To obtain a substantial equivalence determination for the Colibrí for use with the Beckman Coulter MicroScan WalkAway AST system and update the package insert AST data summary tables to be consistent across both claimed AST devices (Beckman Coulter MicroScan WalkAway, subject of this submission, and bioMérieux VITEK 2, cleared for use with the Colibrí in K220546).

B Type of Test:

Qualitative *in vitro* diagnostic device for identification of bacteria cultured from human specimens by automation of target preparation for mass spectrometry analysis and antimicrobial susceptibility test (AST) assessment of bacteria cultured from human specimens by automation of culture suspensions for AST analysis.

III Intended Use/Indications for Use:

A Intended Use(s):
See Indications for Use below.

B Indication(s) for Use:
The Colibrí is an automated in vitro diagnostic specimen preparation system for use with WASPLab to prepare MALDI-TOF targets for the bioMérieux VITEK MS systems or Bruker MALDI Biotyper CA mass spectrometry systems for qualitative identification and microbial suspension for the bioMérieux VITEK 2 systems or Beckman Coulter MicroScan WalkAway Antimicrobial Susceptibility Testing (AST) systems for qualitative testing of isolated colonies of gram-negative and gram-positive bacterial species grown on solid culture media.

The Colibrí is an automated pre-analytical processor that picks isolated colonies designated by the operator and uses a pipetting system to prepare MALDI-TOF MS (Matrix-Assisted Laser Desorption/Ionization-Time of Flight Mass Spectrometry) target slides for bacterial identification and microbial suspension at known concentration for Antimicrobial Susceptibility Testing and purity assessment.

The Colibrí software records the identity of each sample and its position on the target slide and communicates this information electronically to the MALDI-TOF MS analyzers.

Bacterial suspensions for AST and purity plates are identified by barcode label.

The Colibrí is intended for use by trained healthcare professionals in clinical laboratories in conjunction with other clinical and laboratory findings, including Gram staining, to aid in the diagnosis of bacterial infections.

The Colibrí has not been validated for use in the identification or processing of yeast species, molds, Nocardia, or mycobacteria.

C Special Conditions for Use Statement(s):
Rx - For Prescription Use Only

IVD - For In Vitro Diagnostic Use Only

Special Instruments for Use:
Bruker MALDI Biotyper for Clinical Applications (MBT-CA)
bioMerieux VITEK MS
bioMerieux VITEK 2
Beckman Coulter MicroScan WalkAway
WASPLab

[Refer to the K193138 Decision Summary for Special Conditions for Use Statements that are only applicable to the sample preparation for bacterial identification and MALDI-TOF MS workflow.]

The following Special Conditions for Use Statements related to microbial suspension preparation for AST were modified from K220546 to include the MicroScan:

• Use of this device is permitted only in association with bioMérieux VITEK MS systems or Bruker MALDI Biotyper CA System for microbial identification and in association with bioMérieux VITEK 2 or Beckman Coulter MicroScan WalkAway systems for AST.

• The performance of Colibrí in conjunction with the VITEK 2 and MicroScan WalkAway systems was evaluated with Trypticase Soy Agar + 5% sheep blood (BD), Columbia Agar + 5% sheep blood (bioMerieux), MacConkey Agar (bioMerieux), Trypticase Soy Agar + 5% sheep blood / MacConkey Agar (BD). The use of other types of culture media has not been validated.

• Preparation of bacterial suspensions from unclaimed species from VITEK 2 or MicroScan WalkAway systems has not been evaluated.

The following Special Conditions for Use Statements related to microbial suspension preparation for AST were included in K220546 and are still applicable – the trade name was updated as needed:

• This product is intended for target slides preparation for identification and suspensions preparation for susceptibility testing from colonies grown on solid agar media plates. Do not use for identification from liquid cultures.

• For AST application, make sure that the selected colonies are morphologically similar.

• Results obtained using the Colibrí for sample preparation with the compatible analyzers should be used as an adjunct to clinical observations and other information available to the physician.

• The ability of the Colibrí to prepare samples for analysis with the compatible analyzers was evaluated using only the species listed in the Inclusivity and AST Challenge studies, described in the Performance Characteristics section of this Package Insert. The ability of the Colibrí to prepare samples of other species for mass spectrometry analysis and AST has not been evaluated.

• The Colibrí should be used only for preparation of target slides and microbial suspension from isolated colonies of Gram-negative and Gram-positive bacterial species grown on solid culture media. Colibrí is not intended for processing of yeasts, moulds, Nocardia or Mycobacteria.

