510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY

I Background Information:

A 510(k) Number

K193138

B Applicant

COPAN WASP S.r.l.

C Proprietary and Established Names

Colibrí System

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
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 Copan Colibrí System.

B Type of Test:

Qualitative *in vitro* diagnostic device for identification and differentiation of microorganisms

cultured from human specimens by automation of target preparation for mass spectrometry analysis.

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The Colibrí System is an in vitro diagnostic device comprised of the Colibri Vision System and Colibri Preparation System for use with the bioMérieux VITEK MS or Bruker MALDI Biotyper CA mass spectrometry systems for the qualitative identification of isolated colonies of Gram-negative and Gram-positive bacterial species grown on solid culture media. The Colibrí System is a semi-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. 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 analyzer.

The Colibrí System 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 System has not been validated for use in identification of yeast species.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

IVD - For In Vitro Diagnostic Use Only.

Special Instruments for Use:
bioMérieux VITEK MS
Bruker MALDI Biotyper for Clinical Applications (MBT-CA)
When using the Copan Colibrí System, refer to the most recent version of the bioMérieux VITEK MS or Bruker MALDI Biotyper CA system labeling.

When the Copan Colibrí System is used with the bioMérieux VITEK MS, use only whole or bi-plates of the culture media listed below:
• Columbia Agar + 5% sheep blood (bioMérieux)
• Trypticase Soy Agar + 5% sheep blood (Becton Dickinson)
• MacConkey Agar (bioMérieux)
• Chocolate Agar (Becton Dickinson)

When the Copan Colibrí System is used with the Bruker MALDI Biotyper CA, use only whole or bi-plates of the culture media listed below:
• Columbia Agar + 5% sheep blood (bioMérieux)
• Trypticase Soy Agar + 5% sheep blood (Becton Dickinson)

• MacConkey Agar (bioMérieux)
• Chocolate Agar (Becton Dickinson)
• Columbia Agar + 5% sheep blood supplemented with colistin and nalidixic acid (CNA) (Becton Dickinson)
• Bordet Gengou Agar + 15% sheep blood (Becton Dickinson)

Use of the Copan Colibrí System to prepare samples for analysis with the bioMérieux VITEK MS and Bruker MALDI Biotyper CA System was evaluated using only the species listed in the Inclusivity Study in the Performance Characteristics section.

The Colibrí System is not intended for and has not been validated for use in the identification of yeasts, molds, Nocardia or Mycobacteria.

Colibrí System has been validated for the direct spotting of isolated bacterial colony(ies) grown on solid media and overlaid with matrix. Other methods of target preparation such as overlay with formic acid or extraction have not been validated and should be conducted manually per the applicable MALDI-TOF MS analyzer instructions for use.

Use of the Copan Colibrí System to prepare targets from cultures of Gram-positive organisms resulted in a lower proportion of High Confidence Log(scores) with the Bruker MALDI Biotyper CA System. The operator is instructed to repeat testing of the isolate manually using the extended Direct Transfer (eDT) or Extraction (Ext) Sample Preparation Procedure if a low-confidence identification or no identification result is obtained.

IV Device/System Characteristics:

A Device Description:

The Copan Colibrí System automates various steps in the preparation of targets for the bioMérieux VITEK MS and Bruker MALDI Biotyper CA systems that use Matrix-Assisted Laser Desorption/Ionization-Time of Flight Mass Spectrometry (MALDI-TOF MS) for the identification of organisms grown on plated culture media. The Colibrí System comprises the Colibrí Vision System for digital imaging of culture plates and operator-designation of colonies for picking and the Colibrí Preparation Station for automated picking of designated colonies and spotting of the MALDI targets.

The Colibrí System follows the direct transfer method of sample deposition on the target slides for both the VITEK MS and MALDI Biotyper CA in which colonies are spotted directly on targets and then overlaid with MALDI matrix. To use the system, the operator manually sorts culture plates based on the type of medium, presence of visible growth and Gram stain results, and applies a unique barcode to each plate for sample identification. The operator then loads the pre-sorted plates into the Colibrí Vision System for digital image acquisition and designates well-isolated bacterial colonies for identification using the Image Reading Interface.

Following image acquisition and colony designation, the operator manually transfers the appropriate plates to the Colibrí Preparation Station for automated colony picking, spotting of the

target and overlay of the dried target spots with matrix. The coordinates of the individual colonies for picking are retrieved automatically by the Colibrí Preparation Station from the Colibrí Vision System.

Once the Colibrí System has finished processing the culture plates, the operator removes the target slides and manually spots the appropriate controls for the applicable downstream MALDI-TOF MS instrument before initiating analysis of the samples. The location of each sample to be identified is sent electronically from the Colibrí System to the applicable downstream MALDI-TOF MS instrument prior to processing of the target. Identification results are reported by the MALDI-TOF MS instruments according to the algorithms specific to each system.

B Instrument Description Information:

Modes of Operation	Yes	No
Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?	☒	☐
Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?	☐	☒
Software		
FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types.	☒	☐

1. Instrument Name:

   Copan Colibrí System comprised of the Colibrí Vision System and Colibrí Preparation Station

2. Specimen Sampling and Handling:

   Culture plates for processing by the Colibrí System are sorted manually to identify those with isolated colonies of Gram-positive or Gram-negative bacteria and then labeled by applying a linear barcode to the base of the plate. After loading the plates into the Colibrí Vision System, the operator must select the appropriate plate type (i.e., culture medium type) for image acquisition to ensure that the appropriate optical parameters are applied. Following image acquisition, the operator designates well-isolated colonies for picking and then manually transfers the plates from the Colibrí Vision System to the Colibrí Preparation Station, where the designated colonies are picked automatically and used to prepare the appropriate MALDI target, using either the bioMérieux VITEK MS-DS target slides or the Bruker US IVD 48-spot reusable or 96-spot disposable targets.

3. Specimen Identification:

   Culture plates for processing are identified by the Colibrí Vision System by scanning the manually applied linear barcode on the side of each plate. 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. This information is retrieved by the Colibrí Preparation Station, which picks the designated colonies from the

agar surface and deposits them into target spots and overlays the spots with the appropriate matrix (bioMérieux VITEK MS-CHCA matrix or the Bruker US IVD HCCA portioned) using the pipetting unit. The Colibrí Preparation Station records the location on the MALDI target into which each designated colony is spotted. The layout of the target is sent electronically to the downstream MALDI-TOF MS instrument prior to analysis. The bioMérieux VITEK MS or the Bruker MALDI Biotyper CA system then performs species identification according to their respective procedures. There are no changes to the methods of data analysis or result algorithms for either the VITEK MS or MALDI Biotyper CA compared to those used in the 510(k)-cleared devices.

4. Calibration:

Three calibrations are performed for the Copan Colibrí System.

Set-up Calibration
Set-up calibration refers to the camera and positional calibrations that are performed by the technical engineer as part of the camera and vision system hardware setup during the initial device installation.

Auto-calibration
Auto-calibration is applicable to the Colibrí Preparation System and is performed automatically by the instrument following mechanical calibration by the technical engineer during initial device installation and periodically thereafter during preventative maintenance (every 6 months) over the entire device lifecycle. During this procedure, the Colibrí Vision Software performs specific calls to the cameras and to the hardware related to the visual system to check that all the mechanical references can be found inside the positioning tolerances, that the input/output interfaces are responsive and that the spaces subject to verification during the cycle are clean and free from obstacles.

Run-time Calibration Checks
This calibration refers to all activities that the Image Acquisition and Colibrí Vision software perform during normal usage.

5. Quality Control:

Quality Control testing is performed according to manufacturer's instructions of the bioMérieux VITEK MS and Bruker MALDI Biotyper mass spectrometry systems using cultures of *Escherichia coli* ATCC 8739 (calibrator strain) and *Klebsiella aerogenes* ATCC 13048 (positive control strain) grown on Columbia or Trypticase Soy Agar plates (both with 5% sheep blood) for the VITEK MS or US IVD Bacterial Test Standard (BTS) containing lyophilized *Escherichia coli* ATCC 25922 reconstituted in Standard Solvent for the MALDI Biotyper CA. Spots are prepared using the appropriate mode of target deposition (single or duplicate) and in each case the expected MALDI-TOF MS identification result(s) should be obtained with a high confidence value (VITEK MS) or Log(Score) (MALDI Biotyper CA). Negative quality control spots are prepared using matrix alone. Quality control testing was performed during analytical performance testing, and all results were obtained as expected. Results are summarized below.

Quality Control	**N**	**# agreement (%)**
Klebsiella aerogenes ATCC 13048	207	207 (100)
US IVD Bacterial Test Standard	234	234 (100)

Negative control (matrix alone)	441	441 (100)
TOTAL	882	882 (100)

In addition, culture plates of *E. coli* (ATCC 25922) grown on Columbia or Trypticase Soy Agar plates (both with 5% sheep blood) are processed through the Copan Colibrí System workflow as described in the Colibrí Vision System and Colibrí Preparation Station Operator Manuals. *E. coli* ATCC 25922 was evaluated as a test strain in all analytical studies, excluding the Specificity Study and all results were obtained as expected.

V Substantial Equivalence Information:

A Predicate Device Name(s):
bioMérieux VITEK MS System

B Predicate 510(k) Number(s):
K181412

C Comparison with Predicate(s):

Device & Predicate Device(s):	K193138	K181412	DEN170081
Device Trade Name	**Copan Colibrí System**	**bioMérieux VITEK MS**	**Bruker MALDI Biotyper CA System**
Intended Use/Indications for Use	The Colibrí System is an in vitro diagnostic device comprised of the Colibrí Vision System and Colibrí Preparation Station for use with the bioMérieux VITEK MS or Bruker MALDI Biotyper CA mass spectrometry systems for qualitative identification of isolated colonies of Gram-negative and Gram-positive bacterial species grown on solid culture media. The Colibrí System is a semi-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. 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	VITEK MS is a mass spectrometry system using matrix-assisted laser desorption/ionization time of flight mass spectrometry (MALDI-TOF MS) for the identification of microorganisms cultured from human specimens. The VITEK MS system is a qualitative in vitro diagnostic device indicated for use in conjunction with other clinical and laboratory findings to aid in the diagnosis of bacterial, yeast and mould infections. (list of claimed organisms omitted for brevity; refer to K181412)	The MALDI Biotyper CA System is a mass spectrometer system using matrix-assisted laser desorption/ ionization - time of flight (MALDI-TOF) for the identification and differentiation of microorganisms cultured from human specimens. The MALDI Biotyper CA System is a qualitative *in vitro* diagnostic device indicated for use in conjunction with other clinical and laboratory findings to aid in the diagnosis of bacterial and fungal infections. (list of validated organisms omitted for brevity; refer to DEN170081)