IV Device/System Characteristics:

A Device Description:

The Colibrí is an instrument designed to be used as an accessory for downstream matrix assisted laser desorption/ionization time of flight mass spectrometry (MALDI-TOF MS) and antimicrobial susceptibility testing (AST) analyzers. The Colibrí is comprised of the Colibrí instrument (including on-board pipetting system, spreader, and nephelometer), software, primary tubes for microbial suspension, and daily verification kit which automatically prepares target

slides for ID and microbial suspensions and purity plates for AST from isolated colonies. The Colibrí is designed to be used in conjunction with the Copan WASPLab to automate the plate incubation, plate management, image acquisition, colony selection, target slide preparation (for ID), microbial suspension preparation (for AST), and purity plate preparation steps of the ID and/or AST sample preparation workflow. Refer to the K223245 Decision Summary for the device description and performance characteristics of the Colibrí when used with the WASPLab.

The Colibrí automates the preparation of MALDI target slides for the bioMérieux VITEK MS or the Bruker MALDI Biotyper CA systems that are used in clinical laboratories for identification (ID) of gram-negative and gram-positive bacterial species grown on plated media by MALDI-TOF MS. Refer to the K193138 Decision Summary for the device description and performance characteristics of the sample preparation for bacterial identification and MALDI-TOF MS workflow.

The Colibrí also automates the preparation of gram-negative and gram-positive bacterial suspensions at a known concentration from isolated colonies for the bioMérieux VITEK 2 and Beckman Coulter MicroScan WalkAway that are used in clinical laboratories for AST analyses. The Colibrí is also used for purity plate preparation for purity assessments. Refer to the K220546 Decision Summary for the device description and performance characteristics of the sample preparation for AST workflow with the bioMérieux VITEK 2. The workflow for both AST systems is similar and both rely on isolated colony samples, although there are differences in the Primary and Secondary Tubes. For use with the VITEK 2, the Primary Tube and Secondary Tube are filled with saline for all organisms. For use with the Beckman Coulter MicroScan WalkAway, the operator will need to input the correct Primary Tube (which will contain either saline or water) in accordance with the MicroScan WalkAway IFU. The Secondary Tube will be automatically filled with either water with PLURONIC or Mueller-Hinton Broth with 3% lysed horse blood to prepare the final suspension in accordance with the MicroScan WalkAway IFU. The performance characteristics of the sample preparation for AST from isolated colony workflow with the Beckman Coulter MicroScan WalkAway are described in this submission.

B Instrument Description Information:

1. Instrument Name:

   Colibrí

2. Specimen Identification:

   Culture plates for processing are identified by the WASPLab by scanning a manually applied linear barcode on the side of each plate. The loading conveyor moves the plate inside the Imaging Module in the WASPLab, where the plate is checked in to the system through a barcode reader. The barcode is again scanned when the plate is manually transferred to the Colibrí. The barcode is used to orientate the plate and, together with the plate's geometric center, also used to define the Cartesian coordinates of each of the colonies that are designated for picking. The designated colonies are then picked for the assigned downstream activities.

3. Specimen Sampling and Handling:

Plates labeled with a barcode on the side are loaded onto a conveyor and loaded into the WASPLab. The barcode is scanned, and the plate is incubated within the WASPLab. After appropriate incubation, each plate is photographed, and the image is saved on the WASPLab server and is displayed to the operator on the WebApp interface. After selecting isolated colonies and assigning the downstream task, the user manually transfers the plate to the Colibrí. Within the Colibrí, the plates are prepared for ID (as described in the K193138 Decision Summary) or AST (as described in the K220546 Decision Summary).

4. Calibration:

Colibrí requires four different calibrations: one on the on-board nephelometer and three on the cameras. No changes are made in set-up calibration, auto-calibration, and run-time calibration checks which are performed as described in the K193138 Decision Summary. No changes are made to daily nephelometer verification, which is performed as described in the K220546 Decision Summary.

The WASPLab does not require calibration.