Device & Predicate Device(s):	K193138	K181412	DEN170081
Device Trade Name	**Copan Colibrí System**	**bioMérieux VITEK MS**	**Bruker MALDI Biotyper CA System**
	analyzer. The Colibrí System 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 System has not been validated for use in identification of yeast species.		
General Device Characteristic Similarities			
Sample Type	Isolated colonies on plated culture media Acceptable media when used with the VITEK MS: • Columbia blood agar with 5% sheep blood • Trypticase soy agar with 5% sheep blood • Chocolate agar • MacConkey agar Acceptable media when used with the MALDI Biotyper CA: • Columbia blood agar with 5% sheep blood • Trypticase soy agar with 5% sheep blood • Chocolate agar • MacConkey agar • Columbia CNA agar with 5% sheep blood • Bordet Gengou Agar with 15% sheep blood	Isolated colonies on plated culture media Acceptable media: • Columbia blood agar with 5% sheep blood • Trypticase soy agar with 5% sheep blood • Chocolate agar • MacConkey agar	Isolated colonies on plated culture media Acceptable media: • Columbia blood agar with 5% sheep blood • Trypticase soy agar with 5% sheep Blood • Chocolate agar • MacConkey Agar • Columbia CNA agar with 5% sheep blood • Bordet Gengou Agar with 15% sheep blood
Target Preparation	Direct Transfer of colony to target spot and overlay with matrix	Same	Same
Quality Control Preparation	Manual	Same	Same
Calibration/ Quality Controls	Escherichia coli ATCC 8739 and Klebsiella	Escherichia coli ATCC 8739 (calibrator strain)	US IVD Bacterial Test Standard (BTS)

Device & Predicate Device(s):	K193138	K181412	DEN170081
Device Trade Name	**Copan Colibrí System**	**bioMérieux VITEK MS**	**Bruker MALDI Biotyper CA System**
	aerogenes ATCC 13048 -*OR*- US IVD Bacterial Test Standard (BTS)	and Klebsiella aerogenes ATCC 13048 (positive control strain) cultured on plated media	lyophilized Escherichia coli ATCC 25922 reconstituted in Standard Solvent
Matrix	VITEK MS-CHCA -*OR*- US IVD HCCA Portioned	VITEK MS-CHCA	US IVD HCCA Portioned
Targets	VITEK MS-DS target slide -*OR*- MBT Biotarget 96 US IVD (96-spot disposable) target US IVD 48 Spot (48-spot reusable) target	VITEK MS-DS target slide	MBT Biotarget 96 US IVD (96-spot disposable) target US IVD 48 Spot (48-spot reusable) target
Colonies per Target Spot	One	Same	Same
MALDI-TOF MS Analyzer	bioMérieux VITEK MS -*OR*- Bruker MALDI Biotyper CA	bioMérieux VITEK MS	Bruker MALDI Biotyper CA
Results Reported	Organism identification	Same	Same
General Device Characteristic Differences			
Target Organisms	Gram-positive/Gram-negative bacteria only	Gram-positive/Gram-negative bacteria, yeasts, Mycobacteria, Nocardia and molds	Gram-positive/Gram-negative bacteria and yeasts
Colony/Plate Visualization	Digital image from the Colibrí Vision System module	Direct	Direct
Target Preparation	Automated	Manual	Manual
Alternative Methods of Target Preparation	None	None	Extended Direct Transfer (eDT) Test Procedure Extraction (Ext) Test Procedure
Compatible Culture Media	VITEK MS: • Columbia Agar + 5% sheep blood • Trypticase Soy Agar + 5% sheep blood • MacConkey Agar	Same *PLUS*: • BacT/ALERT MP • Brucella agar base • Buffered charcoal yeast extract • Campylosel agar	Same *PLUS*: • Brucella Agar + 5% horse blood • CDC Anaerobe Agar + 5% sheep blood • CDC Anaerobe Agar + 5%

Device & Predicate Device(s):	K193138	K181412	DEN170081
Device Trade Name	**Copan Colibrí System**	**bioMérieux VITEK MS**	**Bruker MALDI Biotyper CA System**
	• Chocolate Agar Bruker MALDI Biotyper CA: as above *PLUS* • Columbia Agar + 5% sheep blood supplemented with colistin and nalidixic acid (CNA) • Bordet Gengou Agar + 15% sheep blood	• chromID CPS • Coletsos • Lowenstein-Jensen • MGIT • Middlebrook 7H10 agar • Middlebrook 7H11 agar • Modified Sabouraud dextrose agar (glucose: 20 g/L - pH: 6.1) • Potato dextrose agar • Sabouraud dextrose agar (glucose: 40 g/L pH: 5.6) • Sabouraud dextrose agar with Gentamicin & Chloramphenicol • Trypticase soy agar • Trypticase soy agar with neutralizers	sheep blood with phenylethyl alcohol • CDC Anaerobe Laked Sheep Blood Agar with kanamycin and vancomycin • Bacteroides Bile Esculin Agar with Amikacin • Clostridium difficile Agar + 7% sheep blood • Sabouraud-Dextrose Agar • Campylobacter Agar with 5 Antimicrobics and 10% Sheep Blood • Buffer Charcoal Yeast Extract Agar • Buffered Charcoal Yeast Extract Selective Agar with polymyxin, anisomycin and vancomycin • Modified Thayer-Martin Agar
Technology	Automated imaging and pipetting system with downstream MALDI-TOF MS organism identification	Direct visual inspection and selection and manual preparation of MALDI-TOF MS targets for organism identification	Direct visual inspection and selection and manual preparation of MALDI-TOF MS targets for organism identification

VI Standards/Guidance Documents Referenced:

IEC 61010-1. Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use - Part 1: General Requirements [including corrigendum 1] (Third Edition; 2010-06).

IEC 61010-2-010. Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials.

IEC 61010-2-081. Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes.

IEC 61010-2-101. Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for *in vitro* diagnostic (IVD) medical equipment.

IEC 61326-1. Electrical equipment for measurement, control and laboratory use - EMC

requirements - Part 1: General requirements.

IEC 61326-2-6: Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - *In vitro* diagnostic (IVD) medical equipment.

IEC 62304. Medical Device Software – Software Life Cycle Processes (Edition 1.1; 2015-06).

IEC 60825-1. Safety of Laser Products – Part 1: Equipment Classification and Requirements [Including: Technical Corrigendum 1 (2008), Interpretation Sheet 1 (2007), Interpretation Sheet 2 (2007)] (Second Edition; 2007-03).

IEC 62366-1. Medical Devices – Part 1: Application of Usability Engineering to Medical Devices [including Corrigendum 1 (2016)] (First Edition; 2015-02).

ISO 15223-1. Medical Devices – Symbols to be Used with Medical Device Labels, Labelling and Information to be Supplied – Part 1: General Requirements (Third Edition; 2016-11-01).

ISO 14971. Medical Devices – Application of Risk Management to Medical Devices (Second Edition; 2007-03-01).

CLSI. Methods for the Identification of Cultured Microorganisms Using Matrix-Assisted Laser Desorption/Ionization Time-of-Flight Mass Spectrometry. 1st ed. CLSI guideline M58. Wayne, PA: Clinical and Laboratory Standards Institute; 2017.

VII Performance Characteristics (if/when applicable):

The performance of the Copan Colibrí System was evaluated in conjunction with the bioMérieux VITEK MS and Bruker MALDI Biotyper CA instruments using the confidence level and interpretive criteria for species identification as described in the labeling for each respective mass spectrometer, as summarized in **Tables 1** and **2**.

Table 1. Interpretive criteria for species identification using the bioMérieux VITEK MS.

Confidence Level	Number of Organisms Reported	Confidence Value
Good	1	60 - 99.9%
Low Discrimination	2 - 4 [1]	Sum = 100%
No identification	None or > 4 [1]	Not applicable or sum < 100%

[1] Additional testing required to determine or confirm organism identity.

Table 2. Interpretive criteria for species identification using the Bruker MALDI Biotyper CA.

Confidence Level	Log(Score) Value
High	≥ 2.00
Low	1.70 - 1.99 [1]
No identification	< 1.70 [1]

[1] Additional testing required to determine or confirm organism identity.

A Analytical Performance:

1. Precision/Reproducibility:

The reproducibility of bacterial identification results obtained following automated sample preparation by the Colibrí System was evaluated in separate studies with the VITEK MS and MALDI Biotyper CA analyzers (both with 48-spot targets). In each study, three Colibrí Systems (each comprised of a Colibrí Vison System and Colibrí Preparation Station) were

used to prepare targets from overnight (18 to 24 hour) cultures of representative, clinically relevant Gram-positive and Gram-negative bacterial species grown on Trypticase Soy Agar with 5% sheep blood. The three Colibrí Systems were used in rotation in conjunction with a single mass spectrometry instrument of each type. Each Colibrí System was used to prepare targets of each bacterial species on five separate days. On each day on which testing was performed, two operators with different levels of microbiological experience each designated two colonies for automated picking from digital images of each of three culture plates corresponding to each bacterial species (3 Colibrí Systems × 5 days × 2 operators × 3 plates × 2 colonies = 180 colonies per species). Following designation of the colonies for picking using the Colibrí Vision System, the culture plates were transferred by hand to the corresponding Colibrí Preparation Station. After automated processing of the designated colonies, the appropriate calibrators were spotted manually onto the targets, which were then transferred to the applicable downstream MALDI-TOF MS analyzer. The reported organism identity was compared to the expected identity, i.e. the known species identifications for the reference isolates, and within-run, between-run and between-user reproducibility were investigated. Reproducibility of Copan Colibrí with the bioMérieux VITEK MS and with the Bruker MALDI Biotyper CA are outlined below in sections *a* and *b*, respectively.

a. Reproducibility of Copan Colibrí with the bioMérieux VITEK MS

Overall, for the Copan Colibrí System in conjunction with the bioMérieux VITEK MS, there was 89.9% agreement (1619/1800) between the reported Good Confidence identification results and the expected identity of each colony in the Reproducibility Study (for all Gram-positive and Gram-negative species combined) (**Table 3**). In addition, all 180 colonies of *Enterobacter cloacae* were reported with Low Discrimination as *Enterobacter cloacae/Enterobacter asburiae*, in accordance with the labeling for the VITEK MS analyzer. Therefore, in total 1799/1800 (99.9%) results obtained were as expected. No significant differences in agreement were observed using Fisher's Exact test between instruments and operators, and none of the samples in the study were incorrectly identified. The reproducibility of the Copan Colibrí System with VITEK MS was therefore determined to be acceptable.

Table 3. Reproducibility of the Copan Colibrí System with the bioMérieux VITEK MS.