5. Quality Control:

Quality Control for AST testing was performed in accordance with the manufacturer's instructions for the Beckman Coulter MicroScan. CLSI-recommended reference strains *Escherichia coli* ATCC 25922, *Pseudomonas aeruginosa* ATCC 27853, *Staphylococcus aureus* ATCC 29213, and *Enterococcus faecalis* ATCC 29212 were grown on trypticase soy agar + 5% sheep blood. Microbial suspensions were prepared using three separate Colibrí instruments and loaded in the appropriate MicroScan panel. MIC values for each drug/organism combination were compared to the established ranges reported in the MicroScan panel labeling. Purity of all the suspensions was confirmed by purity plates prepared by the Colibrí, with 100% of purity plates showing monomicrobial growth. Quality control testing was performed daily during analytical performance testing using the quality control bacterial strains in rotation, and all results obtained were in-range. Results are summarized in **Table 1**. The quality control testing is acceptable.

Quality control for bacterial identification is described in the K193138 Decision Summary. Quality control for AST with the bioMérieux VITEK 2 was conducted in a similar manner and is described in the K220546 Decision Summary. Additional quality control measures are not needed for the WASPLab.

Table 1. Quality Control Organisms and Antimicrobial Agents Tested

QC organism	Antimicrobial agent	QC range (CLSI M100)	On panel values * (panel IFU)	No. MIC within QC Range
Escherichia coli ATCC 25922	Amikacin	0.5 - 4	≤4 - 8	36/36 (100%)
	Ampicillin/Sulbactam	2/1 - 8/4	≤4/2	36/36 (100%)
	Aztreonam	0.06 - 0.25	≤0.5	36/36 (100%)

QC organism	Antimicrobial agent	QC range (CLSI M100)	On panel values * (panel IFU)	No. MIC within QC Range
	Ceftazidime	0.06 - 0.5	≤1	36/36 (100%)
	Cefotaxime	0.03 - 0.12	≤4	36/36 (100%)
	Ciprofloxacin	0.004 - 0.016	≤0.12	36/36 (100%)
	Cefepime	0.016 - 0.12	≤1	36/36 (100%)
	Gentamicin	0.25 - 1	≤1 - 2	36/36 (100%)
	Imipenem	0.06 - 0.5	≤0.5	36/36 (100%)
	Levofloxacin	0.008 - 0.06	≤0.5	36/36 (100%)
	Meropenem	0.008 - 0.06	≤0.12	36/36 (100%)
	Minocycline	0.25 - 1	≤2	36/36 (100%)
	Piperacillin/Tazobactam	1/4 - 8/4	≤8/4	36/36 (100%)
	Tetracycline	0.5 - 2	≤2	36/36 (100%)
	Ticarcillin/K Clavulanate	4/2 - 16/2	≤16/2	36/36 (100%)
	Tobramycin	0.25 - 1	≤2	36/36 (100%)
	Trimethoprim/Sulfamethoxazole	≤0.5/9.5	≤1/19	36/36 (100%)
Staphylococcus aureus ATCC 29213	Ciprofloxacin	0.12 - 0.5	≤0.5	42/42 (100%)
	Clindamycin	0.06 - 0.25	≤0.25	42/42 (100%)
	Daptomycin	0.12 - 1	≤0.25 - 1	42/42 (100%)
	Erythromycin	0.25 - 1	≤0.25 - 1	42/42 (100%)
	Levofloxacin	0.06 - 0.5	≤1	42/42 (100%)
	Linezolid	1 - 4	≤1 - 4	42/42 (100%)
	Minocycline	0.06 - 0.5	≤1	42/42 (100%)
	Moxifloxacin	0.016 - 0.12	≤0.25	42/42 (100%)
	Nitrofurantoin	8 - 32	≤32	42/42 (100%)
	Penicillin G	0.25 - 2	0.25 - >8	42/42 (100%)
	Tetracycline	0.12 - 1	≤1	42/42 (100%)
	Tigecycline	0.03 - 0.25	≤0.25	42/42 (100%)
	Vancomycin	0.5 - 2	0.5 - 2	42/42 (100%)
Pseudomonas aeruginosa ATCC 27853	Amikacin	1 - 4	≤4 - 8	30/30 (100%)
	Aztreonam	2 - 8	2 - 8	30/30 (100%)
	Cefepime	0.5 - 4	≤1 - 4	30/30 (100%)
	Cefotaxime	8 - 32	8 - 32	30/30 (100%)
	Ceftazidime	1 - 4	≤1 - 4	30/30 (100%)
	Ciprofloxacin	0.12 - 1	≤0.12 - 1	30/30 (100%)