Gram Stain Phenotype	Species/Strain	Colibrí System	VITEK MS Identification Result (%)		
			Good Confidence	Low Discrimination	None
Gram-Negative	*Enterobacter cloacae* [1] ATCC 13047	008	0 (0)	60 (100)	0 (0)
		009	0 (0)	60 (100)	0 (0)
		010	0 (0)	60 (100)	0 (0)
		All	**0 (0)**	**180 (100)**	**0 (0)**
	Escherichia coli ATCC 25922	008	60 (100)	0 (0)	0 (0)
		009	60 (100)	0 (0)	0 (0)
		010	60 (100)	0 (0)	0 (0)
		All	**180 (100)**	**0 (0)**	**0 (0)**
	Klebsiella pneumoniae ATCC BAA 1705	008	60 (100)	0 (0)	0 (0)
		009	60 (100)	0 (0)	0 (0)
		010	60 (100)	0 (0)	0 (0)
		All	**180 (100)**	**0 (0)**	**0 (0)**
	Proteus mirabilis ATCC 7002	008	60 (100)	0 (0)	0 (0)
		009	60 (100)	0 (0)	0 (0)
		010	60 (100)	0 (0)	0 (0)
		All	**180 (100)**	**0 (0)**	**0 (0)**
	Pseudomonas aeruginosa ATCC 27853	008	60 (100)	0 (0)	0 (0)
		009	60 (100)	0 (0)	0 (0)
		010	60 (100)	0 (0)	0 (0)

Gram Stain Phenotype	Species/Strain	Colibrí System	VITEK MS Identification Result (%)		
			Good Confidence	Low Discrimination	None
		All	**180 (100)**	**0 (0)**	**0 (0)**
	All Gram-Negative species (n=900)	008	240 (100)	60 (20.0)	0 (0)
		009	240 (100)	60 (20.0)	0 (0)
		010	240 (100)	60 (20.0)	0 (0)
		All	**720 (80.0)**	**180 (20.0)**	**0 (0)**
Gram-Positive	*Enterococcus faecalis* ATCC 29212	008	60 (100)	0 (0)	0 (0)
		009	60 (100)	0 (0)	0 (0)
		010	60 (100)	0 (0)	0 (0)
		All	**180 (100)**	**0 (0)**	**0 (0)**
	Staphylococcus aureus ATCC 29213	008	60 (100)	0 (0)	0 (0)
		009	60 (100)	0 (0)	0 (0)
		010	60 (100)	0 (0)	0 (0)
		All	**180 (100)**	**0 (0)**	**0 (0)**
	Staphylococcus epidermidis ATCC 12228	008	60 (100)	0 (0)	0 (0)
		009	60 (100)	0 (0)	0 (0)
		010	60 (100)	0 (0)	0 (0)
		All	**180 (100)**	**0 (0)**	**0 (0)**
	Staphylococcus saprophyticus ATCC 15305	008	60 (100)	0 (0)	0 (0)
		009	60 (100)	0 (0)	0 (0)
		010	60 (100)	0 (0)	0 (0)
		All	**180 (100)**	**0 (0)**	**0 (0)**
	Streptococcus agalactiae ATCC 12386	008	60 (100)	0 (0)	0 (0)
		009	60 (100)	0 (0)	0 (0)
		010	59 (98.3)	0 (0)	1 (1.7)
		All	**179 (99.4)**	**0 (0)**	**1 (0.6)**
	All Gram-Positive species (n=900)	008	300 (100)	0 (0)	0 (0)
		009	300 (100)	0 (0)	0 (0)
		010	300 (100)	0 (0)	0 (0)
		All	**899 (99.9)**	**0 (0)**	**1 (0.1)**
All Species (n=1800)		008	540 (90.0)	60 (10.0)	0 (0)
		009	540 (90.0)	60 (10.0)	0 (0)
		010	539 (89.8)	60 (10.0)	1 (0.2)
		All	**1619 (89.9)**	**180 (10.0)**	**1 (0.1)**

ATCC: American Type Culture Collection

[1] Identified by VITEK MS as "*Enterobacter cloacae/Enterobacter asburiae*" in accordance with the labeling for the analyzer.

b. Reproducibility of Copan Colibrí with the Bruker MALDI Biotyper CA

Overall, for the Copan Colibrí System in conjunction with the Bruker MALDI Biotyper CA, there was 88.1% agreement (1585/1800) between the reported High Confidence identification results (Log(Score) ≥ 2.00) and the expected identity of each colony in the Reproducibility Study (Gram-positive and Gram-negative species combined) (**Table 4**). However, for Gram-positive species, 179/900 colonies (19.9%) were only identified with Low Confidence (Log(Score) = 1.70-1.99), compared with 1/900 colonies (0.1%) of Gram-negative species. In addition, 31/900 Gram-positive colonies (3.4%) produced no identification result compared with 4/900 (0.4%) Gram-negative colonies. Nevertheless, no significant differences in agreement were observed using Fisher's Exact test between instruments and operators, and none of the samples in the study were incorrectly identified. Because the instructions for use require additional testing to confirm organism identity when a low confidence result or no identification is obtained, the study results were determined to be acceptable.

The reproducibility of the Copan Colibrí System with Gram-positive and Gram-negative species is reported separately in the device labeling with instructions for the operator to

perform additional testing to determine the identity of any isolate that yields either a Low Confidence identification result or no identification in accordance with the Bruker predicate device's labeling.

Table 4. Reproducibility of the Copan Colibrí System with the Bruker MALDI Biotyper CA.

Gram Stain Phenotype	Species/Strain	Colibrí System	Bruker MALDI Biotyper CA Identification Result		
			High Confidence	Low Confidence	None
Gram-Negative	*Enterobacter cloacae* [1] ATCC 13047	008	60 (100)	0 (0)	0 (0)
		009	60 (100)	0 (0)	0 (0)
		010	60 (100)	0 (0)	0 (0)
		All	**180 (100)**	**0 (0)**	**0 (0)**
	Escherichia coli ATCC 25922	008	60 (100)	0 (0)	0 (0)
		009	58 (96.7)	1 (1.7)	1 (1.7)
		010	60 (100)	0 (0)	0 (0)
		All	**178 (98.9)**	**1 (0.6)**	**1 (0.6)**
	Klebsiella pneumoniae ATCC BAA 1705	008	60 (100)	0 (0)	0 (0)
		009	60 (100)	0 (0)	0 (0)
		010	60 (100)	0 (0)	0 (0)
		All	**180 (100)**	**0 (0)**	**0 (0)**
	Proteus mirabilis ATCC 7002	008	60 (100)	0 (0)	0 (0)
		009	60 (100)	0 (0)	0 (0)
		010	60 (100)	0 (0)	0 (0)
		All	**180 (100)**	**0 (0)**	**0 (0)**
	Pseudomonas aeruginosa ATCC 27853	008	59 (98.3)	0 (0)	1 (1.7)
		009	60 (100)	0 (0)	0 (0)
		010	58 (96.7)	0 (0)	2 (3.3)
		All	**177 (98.3)**	**0 (0)**	**3 (1.7)**
	All Gram-Negative species (n=900)	008	299 (99.7)	0 (0)	1 (0.3)
		009	298 (99.3)	1 (0.3)	1 (0.3)
		010	298 (99.3)	0 (0)	2 (0.7)
		All	**895 (99.4)**	**1 (0.1)**	**4 (0.4)**
Gram-Positive	*Enterococcus faecalis* ATCC 29212	008	47 (78.3)	12 (20.0)	1 (1.7)
		009	42 (70.00	18 (30.0)	0 (0)
		010	50 (83.3)	10 (16.7)	0 (0)
		All	**139 (77.2)**	**40 (22.2)**	**1 (0.6)**
	Staphylococcus aureus ATCC 29213	008	56 (93.3)	4 (6.7)	0 (0)
		009	56 (93.3)	4 (6.7)	0 (0)
		010	47 (78.3)	13 (21.7)	0 (0)
		All	**159 (88.3)**	**21 (11.7)**	**0 (0)**
	Staphylococcus epidermidis ATCC 12228	008	43 (71.7)	15 (25.0)	2 (3.3)
		009	45 (75.0)	12 (20.0)	3 (5.0)
		010	41 (68.3)	15 (25.0)	4 (6.7)
		All	**129 (71.7)**	**42 (23.3)**	**9 (5.0)**
	Staphylococcus saprophyticus ATCC 15305	008	48 (80.0)	8 (13.3)	4 (6.7)
		009	48 (80.0)	8 (13.3)	4 (6.7)
		010	47 (78.3)	10 (16.7)	3 (5.0)
		All	**143 (79.4)**	**26 (14.4)**	**11 (6.1)**
	Streptococcus agalactiae ATCC 12386	008	42 (70.0)	15 (25.0)	3 (5.0)
		009	40 (66.7)	16 (26.7)	4 (6.7)
		010	38 (63.3)	19 (31.7)	3 (5.0)
		All	**120 (66.7)**	**50 (27.8)**	**10 (5.6)**
	All Gram-Positive species (n=900)	008	236 (78.7)	54 (18.0)	10 (3.3)
		009	232 (77.3)	57 (19.0)	11 (3.7)
		010	222 (74.0)	68 (22.7)	10 (3.3)
		All	**690 (76.7)**	**179 (19.9)**	**31 (3.4)**
All Species (n=1800)		008	535 (89.2)	54 (9.0)	11 (1.8)
		009	529 (88.2)	59 (9.8)	12 (2.0)
		010	521 (86.8)	67 (11.2)	12 (2.0)
		All	**1585 (88.1)**	**180 (10.0)**	**35 (1.9)**

Note: The Reproducibility Study with the Bruker MALDI Biotyper CA was conducted using 48-spot reusable target plates

ATCC: American Type Culture Collection.
[1] Identified by the Bruker MALDI Biotyper CA as "*Enterobacter cloacae* complex" in accordance with the labeling for the analyzer.

2. Linearity:

Not applicable.

3. Analytical Specificity/Interference:

Refer to **Section VII (A)(4)**.

4. Accuracy (Instrument):

Colony Picking Accuracy

The ability of the Copan Colibrí Preparation Station to pick appropriate colonies designated by the operator based on the digital images obtained by the Copan Colibrí Vision System was evaluated in separate studies for each of the two downstream MALDI-TOF MS analyzers, as described below.

In each study, three different Colibrí Systems, with three different operators, were used to prepare targets from isolated colonies of mixed cultures on both whole and bi-plates of representative "on panel" Gram-positive and Gram-negative bacterial species (**Table 5**). Once automated processing of the colonies was completed, the targets were removed from the Colibrí Preparation Station and the appropriate calibration spots were applied manually before transfer to the MALDI-TOF MS analyzers.

Table 5. Organism mixtures and culture media use for evaluation of colony picking accuracy

Mixture	Species	Culture Medium	
		VITEK MS	MALDI Biotyper CA
1	*Escherichia coli* ATCC 25922 *Klebsiella pneumoniae* ATCC BAA 1705 *Staphylococcus aureus* ATCC 29213	Trypticase Soy Agar + 5% Sheep Blood	Trypticase Soy Agar + 5% Sheep Blood
2	*Staphylococcus aureus* ATCC 29213 *Enterococcus faecalis* ATCC 29212 *Streptococcus agalactiae* ATCC 12386	Trypticase Soy Agar + 5% Sheep Blood	Columbia Agar + 5% Sheep Blood with colistin and nalidixic acid (CNA)
3	*Escherichia coli* ATCC 25922 *Klebsiella pneumoniae* ATCC BAA 1705 *Proteus mirabilis* ATCC 7002	MacConkey Agar	MacConkey Agar
4	*Escherichia coli* ATCC 25922 *Klebsiella pneumoniae* ATCC BAA 1705 *Staphylococcus aureus* ATCC 29213	Trypticase Soy Agar + 5% Sheep Blood/MacConkey Agar Bi-plate	Trypticase Soy Agar + 5% Sheep Blood/ MacConkey Agar Bi-plate
5	*Escherichia coli* ATCC 25922 *Klebsiella pneumoniae* ATCC BAA 1705 *Staphylococcus aureus* ATCC 29213 *Staphylococcus epidermidis* ATCC 12228	N/A	Columbia Agar + 5% Sheep Blood/ MacConkey Agar Bi-plate

Processed culture plates were inspected manually in comparison to the corresponding digital

images to determine whether the designated colonies had been picked. Additional colonies were also picked manually and used to prepare targets for mass spectrometry analysis. The results obtained with targets prepared by the Colibrí System were compared to the expected identity of each organism, i.e., the known species identifications of the reference isolates obtained from ATCC, as well as to the identification results obtained with manually prepared targets, as described below. Colony picking accuracy of Copan Colibrí with the bioMérieux VITEK MS and with the Bruker MALDI Biotyper CA are outlined below in sections *a* and *b*, respectively.

a. Colony Picking Accuracy for bioMérieux VITEK MS

Three Colibrí System instruments were used in this study. A total of 1390 colonies were picked by the three instruments to prepare target slides for the VITEK MS. Of those, 924 and 466 colonies were from whole plates and bi-plates, respectively. All colonies (100%) were successfully picked by visual inspection. For all species excluding *E. faecalis*, ≥ 95% of designated colonies were correctly identified with good confidence (Confidence Value ≥ 60%) compared to the expected identity.

Results were stratified according to species, Colibrí System and whole plate (**Table 6**) or bi-plate configuration (**Table 7**). The Copan Colibrí System performed equivalently between the three instruments and between whole plates and bi-plates. For the combined data for whole plates and bi-plates, 1368/1390 (98.4%) produced Good Confidence identification results that agreed with the expected organism identity (**Table 8**). The percent agreement for Gram-negative species was higher than for Gram-positive organisms (100% vs 96.5%), although no incorrect identification results were reported for any organism. In comparison, manual preparation of VITEK MS target slides yielded 1351/1390 (97.2%) Good Confidence identification results that agreed with the expected organism identity. When used in conjunction with the VITEK MS, the accuracy of colony picking by the Copan Colibrí System was therefore determined to be acceptable.

Table 6. Comparison of expected identifications to bioMérieux VITEK MS results from target slides prepared on the Copan Colibrí System from whole plates.

Expected Identification	Colibrí System	N [1]	VITEK MS Identification Result (%) [2]		
			Good Confidence	Low Discrimination	No Identification
Escherichia coli	008	46	46 (100)	0 (0)	0 (0)
	009	50	50 (100)	0 (0)	0 (0)
	010	50	50 (100)	0 (0)	0 (0)
	Overall	**146**	**146 (100)**	**0 (0)**	**0 (0)**
Klebsiella pneumoniae	008	44	44 (100)	0 (0)	0 (0)
	009	52	52 (100)	0 (0)	0 (0)
	010	50	50 (100)	0 (0)	0 (0)
	Overall	**146**	**146 (100)**	**0 (0)**	**0 (0)**
Proteus mirabilis	008	50	50 (100)	0 (0)	0 (0)
	009	56	56 (100)	0 (0)	0 (0)
	010	52	52 (100)	0 (0)	0 (0)
	Overall	**158**	**158 (100)**	**0 (0)**	**0 (0)**
Enterococcus faecalis	008	50	41 (82.0)	1 (2.0)	8 (16.0)
	009	54	48 (88.9)	0 (0)	6 (11.1)
	010	64	63 (98.4)	0 (0)	1 (1.6)

Expected Identification	Colibrí System	N [1]	VITEK MS Identification Result (%) [2]		
			Good Confidence	Low Discrimination	No Identification
	Overall	**168**	**152 (90.5)**	**1 (0.6)**	**15 (8.9)**
Staphylococcus aureus	008	48	48 (100)	0 (0)	0 (0)
	009	48	48 (100)	0 (0)	0 (0)
	010	48	48 (100)	0(0)	0 (0)
	Overall	**144**	**144 (100)**	**0 (0)**	**0 (0)**
Streptococcus agalactiae	008	50	48 (96.0)	0 (0)	2 (4.0)
	009	56	54 (96.4)	0 (0)	2 (3.6)
	010	56	54 (96.4)	0 (0)	2 (3.6)
	Overall	**162**	**156 (96.3)**	**0 (0)**	**6 (3.7)**
All Species	008	288	277 (96.2)	1 (0.3)	10 (3.5)
	009	316	308 (97.5)	0 (0)	8 (2.5)
	010	320	317 (99.1)	0 (0)	3 (0.9)
	Overall	**924**	**902 (97.6)**	**1 (0.1)**	**21 (2.3)**

[1] Number of colonies processed.
[2] No incorrect identifications were reported.

Table 7. Comparison of expected identifications to bioMérieux VITEK MS results from target slides prepared on the Copan Colibrí System from bi-plates.

Expected Identification	Colibrí System	N [1]	VITEK MS Identification Result (%) [2]		
			Good Confidence	Low Discrimination	No Identification
Escherichia coli	008	46	46 (100)	0 (0)	0 (0)
	011	58	58 (100)	0 (0)	0 (0)
	013	50	50 (100)	0 (0)	0 (0)
	Overall	**154**	**154 (100)**	**0 (0)**	**0 (0)**
Klebsiella pneumoniae	008	44	44 (100)	0 (0)	0 (0)
	011	72	72 (100)	0 (0)	0 (0)
	013	48	48 (100)	0 (0)	0 (0)
	Overall	**164**	**164 (100)**	**0 (0)**	**0 (0)**
Staphylococcus aureus	008	56	56 (100)	0 (0)	0 (0)
	011	48	48 (100)	0 (0)	0 (0)
	013	44	44 (100)	0 (0)	0 (0)
	Overall	**148**	**148 (100)**	**0 (0)**	**0 (0)**
All Species	008	146	146 (100)	0 (0)	0 (0)
	011	178	178 (100)	0 (0)	0 (0)
	013	142	142 (100)	0 (0)	0 (0)
	Overall	**466**	**466 (100)**	**0 (0)**	**0 (0)**

[1] Number of colonies processed.
[2] No incorrect identifications were reported.

Table 8. Summary of bioMérieux VITEK MS results from target slides prepared on the Copan Colibrí System compared to manual preparation.

Organism	N [1]	VITEK MS Identification Result (%) [2]					
		Good Confidence		Low Discrimination		No Identification	
		Colibrí	Manual	Colibrí	Manual	Colibrí	Manual
Escherichia coli	300	300 (100)	298 (99.3)	0 (0)	0 (0)	0 (0)	2 (0.7)
Klebsiella pneumoniae	310	310 (100)	300 (96.8)	0 (0)	0 (0)	0 (0)	10 (3.2)
Proteus mirabilis	158	158 (100)	154 (97.5)	0 (0)	0 (0)	0 (0)	4 (2.5)
All Gram-Negative Species	**768**	**768 (100)**	**752 (97.9)**	**0 (0)**	**0 (0)**	**0 (0)**	**16 (2.1)**
Enterococcus faecalis	168	152 (90.5)	156 (92.9)	1 (2.0)	0 (0)	15 (8.9)	12 (7.1)
Staphylococcus aureus	292	292 (100)	291 (99.7)	0 (0)	0 (0)	0 (0)	1 (0.3)
Streptococcus agalactiae	162	156 (96.3)	152 (93.8)	0 (0)	1 (0.6)	6 (3.7)	9 (5.6)
All Gram-Positive Species	**622**	**600 (96.5)**	**599 (96.3)**	**1 (0.2)**	**1 (0.2)**	**21 (3.4)**	**22 (3.5)**
Overall	**1390**	**1368 (98.4)**	**1351 (97.2)**	**1 (0.1)**	**1 (0.1)**	**21 (1.5)**	**38 (2.7)**

[1] Number of colonies processed.
[2] No incorrect identifications were reported.

b. Colony Picking Accuracy for Bruker MALDI Biotyper CA

Three Colibrí System instruments were used in this study. A total of 1690 colonies were picked by the three instruments to prepare 48-spot reusable targets for the MALDI Biotyper CA. Of these, 898 and 792 colonies were from whole plates and bi-plates, respectively. All colonies (100%) were successfully picked by visual inspection.

Identification results were stratified according to species, Colibrí System and whole plate (**Table 9)** or bi-plate configuration (**Table 10**). The Copan Colibrí System performed equivalently between instruments and between whole plates and bi-plates. For the combined data for whole plates and bi-plates, 1534/1690 (90.8%) produced high confidence identification results that agreed with the expected organism identity (**Table 11**). The percent agreement for Gram-negative species was higher than for Gram-positive organisms [873/878 (99.4%) vs. 661/812 (81.4%)], although no incorrect identification results were reported for any organism. Manual preparation of MALDI targets yielded 1604/1690 (94.9%) high confidence identification results that agreed with the expected organism identity, with 99.2% agreement for Gram-negatives and 90.3% agreement for Gram-positives.

Table 9. Comparison of expected identifications to Bruker MALDI Biotyper CA results from targets prepared on the Copan Colibrí System from whole plates.

Expected Identification	Colibri System	N [1]	MALDI Biotyper CA Identification Result (%) [2]		
			High Confidence	Low Confidence	No Identification
Escherichia coli	008	40	40 (100)	0 (0)	0 (0)
	009	40	39 (97.5)	1 (2.5)	0 (0)
	010	64	61 (95.3)	3 (4.7)	0 (0)
	Overall	**144**	**140 (97.2)**	**4 (2.8)**	**0 (0)**
Klebsiella pneumoniae	008	46	46 (100)	0 (0)	0 (0)

Expected Identification	Colibri System	N [1]	MALDI Biotyper CA Identification Result (%) [2]		
			High Confidence	Low Confidence	No Identification
	009	48	48 (100)	0 (0)	0 (0)
	010	48	48 (100)	0 (0)	0 (0)
	Overall	**142**	**142 (100)**	**0 (0)**	**0 (0)**
Proteus mirabilis	008	56	56 (100)	0 (0)	0 (0)
	009	56	56 (100)	0 (0)	0 (0)
	010	56	56 (100)	0 (0)	0 (0)
	Overall	**168**	**168 (100)**	**0 (0)**	**0 (0)**
Enterococcus faecalis	008	50	41 (82.0)	7 (14.0)	2 (4.0)
	009	50	39 (78.0)	8 (16.0)	3 (6.0)
	010	50	42 (84.0)	7 (14.0)	1 (2.0)
	Overall	**150**	**122 (81.3)**	**22 (14.7)**	**6 (4.0)**
Staphylococcus aureus	008	48	43 (89.6)	5 (10.4)	0 (0)
	009	48	35 (72.9)	13 (27.1)	0 (0)
	010	48	44 (91.7)	4 (8.3)	0 (0)
	Overall	**144**	**122 (84.7)**	**22 (15.3)**	**0 (0)**
Streptococcus agalactiae	008	50	26 (52.0)	17 (34.0)	7 (14.0)
	009	50	40 (80.0)	5 (10.0)	5 (10.0)
	010	50	39 (78.0)	4 (8.0)	7 (14.0)
	Overall	**150**	**105 (70.0)**	**26 (17.3)**	**19 (12.7)**
All Species	008	290	252 (86.9)	29 (10.0)	9 (3.1)
	009	292	257 (88.0)	27 (9.2)	8 (2.7)
	010	316	290 (91.8)	18 (5.7)	8 (2.5)
	Overall	**898**	**799 (89.0)**	**74 (8.2)**	**25 (2.8)**

[1] Number of colonies processed.
[2] No incorrect identifications were reported.