QC organism	Antimicrobial agent	QC range (CLSI M100)	On panel values * (panel IFU)	No. MIC within QC Range
	Gentamicin	0.5 - 2	≤1 - 4	30/30 (100%)
	Imipenem	1 - 4	1 - 4	30/30 (100%)
	Levofloxacin	0.5 - 4	≤0.5 - 4	30/30 (100%)
	Meropenem	0.12 - 1	≤0.12 - 1	30/30 (100%)
	Piperacillin/Tazobactam	1/4 - 8/4	≤8/4	30/30 (100%)
	Tetracycline	8 - 32	8 - >8	30/30 (100%)
	Ticarcillin/K Clavulanate	8/2 - 32/2	≤16/2 - 32/2	30/30 (100%)
	Tobramycin	0.25 - 1	≤2	30/30 (100%)
Enterococcus faecalis ATCC 29212	Ampicillin	0.5 - 2	≤1	30/30 (100%)
	Ciprofloxacin	0.25 - 2	≤0.5 - 1	30/30 (100%)
	Daptomycin	1 - 4	1 - 4	30/30 (100%)
	Erythromycin	1 - 4	1 - 4	30/30 (100%)
	Levofloxacin	0.25 - 2	≤1 - 2	30/30 (100%)
	Linezolid	1 - 4	≤1 - 4	30/30 (100%)
	Moxifloxacin	0.06 - 0.5	≤0.25 - 0.5	30/30 (100%)
	Nitrofurantoin	4 - 16	≤32	30/30 (100%)
	Penicillin G	1 - 4	0.5 - 2	30/30 (100%)
	Tetracycline	8 - 32	4 - >8	30/30 (100%)
	Tigecycline	0.03 - 0.12	≤0.25	30/30 (100%)
	Vancomycin	1 - 4	1 - 4	30/30 (100%)

*Due to MicroScan panel design, the full QC range was not available for all organism/drug combinations. For the drugs where the concentrations on the MicroScan panel do not cover the full CLSI/FDA-recommended QC range, the reported value was taken as an indication of acceptable QC.

V Substantial Equivalence Information:

A Predicate Device Name(s):
Colibrí

B Predicate 510(k) Number(s):
K223245

C Comparison with Predicate(s):

Device & Predicate Device(s):	DEVICE K232756	PREDICATE K223245
Device Trade Name	Colibrí	Colibrí
General Device Characteristic Similarities		
Intended Use/Indications For Use	The Colibrí is an automated in vitro diagnostic specimen preparation system for use with WASPLab to prepare MALDI-TOF targets for the bioMérieux VITEK MS systems or Bruker MALDI Biotyper CA mass spectrometry systems for qualitative identification and microbial suspension for the bioMérieux VITEK 2 systems or Beckman Coulter MicroScan WalkAway Antimicrobial Susceptibility Testing (AST) systems for qualitative testing of isolated colonies of gram-negative and gram-positive bacterial species grown on solid culture media. The Colibrí is an automated pre-analytical processor that picks isolated colonies designated by the operator and uses a pipetting system to prepare MALDI-TOF MS (Matrix-Assisted Laser Desorption/ Ionization-Time of Flight Mass Spectrometry) target slides for bacterial identification and microbial suspension at known concentration for Antimicrobial Susceptibility Testing and purity assessment. The Colibrí software records the identity of each sample and its position on the target slide and communicates this information electronically to the MALDI-TOF MS analyzers. Bacterial suspensions for AST and purity plates are identified by barcode label. The Colibrí is intended for use by trained healthcare professionals in clinical laboratories in conjunction with other clinical and laboratory findings, including Gram staining, to aid in the diagnosis of bacterial infections. The Colibrí has not been validated for use in the identification or processing of yeast species, molds, Nocardia, or mycobacteria.	The Colibrí is an automated in vitro diagnostic specimen preparation system for use with WASPLab to prepare MALDI-TOF targets for the bioMérieux VITEK MS or Bruker MALDI Biotyper CA mass spectrometry systems for qualitative identification and microbial suspensions for the bioMérieux VITEK 2 Antimicrobial Susceptibility Testing (AST) system for qualitative testing of isolated colonies of gram-negative and gram-positive bacterial species grown on solid culture media. The Colibrí is an automated pre-analytical processor that picks isolated colonies designated by the operator and uses a pipetting system to prepare MALDI-TOF MS (Matrix-Assisted Laser Desorption/Ionization-Time of Flight Mass Spectrometry) target slides for bacterial identification and microbial suspension at known concentration for Antimicrobial Susceptibility Testing and purity assessment. The Colibrí software records the identity of each sample and its position on the target slide and communicates this information electronically to the MALDI-TOF MS analyzers. Bacterial suspensions for AST and purity plates are identified by barcode label. The Colibrí is intended for use by trained healthcare professionals in clinical laboratories in conjunction with other clinical and laboratory findings, including Gram staining, to aid in the diagnosis of bacterial infections. The Colibrí has not been validated for use in the identification or processing of yeast species, molds, Nocardia, or mycobacteria.
Method of Testing	Direct testing from isolated colonies for ID purposes in conjunction with	Direct testing from isolated colonies for ID purposes in conjunction with