Table 10. Comparison of expected identifications to Bruker MALDI Biotyper CA results from targets prepared on the Copan Colibrí System from bi-plates.

Expected Identification	Colibrí System	N [1]	MALDI Biotyper CA Identification Result (%) [2]		
			High Confidence	Low Confidence	No Identification
Escherichia coli	008	70	70 (100)	0 (0)	0 (0)
	011	84	84 (100)	0 (0)	0 (0)
	013	82	81 (98.8)	1 (1.2)	0 (0)
	Overall	**236**	**235 (99.6)**	**1 (0.4)**	**0 (0)**
Klebsiella pneumoniae	008	70	70 (100)	0 (0)	0 (0)
	011	70	70 (100)	0 (0)	0 (0)
	013	48	48 (100)	0 (0)	0 (0)
	Overall	**188**	**188 (100)**	**0 (0)**	**0 (0)**
Staphylococcus aureus	008	74	61 (82.4)	13 (17.6)	0 (0)
	011	70	62 (88.6)	8 (11.4)	0 (0)
	013	76	71 (93.4)	5 (6.6)	0 (0)
	Overall	**220**	**194 (88.2)**	**26 (11.8)**	**0 (0)**
Staphylococcus epidermidis	008	50	39 (78.0)	11 (22.0)	0 (0)
	011	50	41 (82.0)	9 (18.0)	0 (0)

Expected Identification	Colibrí System	N [1]	MALDI Biotyper CA Identification Result (%) [2]		
			High Confidence	Low Confidence	No Identification
	013	48	38 (79.2)	10 (20.8)	0 (0)
	Overall	**148**	**118 (79.7)**	**30 (20.3)**	**0 (0)**
All Species	008	264	240 (90.9)	24 (9.1)	0 (0)
	011	274	257 (93.8)	17 (6.2)	0 (0)
	013	254	238 (93.7)	16 (6.3)	0 (0)
	Overall	**792**	**735 (92.8)**	**57 (7.2)**	**0 (0)**

[1] Number of colonies processed.
[2] No incorrect identifications were reported.

Table 11. Summary of Bruker MALDI Biotyper CA results from targets prepared on the Copan Colibrí System compared to manual preparation.

Organism	N [1]	MALDI Biotyper CA Identification Result (%) [2]					
		High Confidence		Low Confidence		No Identification	
		Colibrí	Manual	Colibrí	Manual	Colibrí	Manual
Escherichia coli	380	375 (98.7)	377 (99.2)	5 (1.3)	3 (0.8)	0 (0)	0 (0)
Klebsiella pneumoniae	330	330 (100)	326 (98.8)	0 (0)	1 (0.3)	0 (0)	3 (0.9)
Proteus mirabilis	168	168 (100)	168 (100)	0 (0)	0 (0)	0 (0)	0 (0)
All Gram-Negative Species	**878**	**873 (99.4)**	**871 (99.2)**	**5 (0.6)**	**4 (0.5)**	**0 (0)**	**3 (0.3)**
Enterococcus faecalis	150	122 (81.3)	144 (96.0)	22 (14.7)	4 (2.7)	6 (4.0)	2 (1.3)
Staphylococcus aureus	364	316 (86.8)	334 (91.8)	48 (13.2)	30 (8.2)	0 (0)	0 (0)
Staphylococcus epidermidis	148	118 (79.7)	117 (79.1)	30 (20.3)	31 (20.9)	0 (0)	0 (0)
Streptococcus agalactiae	150	105 (70.0)	138 (92.0)	26 (17.3)	8 (5.3)	19 (12.7)	4 (2.7)
All Gram-Positive Species	**812**	**661 (81.4)**	**733 (90.3)**	**126 (15.5)**	**73 (9.0)**	**25 (3.1)**	**6 (0.7)**
Overall	**1690**	**1534 (90.8)**	**1604 (94.9)**	**131 (7.7)**	**77 (4.5)**	**25 (1.5)**	**9 (0.4)**

[1] Number of colonies processed.
[2] No incorrect identifications were reported.

The accuracy of colony picking by the Copan Colibrí System for preparation of targets for the Bruker MALDI Biotyper CA was determined to be acceptable because, the designated colonies were picked accurately, and no incorrect identification results were reported. In addition, according to the Instructions for Use of the Bruker MALDI Biotyper CA System, if a low-confidence identification or a no identification result is obtained using the Direct Transfer (DT) Sample Preparation Procedure, as implemented with the Copan Colibrí System, the operator is instructed to repeat testing of the isolate manually using the extended Direct Transfer (eDT) or Extraction (Ext) Sample Preparation Procedure.

Accuracy of Bacterial Identification (Inclusivity)

The accuracy of MALDI-TOF MS organism identification with targets prepared by the

Copan Colibrí System was evaluated by testing representative strains of clinically relevant Gram-positive and Gram-negative bacteria that exhibited a range of colony characteristics in terms of size, consistency and morphology. Isolates were obtained from the American Type Culture Collection (ATCC) as well as other sources (i.e., clinical isolates). The identity of the clinical isolates was confirmed using the bioMérieux VITEK MS or VITEK 2. Results obtained using Copan Colibrí and the VITEK MS or Bruker MALDI Biotyper CA analyzers were compared to the expected organism identity as well as results from manually prepared samples. Accuracy of bacterial identification by Copan Colibrí with the bioMérieux VITEK MS and with the Bruker MALDI Biotyper CA are outlined below in sections *a* and *b*, respectively.

a. Accuracy of Bacterial Identification with the bioMérieux VITEK MS

A total of 123 strains from 29 "on panel" bacterial species, i.e. represented in the FDA cleared MS reference database, were cultured on appropriate media and under appropriate conditions. Targets were prepared in duplicate, using 1 colony per spot and 2 spots per isolate. The results of the study with the VITEK MS are summarized in **Tables 12** and **13,** for Gram-negative and Gram-positive species, respectively, and stratified according to species. The percentage of target spots correctly identified with Good Confidence discrimination (Confidence Value ≥ 60%) in comparison to the expected identity was calculated.

For Gram-negative species, 258/308 colonies (83.8%) had Good Confidence identification results that matched the expected organism identity. Twenty-three colonies of *Enterobacter cloacae* complex were reported with Low Discrimination as *E. cloacae*/*E. asburiae* in accordance with the labeling for the VITEK MS analyzer. In addition, 24 colonies of *P. vulgaris* processed by the Colibrí System were identified with Low Discrimination as *P. vulgaris*/*P. penneri* in accordance with the labeling for the VITEK MS analyzer, which also agreed with the organism identity obtained by manual processing of 23/24 colonies from the same culture plates.

For Gram-positive species, 78/84 colonies (92.9%) were identified correctly with Good Confidence values.

None of the colonies of either the Gram-positive or Gram-negative species that were processed by the Copan Colibrí System produced an incorrect identification result.

The results obtained from manual and automated preparation of targets on the Copan Colibrí System are compared in **Table 14**.

When low discrimination occurred, results were as expected in accordance with labeling and there were no misidentifications. Therefore, the accuracy of bacterial identification obtained using the Colibrí System in conjunction with the VITEK MS analyzer was therefore determined to be acceptable.

Table 12. Summary of results from representative Gram-negative bacteria using the Copan Colibrí System in conjunction with the bioMérieux VITEK MS.

Expected Organism Identity	Culture Medium	Strains Tested	Colonies Picked [1]	VITEK MS Identification Result			% Agreement [2]	
				Good Confidence	Low Discrimination	No ID	Culture Medium	Species/ Group
Acinetobacter baumannii	MAC	6	12	12	--	--	**100**	**100**
	TSA	6	12	12	--	--	**100**	
Bacteroides fragilis	TSA	1	2	2	--	--	**100**	**100**

Expected Organism Identity	Culture Medium	Strains Tested	Colonies Picked [1]	VITEK MS Identification Result			% Agreement [2]	
				Good Confidence	Low Discrimination	No ID	Culture Medium	Species/ Group
Citrobacter koseri	MAC	6	12	12	--	--	**100**	**100**
	TSA	6	12	12	--	--	**100**	
Eikenella corrodens	TSA	1	2	2	--	--	**100**	**100**
Enterobacter aerogenes	MAC	6	12	11	--	1	**91.7**	**95.8**
	TSA	6	12	12	--	--	**100**	
Enterobacter cloacae complex	MAC	6	12	--	11 [3]	1	**91.7** [3]	**95.8** [3]
	TSA	6	12	--	12 [3]	--	**100** [3]	
Escherichia coli	MAC	6	12	12	--	--	**100**	**100**
	TSA	6	12	12	--	--	**100**	
Haemophilus influenzae	CHO	2	4	4	--	--	**100**	**100**
Klebsiella oxytoca	MAC	6	12	12	--	--	**100**	**100**
	TSA	6	12	12	--	--	**100**	
Klebsiella pneumoniae	MAC	6	12	12	--	--	**100**	**95.8**
	TSA	6	12	11	--	1	**91.7**	
Moraxella catarrhalis	CHO	1	2	2	--	--	**100**	**100**
	TSA	1	2	2	--	--	**100**	
Morganella morganii	MAC	4	8	8	--	--	**100**	**100**
	TSA	4	8	8	--	--	**100**	
Neisseria gonorrhoeae	CHO	2	4	4	--	--	**100**	**100**
Neisseria meningitidis	CHO	1	2	2	--	--	**100**	**100**
Proteus mirabilis	MAC	6	12	12	--	--	**100**	**100**
	TSA	6	12	12	--	--	**100**	
Proteus vulgaris	MAC	6	12	--	12 [4]	--	**100** [4]	**100** [4]
	TSA	6	12	--	12 [4]	--	**100** [4]	
Pseudomonas aeruginosa	MAC	6	12	12	--	--	**100**	**100**
	TSA	6	12	12	--	--	**100**	
Salmonella typhimurium	MAC	2	4	4 [5]	--	--	**100**	**100**
	TSA	2	4	4 [5]	--	--	**100**	
Serratia marcescens	MAC	4	8	8	--	--	**100**	**100**
	TSA	4	8	8	--	--	**100**	
Stenotrophomonas maltophilia	MAC	2	4	4	--	--	**100**	**100**
	TSA	2	4	4	--	--	**100**	
Vibrio parahaemolyticus	TSA	1	2	2	--	--	**100**	**100**
	Total (%)	**154**	**308 (100)**	**258 (83.8)**	**47 (15.3)**	**3 (1.0)**		**305 (99.0)** [6]

No ID: No identification; CHO: Chocolate Agar; MAC: MacConkey Agar; TSA: Trypticase Soy Agar + 5% Sheep Blood

[1] 2 colonies of each strain were designated for picking by the Colibrí System and each was used to prepare a separate target spot.