Device & Predicate Device(s):	DEVICE K232756	PREDICATE K223245
	bioMérieux VITEK MS systems or Bruker MALDI Biotyper CA systems. Direct testing from isolated colonies for AST purposes in conjunction with bioMérieux VITEK 2 systems or Beckman Coulter MicroScan WalkAway systems.	bioMérieux VITEK MS systems or Bruker MALDI Biotyper CA systems. Direct testing from isolated colonies for AST purposes in conjunction with bioMérieux VITEK 2 systems.
Sample/Media Type	Isolated bacterial colonies from any patient source grown on solid media plates included in K193138 and K220546.	Same
Plate Management	Barcode-labeling plates are manually loaded into the Colibrí after image acquisition.	Same
Plate Image Acquisition	WASPLab camera	Same
Colony Selection	Colonies to be picked are identified on a digital plate image using a Graphical User Interface on a dedicated workstation.	Same
Method of Colony Picking	Automatic picking of colonies using pipette tips.	Same
ID Target Preparation	When connected with VITEK MS, a portion of microbial colony from an agar plate is automatically spotted on a VITEK MS-DS target slide (VITEK MS DS Target Slides, 48 positions disposable plastic targets) by using the pipetting system. 1µL of matrix is automatically applied to the spot using the pipetting system. The dried target slide is then manually loaded into the VITEK MS. When connected with MALDI Biotyper CA instrument, a portion of microbial colony from an agar plate is automatically spotted on a Bruker Target Plate (IVD 48 Spot Target plate or MBT Biotarget 96 US IVD) by using the pipetting system. 1µL of matrix is automatically applied to the spot using the pipetting system. The dried target slide is then manually loaded into the MALDI Biotyper CA instrument.	Same
AST Suspension Preparation	Using a pipetting system, a predefined number of morphologically similar colonies are transferred into the Primary Tube that is successively vortexed. A homogenous heavy suspension of organisms is prepared and checked by using on-board Colibrí nephelometer. A variable aliquot of the heavy suspension is automatically transferred into the Secondary Tube to obtain the final	Same

Device & Predicate Device(s):	DEVICE K232756	PREDICATE K223245
	microbial concentration according to IVD package insert. The suspensions prepared by Colibrí must be tested in MANUAL MODE on the VITEK 2 or used to rehydrate MicroScan AST panels.	
Calibration	Colibrí requires four different calibrations, one on the nephelometer, three on the cameras. None require user intervention.	Same
Preparatory Activities	Nephelometer verification by check using Daily Verification Kit.	Same
Quality Control	Dependent on next-step IVD analyzers.	Same
General Device Characteristic Differences		
Primary Tubes	VITEK 2: contains saline solution (with a yellow cap) MicroScan: contains water (with a red cap) or saline solution (with a blue cap)	VITEK 2: contains saline solution (with a yellow cap) MicroScan: n/a
Secondary Tubes	VITEK 2: manually prefilled with PBS solution 0.45% NaCl, pH 4.5-7.0 (sterile); manually loaded MicroScan: contains Inoculum Water with PLURONIC or Mueller Hinton Broth with 3% Lysed Horse Blood; manually loaded	VITEK 2: manually prefilled with PBS solution 0.45% NaCl, pH 4.5-7.0 (sterile); manually loaded MicroScan: n/a
Card Inoculation	VITEK 2: the prepared Secondary Tube is placed in the cassette with a susceptibility card following the warning / recommendation written in the VITEK 2 Instructions for Use. MicroScan: The prepared Secondary Tube is manually inoculated in a susceptibility panel following the MicroScan Instructions for Use.	VITEK 2: the prepared Secondary Tube is placed in the cassette with a susceptibility card following the warning / recommendation written in the VITEK 2 Instructions for Use. MicroScan: n/a

VI Standards/Guidance Documents Referenced:

The following specific standards and guidances were used to inform device and study design for preparation of samples for AST, as previously described in the Decision Summary for K220546:

- Guidance for Industry and Food and Drug Administration Staff – Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems (August 28, 2009)
- CLSI M100. Performance Standards for Antimicrobial Susceptibility Testing. (33rd Edition)
- CLSI M07. Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically (11th Edition)

Specific standards and guidances used to inform device and study design for the preparation of samples for ID can be found in the K193138 Decision Summary.