[2] Agreement with Expected Organism Identity with Good Confidence.

[3] Reported as *Enterobacter cloacae*/*Enterobacter asburiae* in accordance with VITEK MS device labeling so low discrimination results for this strain are included in the calculation of agreement.

[4] Reported as *Proteus vulgaris*/*Proteus penneri* in accordance with VITEK MS device labeling so low discrimination results for this strain are included in the calculation of agreement (23/24 colonies processed manually from the same culture plates were also reported as *P. vulgaris*/*P. penneri*).

[5] Reported as *Salmonella* group.

[6] Calculation of agreement includes the 47/48 slashline results for *Enterobacter cloacae* and *Proteus vulgaris* that are reported

with low discrimination in accordance with the labeling for the VITEK MS analyzer.

Table 13. Summary of results from representative Gram-positive bacteria using the Copan Colibrí System in conjunction with the bioMérieux VITEK MS.

Expected Organism Identity	Strains Tested	Colonies Picked [2]	VITEK MS Identification Result			% Agreement [3]
			Good Confidence	Low Discrimination	No ID	
Enterococcus faecium	6	12	11	--	1	**91.7**
Enterococcus faecalis	6	12	11	--	1	**91.7**
Listeria monocytogenes	2	4	4	--	--	**100**
Staphylococcus aureus	6	12	12	--	--	**100**
Staphylococcus epidermidis	6	12	12	--	--	**100**
Staphylococcus saprophyticus	4	8	6	--	2	**75.0**
Streptococcus agalactiae	6	16 [4]	13	--	3	**81.3**
Streptococcus pyogenes	4	8	7	--	1	**87.5**
Total (%)	**40**	**84 (100)**	**76 (90.5)**	**0 (0.0)**	**8 (9.5)**	

No ID: No Identification

[1] All Gram-positive organisms evaluated with VITEK MS were cultured on Trypticase Soy Agar + 5% Sheep Blood.

[2] 2 colonies of each strain were designated for picking by the Colibrí System and each was used to prepare a separate target spot.

[3] Agreement with Expected Organism Identity with Good Confidence (60 - 99.9%).

[4] 1 strain was tested twice (total 4 colonies, 3 of which produced the expected identification result with Good Confidence).

Table 14. Comparison of bioMérieux VITEK MS results from targets prepared on the Copan Colibrí System or manually.

Organism	Colonies Picked	VITEK MS Identification Result					
		Good Confidence		Low Discrimination		No Identification	
		Colibrí	Manual	Colibrí	Manual	Colibrí	Manual
Gram-Negative	308	258 [1] (83.8)	238 (77.3)	47 (15.3)	43 (14.0)	3 (1.0)	27 (8.8)
Gram-Positive	84	76 (90.5)	78 (92.9)	0 (0.0)	0 (0.0)	8 (9.5)	6 (7.1)
Total	392	334 [1] (85.2)	316 (80.6)	47 (12.0)	43 (11.0)	11 (2.8)	33 (8.4)

[1] Percent agreement for automated preparation is 99.0% for Gram-negative organisms and 97.2% in total when the 47 low discrimination results for *Enterobacter cloacae* and *Proteus vulgaris* are included. This is in accordance with the VITEK MS device labeling, which cannot differentiate between *Enterobacter cloacae* and *Enterobacter asburiae* or *Proteus vulgaris* and *Proteus penneri* and reports slashline results with low discrimination.

b. Accuracy of Bacterial Identification with the Bruker MALDI Biotyper CA

A total of 124 strains from 30 "on panel" bacterial species, i.e. represented in the validated MS reference database, were cultured on appropriate media and under appropriate conditions. Targets were prepared in duplicate, using 1 colony per spot and 2 spots per isolate. Testing was performed separately with both the reusable (48-spot) and disposable (96-spot) targets. Results obtained from the Inclusivity Study with the Bruker MALDI Biotyper CA 48-spot targets are summarized in **Tables 15** and **16** and those obtained with 96-spot targets are shown in **Tables 17** and **18**, stratified according to species. The percentage of target spots correctly identified with High Confidence (Log(Score) Value ≥ 2.00) in comparison to the expected identity was calculated.

For Gram-negative species, the expected organism identity was reported with High

Confidence Log(Score) values for 308/312 colonies (98.7%) spotted onto 48-spot reusable targets and 296/312 colonies (94.9%) that were processed using 96-spot disposable targets. In contrast, a lower proportion of colonies of Gram-positive organisms yielded High Confidence identification results that agreed with the expected identity. With 48-spot reusable targets, 128/156 colonies (82.1%) were identified with High Confidence Log(Score) values, as were 105/156 colonies (67.3%) spotted on 96-spot disposable targets.

A comparison of results from targets prepared on 48-spot slides on the Copan Colibrí System and from those prepared manually is shown in **Table 19**.

The performance of the Copan Colibrí System for preparation of Gram-positive target organisms for the Bruker MALDI Biotyper CA is lower when compared to manual preparation. However, no incorrect identification results were reported, and instructions will be included in the Copan Colibrí System Operator Manual for the operator to repeat testing of the isolate manually using the extended Direct Transfer (eDT) or Extraction (Ext) Sample Preparation Procedure if a low-confidence identification or no identification result is obtained. This is consistent with the Instructions for Use of the Bruker MALDI Biotyper CA System. Therefore, the results of the Inclusivity Study with the Bruker MALDI Biotyper CA were determined to be acceptable.

Table 15. Summary of results from representative Gram-negative bacteria using the Copan Colibrí System in conjunction with the Bruker MALDI Biotyper CA using 48-spot targets.

Expected Organism Identity	**Culture Medium**	**Strains Tested**	**Colonies Picked [3]**	**MALDI Biotyper CA Identification Result**			**% Agreement [1]**	
				Confidence		**No ID [2]**	**Culture Medium**	**Species/ Group**
				High	**Low**			
Acinetobacter baumannii	MAC	6	12	11	1	--	**91.7**	**95.8**
	TSA	6	12	12	--	--	**100**	
Bacteroides fragilis	TSA	1	2	2	--	--	**100**	**100**
Bordetella pertussis	BG	1	2	2	--	--	**100**	**100**
Citrobacter koseri	MAC	6	12	12	--	--	**100**	**100**
	TSA	6	12	12	--	--	**100**	
Eikenella corrodens	TSA	2	4	4	--	--	**100**	**100**
Enterobacter aerogenes	MAC	6	12	12	--	--	**100**	**100**
	TSA	6	12	12	--	--	**100**	
Enterobacter cloacae complex	MAC	6	12	12	--	--	**100**	**100**
	TSA	6	12	12	--	--	**100**	
Escherichia coli	MAC	6	12	10	2	--	**83.3**	**91.7**
	TSA	6	12	12	--	--	**100**	
Haemophilus influenzae	CHO	2	4	4	--	--	**100**	**100**
Klebsiella oxytoca	MAC	6	12	12	--	--	**100**	**100**
	TSA	6	12	12	--	--	**100**	
Klebsiella pneumoniae	MAC	6	12	12	--	--	**100**	**100**
	TSA	6	12	12	--	--	**100**	
Moraxella catarrhalis	CHO	1	2	2	--	--	**100**	**100**
	TSA	1	2	2	--	--	**100**	
Morganella morganii	MAC	4	8	8	--	--	**100**	**100**

Expected Organism Identity	Culture Medium	Strains Tested	Colonies Picked [3]	MALDI Biotyper CA Identification Result			% Agreement [1]	
				Confidence		No ID [2]	Culture Medium	Species/ Group
				High	Low			
	TSA	4	8	8	--	--	**100**	
Neisseria gonorrhoeae	CHO	2	4	4	--	--	**100**	**100**
Neisseria meningitidis	CHO	1	2	2	--	--	**100**	**100**
Proteus mirabilis	MAC	6	12	12	--	--	**100**	**100**
	TSA	6	12	12	--	--	**100**	
Proteus vulgaris	MAC	6	12	11	1	--	**91.7**	**95.8**
	TSA	6	12	12	--	--	**100**	
Pseudomonas aeruginosa	MAC	6	12	12	--	--	**100**	**100**
	TSA	6	12	12	--	--	**100**	
Salmonella sp.	MAC	2	4	4	--	--	**100**	**100**
	TSA	2	4	4	--	--	**100**	
Serratia marcescens	MAC	4	8	8	--	--	**100**	**100**
	TSA	4	8	8	--	--	**100**	
Stenotrophomonas maltophilia	MAC	2	4	4	--	--	**100**	**100**
	TSA	2	4	4	--	--	**100**	
Vibrio parahaemolyticus	TSA	1	2	2	--	--	**100**	**100**
	Total (%)	**156**	**312 (100)**	**308 (98.7)**	**4 (1.3)**	**0 (0.0)**		

No ID: No identification; BG: Bordet Gengou Agar + 15% Sheep Blood; CHO: Chocolate Agar; MAC: MacConkey Agar; TSA: Trypticase Soy Agar + 5% Sheep Blood

[1] Agreement with Expected Organism Identity with High Confidence Log(Score).

[2] Includes reports of "No Identification" and "No peaks".

[3] 2 colonies of each strain were designated for picking by the Colibrí System and each was used to prepare a separate target spot.

Table 16. Summary of results from representative Gram-positive bacteria using the Copan Colibrí System in conjunction with the Bruker MALDI Biotyper CA using 48-spot targets.

Expected Organism Identity	Culture Medium	Strains Tested	Colonies Picked [3]	MALDI Biotyper CA Identification Result			% Agreement [1]	
				Confidence		No ID [2]	Culture Medium	Species/ Group
				High	Low			
Enterococcus faecalis	TSA	6	12	9	2	1	**75.0**	**79.2**
	CNA	6	12	10	2	--	**83.3**	
Enterococcus faecium	TSA	6	12	10	2	--	**83.3**	**87.5**
	CNA	6	12	11	1	--	**91.7**	
Listeria monocytogenes	TSA	2	4	4	--	--	**100**	**100**
Staphylococcus aureus	TSA	6	12	9	3	--	**75.0**	**87.5**
	CNA	6	12	12	--	--	**100**	
Staphylococcus epidermidis	TSA	6	12	9	3	--	**75.0**	**75.0**
	CNA	6	12	9	3	--	**75.0**	
Staphylococcus saprophyticus	TSA	4	8	8	--	--	**100**	**75.0**
	CNA	4	8	4	2	2	**50.0**	
Streptococcus agalactiae	TSA	6	12	9	2	1	**75.0**	**79.2**
	CNA	6	12	10	--	2	**83.3**	
Streptococcus pyogenes	TSA	4	8	7	1	--	**87.5**	**87.5**
	CNA	4	8	7	1	--	**87.5**	
	Total (%)	**78**	**156 (100)**	**128 (82.1)**	**22 (14.1)**	**6 (3.8)**		

No ID: No identification; CNA: Columbia Agar + 5% Sheep Blood with colistin and nalidixic acid (CNA); TSA: Trypticase Soy Agar +5% Sheep Blood

[1] Agreement with Expected Organism Identity with High Confidence Log(Score).

[2] Includes reports of "No Identification" and "No peaks".

[3] 2 colonies of each strain were designated for picking by the Colibrí System and each was used to prepare a separate target spot.

Table 17. Summary of results from representative Gram-negative bacteria using the Copan Colibrí System in conjunction with the Bruker MALDI Biotyper CA using 96-spot targets.

Expected Organism Identity	Culture Medium	Strains Tested	Colonies Picked [3]	MALDI Biotyper CA Identification Result			% Agreement [1]	
				Confidence		No ID [2]	Culture Medium	Species/ Group
				High	Low			
Acinetobacter baumannii	MAC	6	12	12	--	--	**100**	**100**
	TSA	6	12	12	--	--	**100**	
Bacteroides fragilis	TSA	1	2	2	--	--	**100**	**100**
Bordetella pertussis	BG	1	2	2	--	--	**100**	**100**
Citrobacter koseri	MAC	6	12	11	1	--	**91.7**	**95.8**
	TSA	6	12	12	--	--	**100**	
Eikenella corrodens	TSA	2	4	4	--	--	**100**	**100**
Enterobacter aerogenes	MAC	6	12	12	--	--	**100**	**100**
	TSA	6	12	12	--	--	**100**	
Enterobacter cloacae complex	MAC	6	12	9	2	1	**75.0**	**87.5**
	TSA	6	12	12	--	--	**100**	
Escherichia coli	MAC	6	12	8	4	--	**66.7**	**83.3**
	TSA	6	12	12	--	--	**100**	
Haemophilus influenzae	CHO	2	4	4	--	--	**100**	**100**

Expected Organism Identity	Culture Medium	Strains Tested	Colonies Picked [3]	MALDI Biotyper CA Identification Result			% Agreement [1]	
				Confidence		No ID [2]	Culture Medium	Species/ Group
				High	Low			
Klebsiella oxytoca	MAC	6	12	8	1	3	**66.7**	**79.2**
	TSA	6	12	11	1	--	**91.7**	
Klebsiella pneumoniae	MAC	6	12	10	1	1	**83.3**	**91.7**
	TSA	6	12	12	--	--	**100**	
Moraxella catarrhalis	CHO	1	2	2	--	--	**100**	**100**
	TSA	1	2	2	--	--	**100**	
Morganella morganii	MAC	4	8	8	--	--	**100**	**100**
	TSA	4	8	8	--	--	**100**	
Neisseria gonorrhoeae	CHO	2	4	4	--	--	**100**	**100**
Neisseria meningitidis	CHO	1	2	2	--	--	**100**	**100**
Proteus mirabilis	MAC	6	12	11	--	1	**91.7**	**95.8**
	TSA	6	12	12	--	--	**100**	
Proteus vulgaris	MAC	6	12	12	--	--	**100**	**100**
	TSA	6	12	12	--	--	**100**	
Pseudomonas aeruginosa	MAC	6	12	12	--	--	**100**	**100**
	TSA	6	12	12	--	--	**100**	
Salmonella spp.	MAC	2	4	4	--	--	**100**	**100**
	TSA	2	4	4	--	--	**100**	
Serratia marcescens	MAC	4	8	8	--	--	**100**	**100**
	TSA	4	8	8	--	--	**100**	
Stenotrophomonas maltophilia	MAC	2	4	4	--	--	**100**	**100**
	TSA	2	4	4	--	--	**100**	
Vibrio parahaemolyticus	TSA	1	2	2	--	--	**100**	**100**
	Total (%)	**156**	**312 (100)**	**296 (94.9)**	**10 (3.2)**	**6 (1.9)**		

No ID: No identification; BG: Bordet Gengou Agar + 15% Sheep Blood; CHO: Chocolate Agar; MAC: MacConkey Agar; TSA: Trypticase Soy Agar + 5% Sheep Blood

[1] Agreement with Expected Organism Identity with High Confidence Log(Score).

[2] Includes reports of "No Identification" and "No peaks".

[3] 2 colonies of each strain were designated for picking by the Colibrí System and each was used to prepare a separate target spot.

Table 18. Summary of results from representative Gram-positive bacteria using the Copan Colibrí System in conjunction with the Bruker MALDI Biotyper CA using 96-spot targets.

Colibrí System with MALDI Biotyper CA and 96-spot target: Gram-Positive Bacteria								
Expected Organism Identity	**Culture Medium**	**Strains Tested**	**Colonies Picked [3]**	**MALDI Biotyper CA Identification Result**			**% Agreement [1]**	
				Confidence		**No ID [2]**	**Culture Medium**	**Species/ Group**
				High	**Low**			
Enterococcus faecalis	TSA	6	12	9	--	3	**75.0**	**87.5**
	CNA	6	12	12	--	--	**100**	
Enterococcus faecium	TSA	6	12	9	1	2	**75.0**	**83.3**
	CNA	6	12	11	1	--	**91.7**	
Listeria monocytogenes	TSA	2	4	4	--	--	**100**	**100**
Staphylococcus aureus	TSA	6	12	10	1	1	**83.3**	**91.7**
	CNA	6	12	12	--	--	**100**	
Staphylococcus epidermidis	TSA	6	12	5	5	2	**41.7**	**37.5**
	CNA	6	12	4	6	2	**33.3**	
Staphylococcus saprophyticus	TSA	4	8	4	1	3	**50.0**	**56.3**
	CNA	4	8	5	1	2	**62.5**	
Streptococcus agalactiae	TSA	6	12	4	6	2	**33.3**	**29.2**
	CNA	6	12	3	4	5	**25.0**	
Streptococcus pyogenes	TSA	4	8	7	1	--	**87.5**	**81.3**
	CNA	4	8	6	2	--	**75.0**	
	Total (%)	**78**	**156 (100)**	**105 (67.3)**	**29 (18.6)**	**22 (14.1)**		

No ID: No identification; CNA: Columbia Agar + 5% Sheep Blood with colistin and nalidixic acid (CNA); TSA: Trypticase Soy Agar + 5% Sheep Blood

[1] Agreement with Expected Organism Identity with High Confidence Log(Score).

[2] Includes reports of "No Identification" and "No peaks".

[3] 2 colonies of each strain were designated for picking by the Colibrí System and each was used to prepare a separate target spot.

Table 19. Comparison of Bruker MALDI Biotyper CA results from targets prepared on the Copan Colibrí System or manually.

Organism	**Target Type**	**Colonies Picked**	**MALDI Biotyper CA Identification Result**					
			High Confidence		**Low Confidence**		**No Identification**	
			Colibrí	**Manual**	**Colibrí**	**Manual**	**Colibrí**	**Manual**
Gram-Negative	48-spot	284	281 (98.9)	281 (98.9)	3 (1.1)	2 (0.7)	0 (0.0)	1 (0.3)
	96-spot	312	296 (94.9)	289 (92.6)	10 (3.2)	12 (3.8)	6 (1.9)	11 (3.5)
Gram-Positive	48-spot	156	128 (82.0)	148 (94.9)	22 (14.1)	8 (5.1)	6 (3.8)	0 (0.0)
	96-spot	156	105 (67.3)	123 (78.8)	29 (18.6)	23 (14.7)	22 (14.1)	10 (6.4)
Total		908	810 (89.2)	841 (92.6)	64 (7.0)	50 (5.5)	34 (3.7)	22 (2.4)

Accuracy of Bacterial Identification (Specificity)

To verify the specificity of the Copan Colibrí System and that automated sample preparation does not affect MALDI-TOF MS identification results, targets were prepared using colonies of representative "off-panel" species (10 isolates per analyzer, 2 spots per isolate) that are not

included in the clinically validated databases of the VITEK MS and MALDI Biotyper CA systems. Each of the species tested produced the expected "No identification" results with both mass spectrometers, demonstrating that automated sample preparation did not adversely affect the specificity of MALDI-TOF MS identification. These results are acceptable.

Positional Accuracy

Studies were conducted to evaluate the ability of the Copan Colibrí System to prepare target spots for MALDI-TOF MS analysis at each location on the targets for both the bioMérieux VITEK MS and Bruker MALDI Biotyper CA. Testing was done with isolated colonies of *E. coli* and *S. aureus* grown on Trypticase Soy Agar containing 5% sheep blood. Each of three Colibrí Systems was used to prepare spots at each location on three separate targets for each analyzer. Both 48-spot reusable and 96-spot disposable targets were included in the study with the Bruker MALDI Biotyper CA. The results obtained were analyzed in terms of percent agreement with the expected organism identity at each location (**Table 20**). No positional effects were observed, although lower agreement was observed with *S. aureus* than with *E. coli*, which is consistent with other studies with the Colibrí System in which agreement with the expected organism identity was lower for Gram-positive than Gram-negative species. These results are acceptable.

Table 20. Summary of results from evaluation of Copan Colibrí System positional accuracy.

MALDI-TOF MS Analyzer	Target	Expected Identity	Spots Prepared	Agreement with Expected Organism Identity (%)		No Identification
				High/Good Confidence	Low Confidence/Low Discrimination	
VITEK MS	48-spot	*E. coli*	432	432 (100)	0 (0)	0 (0)
		S. aureus	432	431 (99.8)	0 (0)	1 (0.2)
MALDI Biotyper CA	48-spot	*E. coli*	432	431 (99.8)	1 (0.2)	0 (0)
		S. aureus	432	418 (96.8)	14 (3.2)	0 (0)
	96-spot	*E. coli*	846	845 (99.9)	1 (0.1)	0 (0)
		S. aureus	846	810 (95.7)	34 (4.0)	2 (0.2)

5. Carry-Over:

To evaluate the potential for cross-contamination between target spots due to positional inaccuracy of the Copan Colibrí System, testing was performed by spotting alternating patterns of six "on-panel" and six "off-panel" species onto targets for each of the two mass spectrometry instruments. "On panel" bacterial species, i.e., those represented in the FDA-cleared MS reference databases, were obtained from ATCC, and "off-panel" species that were not included in the databases of the VITEK MS or MALDI Biotyper CA systems were clinical isolates from bioMérieux identified via 16S rRNA sequencing and Copan identified via the MALDI Biotyper MBT Compass (RUO). The targets were analyzed and the reported identity for each spot was compared to the expected value. Results are summarized in **Tables 21** and **22** for the bioMérieux VITEK MS and Bruker MALDI Biotyper CA, respectively. There was no evidence of cross-contamination with targets prepared for either mass spectrometry system, and no incorrect identification results were obtained. However, with *E. faecalis* and *S. agalactiae* on targets for the Bruker MALDI Biotyper CA, fewer High Confidence Log(Score) values were observed than for other bacterial species, leading to lower positive percent agreement. This is consistent with observations in other Analytical Studies using the Colibrí System in conjunction with the Bruker MALDI Biotyper CA to identify Gram-positive organisms and is mitigated by the requirement for additional testing

that is noted in the device labeling. The results from the Carryover/Cross-Contamination Study were therefore determined to be acceptable.

Table 21. Results of the cross-contamination study for the Copan Colibrí System with the bioMérieux VITEK MS.