VII Performance Characteristics:

The performance of the Colibrí was evaluated in conjunction with the Beckman Coulter MicroScan WalkAway using the criteria for MIC interpretation as described in the MicroScan labeling.

Refer to the K193138 Decision Summary for the performance characteristics of the sample preparation for bacterial identification and MALDI-TOF MS workflow. Refer to the K220546 Decision Summary for the performance characteristics of the sample preparation for the AST workflow with bioMérieux VITEK 2. Refer to the Decision Summary for K223245 for the performance characteristics of sample preparation with WASPLab for downstream ID and AST.

A Analytical Performance:

1. Precision/Reproducibility:

The reproducibility of MIC results obtained using microbial suspensions automatically prepared from isolated colonies by the Colibrí was evaluated with the Beckman Coulter MicroScan WalkAway. Inter-operator reproducibility of the Colibrí was previously demonstrated in K220546 and K223245. For the reproducibility study with the MicroScan, three Colibrí instruments paired with one WASPLab instrument were used to prepare microbial suspensions from overnight (18 to 24 hour) cultures of 18 representative, clinically relevant bacterial isolates grown on trypticase soy agar with 5% sheep blood. Representative MicroScan AST panels were chosen for analysis and were tested with pure colonies of nine gram-negative isolates and nine gram-positive isolates (summarized in **Table 2**). Each panel included drugs representing different drug classes.

Table 1. Representative MicroScan Panels Tested in Reproducibility Study

MicroScan Panel	Indicated Organisms Groups	Antimicrobial Agents
MSP6	*Streptococcus* spp.	Ampicillin, Cefepime, Cefotaxime, Ceftriaxone, Clarithromycin, Clindamycin, Daptomycin, Erythromycin, Levofloxacin, Linezolid, Meropenem, Penicillin G, Tetracycline, Vancomycin
NM-NF50	Enterobacterales, Non-fermenters	Amikacin, Gentamicin, Tobramycin, Cefepime, Ceftazidime, Cefotaxime, Meropenem, Imipenem, Ampicillin/Sulbactam, Piperacillin/Tazobactam, Ticarcillin/K Clavulanate, Aztreonam, Levofloxacin, Ciprofloxacin, Minocycline, Tetracycline, Trimethoprim/Sulfamethoxazole

MicroScan Panel	Indicated Organisms Groups	Antimicrobial Agents
PM-E37	*Enterococcus* spp., *Staphylococcus* spp.	Ampicillin, Ciprofloxacin, Clindamycin, Daptomycin, Erythromycin, Levofloxacin, Linezolid, Minocycline, Moxifloxacin, Nitrofurantoin, Penicillin G, Tetracycline, Tigecycline, Vancomycin

Each isolate was tested in triplicate on three separate days using the appropriate MicroScan panel. On each day of testing, one operator designated at least four (for gram negative) or six (for gram positive) colonies for automated picking from digital images acquired by the WASPLab of each of the three culture plates corresponding to each isolate. A minimum of 117 MIC results were analyzed per panel per instrument.

Samples were prepared and assessed for purity consistent with the Colibrí instructions for use. The final suspension in the Secondary Tube was used to manually inoculate the appropriate MicroScan AST panel. The secondary tubes and corresponding AST cards were processed by one MicroScan WalkAway instrument. The reported MIC values were used to calculate within-run and between-run reproducibility.

Reproducibility was calculated as the total number of MIC results that were within one doubling dilution of the mode result divided by total number of results. Both best-case (assumes that off-scale results are within one dilution of the mode) and worst-case (assumes that off-scale results are more than one dilution of the mode) performance was determined for each antimicrobial, as outlined in the AST Special Controls Guidance.

In total, 2,619 MIC results were generated with 2,602 of those results being on-scale. The results for all samples are summarized and stratified by the tested MicroScan panel in **Table 3.** For antimicrobials across all panels evaluated, the combined best-case reproducibility was ≥95% and combined worst-case reproducibility was ≥89%. All purity plates displayed monomicrobial growth. The reproducibility results are acceptable.

Table 3. Reproducibility Results Stratified by MicroScan Panel

MicroScan Panel	Colibrí	Best Case (%)	Worst Case (%)
MSP6	Instrument 1	117/117 (100%)	113/117 (96.6%)
	Instrument 2	117/117 (100%)	110/117 (94.0%)
	Instrument 3	117/117 (100%)	108/117 (92.3%)
	Combined	*351/351 (100%)*	*331/351 (94.3%)*
NM-NF50	Instrument 1	459/459 (100%)	453/459 (98.7%)
	Instrument 2	458/459 (99.8%)	453/459 (99.7%)
	Instrument 3	459/459 (100%)	452/459 (98.5%)
	Combined	*1376/1377 (99.9%)*	*1358/1377 (98.6%)*
PM-E37	Instrument 1	297/297 (100%)	297/297 (100%)
	Instrument 2	297/297 (100%)	295/297 (99.3%)
	Instrument 3	297/297 (100%)	297/297 (100%)

MicroScan Panel	Colibrí	Best Case (%)	Worst Case (%)
	Combined	*891/891 (100%)*	*889/891 (99.8%)*

Reproducibility of MIC results obtained using microbial suspensions automatically prepared by the Colibrí for use with the bioMérieux VITEK 2 was previously demonstrated in K220546. The sponsor updated the reproducibility results tables for the VITEK 2 to the format above to harmonize their data presentation in labeling between both downstream AST analyzers.

2. Linearity:

   Not applicable.

3. Analytical Specificity/Interference:

   See Section 4 below.

4. Accuracy (Instrument):

   Microbial Suspension Accuracy

   The ability of the Colibrí to prepare accurate microbial suspensions in Primary and Secondary Tubes compatible for use with the Beckman Coulter MicroScan WalkAway was assessed using representative organisms. Isolated colonies were used by the Colibrí to automatically prepare microbial suspensions. Briefly, four microorganisms (*E. coli, P. aeruginosa, S. aureus* and *E. faecalis*) were individually plated on trypticase soy agar + 5% sheep blood and incubated for 18-24 hours. *Streptococcus* microbial suspensions were previously evaluated in K220546 and taken together with the AST accuracy study described herein (in which 48 *Streptococcus* isolates were evaluated), the results were deemed acceptable. Accuracy of microbial suspensions prepared with the Colibrí from MacConkey and Chocolate agar media was evaluated in K220546. One operator viewed the plate images acquired by one WASPLab instrument and designated four (for gram-negative) or six (for gram-positive) colonies for picking. Three Colibrí instruments were used to prepare Primary Tubes and Secondary Tubes. Secondary Tubes were manually diluted, plated in triplicate, and incubated overnight to determine colony counts and calculate concentration (CFU/mL).

   Concentrations were deemed acceptable if they were within the expected ranges reported in the AST Special Controls guidance ($3\text{-}7 \times 10^5$ CFU/mL for *E. coli*) or CLSI M07 ($2\text{-}8 \times 10^5$ CFU/mL) documents. Accuracy was calculated as the percentage of Secondary Tubes with microbial concentrations within the expected range. At least 30 microbial suspensions were prepared for each species. For the tested species, Primary Tubes were filled with saline and Secondary Tubes were filled with MicroScan Inoculum Water with PLURONIC, in accordance with the MicroScan IFU. The summary of agreement between the expected concentration and the concentration calculated by colony count is shown in **Table 4** below, stratified by Colibrí instrument and microorganism. Agreement for each species and each instrument was ≥95% and overall agreement was ≥98%. The microbial suspension accuracy results are acceptable.

Table 4. **Percentage Suspensions with Acceptable Microbial Concentration**

Microorganism	Avg. calculated concentration (CFU/mL)	Expected concentration range (CFU/mL)	Colibrí #1	Colibrí #2	Colibrí #3	Overall
E. coli	4.8 x 10^5	3-7x10^5	12/12	12/12	12/12	36/36 (100%)
P. aeruginosa	2.9 x 10^5	2-8x10^5	10/10	9/10	10/10	29/30 (96.7%)
S. aureus	5.7 x 10^5	2-8x10^5	13/14	14/14	14/14	41/42 (97.6%)
E. faecalis	4.2 x 10^5	2-8x10^5	10/10	10/10	10/10	30/30 (100%)
Total	*4.5 x 10^5*	*2-8x10^5*	*43/44 (97.7%)*	*43/44 (97.7%)*	*44/44 (100%)*	*130/132 (98.5%)*

Accuracy of AST Results

The accuracy of MICs obtained by the Beckman Coulter MicroScan WalkAway with microbial suspensions prepared by the Colibrí was evaluated by testing representative MicroScan panels with isolated colonies of clinically relevant gram-negative and gram-positive bacteria. Three different Colibrí instruments with one WASPLab operated by three different operators were used to prepare suspensions for testing of from colonies of 110 representative isolates of different species of *Enterobacterales* (n=50), *Staphylococcus* spp. (n=20), *Streptococcus* spp. (n=12), *Enterococcus* spp. (n=18), and non-fermenting gram-negative bacilli (n=10) grown on trypticase soy agar + 5 % sheep blood and/or MacConkey agar. Refer to **Table 2** for the panels included in the AST challenge study.

MicroScan panels containing broad concentrations of antimicrobials representative of major drug classes (**Table 2**) were tested with representative clinical isolates: NM-NF50 covering *Enterobacterales* and non-fermenters, PM-E37 covering *Staphylococci* and *Enterococci*, and MSP6 covering *Streptococci*. Use of these panels is acceptable because a wider MIC range was validated with the same sample type (i.e., colonies) and determined to be acceptable, as described in the applicable MicroScan decision summaries. Twenty-nine different antimicrobial agents were analyzed, resulting in a total of 1,232 MIC results.

The MIC results obtained with suspensions prepared from isolated colonies by the Colibrí and tested on the MicroScan WalkAway system were compared to the results from manually prepared samples and the MicroScan WalkAway system. Manual samples were prepared from isolated colonies consistent with the MicroScan system instructions for use.

Essential Agreement (EA) was defined as MIC results from Colibrí prepared samples that were within one doubling dilution of the MIC results from the manually prepared samples. Category Agreement (CA) was defined as MIC interpretations (S/I/R) that were the same between the Colibrí-prepared and manually prepared samples. Very major errors were defined as false susceptible results from the Colibrí-prepared samples, major errors were defined as false resistance results from the Colibrí-prepared samples, and minor errors were

defined as results with minor discrepancies (i.e., an intermediate result reported as either resistant or susceptible, or vice versa). Since this is a method-to-method comparison, results were considered acceptable if the EA and CA were ≥95% with no major or very major errors. Additionally, no significant differences should be observed between the Colibrí instruments, operators, culture medium, or incubation time.

Overall performance of MicroScan results using microbial suspensions prepared from isolated colonies by the Colibrí demonstrated that 1232/1232 (100%) of MIC results were within EA and 4187/4254 (98.4%) of results were in CA, which is acceptable. No very major or major errors occurred. All purity plates exhibited 100% monomicrobial growth.

Table 5 summarizes the results stratified by antimicrobial/organism group combinations. Due to the high degree of agreement between MICs obtained from manual and Colibrí-prepared samples, the AST accuracy was determined to be acceptable.

Table 5. Summary of AST Results, Stratified by MicroScan Panel

MicroScan Panel	Organism group	Total tested	# EA	% EA	Total Eval.	# EA Eval.	% EA Eval.	Total cat.	# CA	% CA	# S	# R	# vmj	# maj	# min
NM-NF50	*Enterobacterales*	2454	2454	100%	577	577	100%	2352	2304	98.0%	1197	996	0	0	48
NM-NF50	Non-fermenters	294	294	100%	165	165	100%	291	282	96.9%	126	120	0	0	9
PM-E37	*Staphylococcus*	690	690	100%	157	157	100%	663	656	98.9%	465	159	0	0	7
PM-E37	*Enterococcus*	525	525	100%	258	258	100%	519	516	99.4%	354	102	0	0	3
MSP6	*Streptococcus*	429	429	100%	75	75	100%	429	429	100%	381	39	0	0	0

Accuracy of MIC results obtained using microbial suspensions automatically prepared by the Colibrí for use with the bioMérieux VITEK 2 was previously demonstrated in K220546. The sponsor updated the AST accuracy results tables for the VITEK 2 to the format above to harmonize their data presentation in labeling between both downstream AST analyzers.

5. Carry-Over:

The ability of the on-board incinerator to properly sterilize the spreader after purity plate preparation was described in K220546. Refer to the K220546 Decision Summary for additional details.

B Other Supportive Instrument Performance Characteristics Data:

Refer to the Decision Summaries of K193138, K220546, and K223245 for supportive studies regarding Colibrí use with bacterial ID IVD-analyzers, bioMérieux VITEK 2 AST analyzer, and WASPLab, respectively.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.