Colibrí Spotting Mode	"On-panel" Species	Positive Agreement (%) [1]	"Off-panel" Species	Negative Agreement (%) [2]
Duplicate	*Escherichia coli*	24/24 (100)	*Burkholderia thailandensis*	24/24 (100)
	Klebsiella pneumoniae	24/24 (100)	*Pseudocitrobacter faecalis*	24/24 (100)
	Pseudomonas aeruginosa	24/24 (100)	*Acidovorax delafieldii*	24/24 (100)
	Enterococcus faecalis	22/22 (100)	*Rothia amarae*	22/22 (100)
	Staphylococcus aureus	24/24 (100)	*Leuconostoc carnosum*	24/24 (100)
	Streptococcus agalactiae	23/24 [3] (95.8)	*Aneurinibacillus migulanus*	24/24 (100)
	All "On-panel" Species	**141/142 (99.3)**	**All "Off-panel" Species**	**142/142 (100)**
Single	*Escherichia coli*	24/24 (100)	*Burkholderia thailandensis*	24/24 (100)
	Klebsiella pneumoniae	24/24 (100)	*Pseudocitrobacter faecalis*	24/24 (100)
	Pseudomonas aeruginosa	24/24 (100)	*Acidovorax delafieldii*	24/24 (100)
	Enterococcus faecalis	24/24 (100)	*Rothia amarae*	24/24 (100)
	Staphylococcus aureus	24/24 (100)	*Leuconostoc carnosum*	24/24 (100)
	Streptococcus agalactiae	23/24 [3] (95.8)	*Aneurinibacillus migulanus*	24/24 (100)
	All "On-panel" Species	**143/144 (99.3)**	**All "Off-panel" Species**	**144/144 (100)**

[1] Expected organism identity with Good Confidence.
[2] Expected result = "No identification".
[3] 1 colony gave a result of "No identification".

Table 22. Results of the cross-contamination study for the Copan Colibrí System with the Bruker MALDI Biotyper CA.

Target (Spotting Mode)	"On-panel" Species	Positive Agreement (%) [1]	"Off-panel" Species	Negative Agreement (%) [2]
48-spot Reusable (Duplicate)	*Acinetobacter baumannii*	23/24 (95.8)	*Novosphingobium capsulatum*	24/24 (100)
	Escherichia coli	56/56 (100)	*Cedecea neteri*	56/56 (100)
	Klebsiella pneumoniae	24/24 (100)	*Gallibacterium anatis*	24/24 (100)
	Enterococcus faecalis	19/24 [3] (79.2)	*Bacillus infantis*	24/24 (100)
	Staphylococcus aureus	48/48 (100)	*Bacillus flexus*	48/48 (100)
	Streptococcus agalactiae	20/24 [4] (83.3)	*Bacillus licheniformis*	24/24 (100)
	All "On-panel" Species	**190/200 (95.0)**	**All "Off-panel" Species**	**200/200 (100)**
96-spot Disposable (Single)	*Acinetobacter baumannii*	23/24 (95.8)	*Novosphingobium capsulatum*	24/24 (100)
	Escherichia coli	24/24 (100)	*Cedecea neteri*	24/24 (100)

	Klebsiella pneumoniae	23/24 (95.8)	*Gallibacterium anatis*	24/24 (100)
	Enterococcus faecalis	20/24 [5] (83.3)	*Bacillus infantis*	24/24 (100)
	Staphylococcus aureus	22/24 [6] (91.7)	*Bacillus flexus*	24/24 (100)
	Streptococcus agalactiae	10/23 [7] (43.5)	*Bacillus licheniformis*	23/23 (100)
	All "On-panel" Species	**122/143 (85.3)**	**All "Off-panel" Species**	**143/143 (100)**

[1] Expected organism identity with High Confidence.
[2] Expected result = "No identification".
[3] 5/24 (20.8%) reported as *E. faecalis* with Low Confidence.
[4] 4/24 (16.7%) reported as *S. agalactiae* with Low Confidence.
[5] 1/24 (4.2%) reported as *E. faecalis* with Low Confidence; 3/24 (12.5%) reported as No Identification.
[6] 2/24 (8/.3%) reported as *S. aureus* with Low Confidence.
[7] 8/23 (34.7%) reported as *S. agalactiae* with Low Confidence; 5/23 (21.7%) reported as No Identification or No Peaks.

B Other Supportive Instrument Performance Characteristics Data:

Colony Stability

Testing was performed with 8 representative Gram-positive and 8 representative Gram-negative organisms to evaluate the effect of culture incubation time/colony age on the ability of the Copan Colibrí System to prepare targets for the bioMérieux VITEK MS and Bruker MALDI Biotyper CA. For analysis with the bioMérieux VITEK MS, cultures were incubated at 35 ± 2°C for 18, 24, 48 and 72 hours prior to processing according to manufacturers' recommendations. For the MALDI Biotyper CA, cultures were incubated either 18, 24 or 48 hours, with an additional 12 hours at ambient temperature after the specified incubation period prior to processing. *Bordetella pertussis* on Bordet-Gengou Agar was also evaluated on the MALDI Biotyper CA with incubation for 5 and 7 days + 12 hours at ambient temperature prior to processing. Incubation timepoints were selected according to recommendations of the culture plate manufacturers and the indications for use of the mass spectrometers.

The results obtained with the bioMérieux VITEK MS and Bruker MALDI Biotyper CA are presented in **Tables 23** and **24**, respectively. For the VITEK MS, 99.8% of the colonies from each culture medium produced Good Confidence identification results that agreed with the expected organism identity. One sample for *Staphylococcus saprophyticus* on Trypticase Soy Agar with 5% Sheep Blood for 72 hours produced no identification. In contrast, with the Bruker MALDI Biotyper CA, there was generally good agreement with the expected results for Gram-negative species, irrespective of the culture medium or duration of incubation, whereas lower agreement was observed with Gram-positive species. Nevertheless, no incorrect identification results were reported for any of the isolates included in the study and therefore colony age was not shown to affect the accuracy of organism identification.

For *Bordetella pertussis* on Bordet-Gengou Agar, holding cultures at ambient temperature for 12 hours after incubation for 7 days at 35 ± 2°C prior to analysis with the MALDI Biotyper CA resulted in a decrease in the proportion of High Confidence Log(scores). This is noted as a Limitation in the Copan Colibrí device labeling. These results are acceptable.

Table 23. Effect of colony age on the ability of the Copan Colibrí System to prepare targets for bioMérieux VITEK MS, stratified by culture medium.

Species	Number of Colonies with Expected Organism Identity [1]											
	Trypticase Soy Agar with 5% Sheep Blood [2]			Chocolate Agar [3]		MacConkey Agar [2]			Columbia Agar with 5% Sheep Blood [2]			
	18 hours	24 hours	72 hours	18 hours	48 hours	18 hours	24 hours	72 hours	18 hours	24 hours	48 hours	72 hours
Escherichia coli	8/8	8/8	8/8	--	--	12/12	12/12	12/12	8/8	8/8	8/8	8/8
Klebsiella pneumoniae	4/4	4/4	4/4	--	--	12/12	12/12	12/12	4/4	4/4	4/4	4/4
Proteus mirabilis	2/2	2/2	2/2	--	--	12/12	12/12	12/12	2/2	2/2	2/2	2/2
Salmonella typhimurium	--	--	--	--	--	12/12	12/12	12/12	--	--	--	--
Haemophilus influenzae	--	--	--	16/16	16/16	--	--	--	--	--	--	--
Neisseria gonorrhoeae	--	--	--	16/16	16/16	--	--	--	--	--	--	--
Neisseria meningitidis	--	--	--	16/16	16/16	--	--	--	--	--	--	--
Pseudomonas aeruginosa	2/2	2/2	2/2	--	--	--	--	--	2/2	2/2	2/2	2/2
All Gram-negative	**16/16**	**16/16**	**16/16**	**48/48**	**48/48**	**48/48**	**48/48**	**48/48**	**16/16**	**16/16**	**16/16**	**16/16**
% Agreement	**100**	**100**	**100**	**100**	**100**	**100**	**100**	**100**	**100**	**100**	**100**	**100**
Enterococcus faecalis	4/4	4/4	4/4	--	--	--	--	--	4/4	4/4	4/4	4/4
Enterococcus faecium	4/4	4/4	4/4	--	--	--	--	--	4/4	4/4	4/4	4/4
Listeria monocytogenes	2/2	2/2	2/2	--	--	--	--	--	2/2	2/2	2/2	2/2
Staphylococcus aureus	6/6	6/6	6/6	--	--	--	--	--	6/6	6/6	6/6	6/6
Staphylococcus epidermidis	6/6	6/6	6/6	--	--	--	--	--	6/6	6/6	6/6	6/6
Staphylococcus saprophyticus	6/6	6/6	5/6	--	--	--	--	--	6/6	6/6	6/6	6/6
Streptococcus agalactiae	2/2	2/2	2/2	--	--	--	--	--	2/2	2/2	2/2	2/2
Streptococcus pyogenes	2/2	2/2	2/2	--	--	--	--	--	2/2	2/2	2/2	2/2
All Gram-positive	**32/32**	**32/32**	**31/32**	--	--	--	--	--	**32/32**	**32/32**	**32/32**	**32/32**
% Agreement	**100**	**100**	97.9	--	--	--	--	--	**100**	**100**	**100**	**100**
All Species	**48/48**	**48/48**	**47/48**	**48/48**	**48/48**	**48/48**	**48/48**	**48/48**	**48/48**	**48/48**	**48/48**	**48/48**
% Agreement	**100**	**100**	**99.8**	**100**	**100**	**100**	**100**	**100**	**100**	**100**	**100**	**100**

[1] Expected organism identity reported with Good Confidence.
[2] Incubated in ambient air.
[3] Incubated in a microaerophilic atmosphere with 5% CO_2.

Table 24. Effect of colony age on the ability of the Copan Colibrí System to prepare targets for the Bruker MALDI Biotyper CA, stratified by culture medium.

Culture Medium	Species		Number of Colonies with Expected Organism Identity [1]					
			18 hours	18 + 12 hours [2]	24 hours	24 + 12 hours [2]	48 hours	48 + 12 hours [2]
TSA	Gram-negative	*Escherichia coli*	8/8	8/8	8/8	8/8	8/8	8/8
		Klebsiella pneumoniae	4/4	4/4	4/4	4/4	4/4	4/4
		Proteus mirabilis	2/2	2/2	2/2	2/2	2/2	2/2
		Pseudomonas aeruginosa	2/2	2/2	2/2	2/2	2/2	2/2
		All Gram-negative Species	**16/16**	**16/16**	**16/16**	**16/16**	**16/16**	**16/16**
		% Agreement	**100**	**100**	**100**	**100**	**100**	**100**
	Gram-positive	*Enterococcus faecalis*	4/4	4/4	3/4	2/4	3/4	4/4
		Enterococcus faecium	4/4	2/4	4/4	4/4	4/4	4/4
		Listeria monocytogenes	2/2	2/2	1/2	2/2	2/2	2/2
		Staphylococcus aureus	4/6	4/6	6/6	6/6	5/6	6/6
		Staphylococcus epidermidis	3/6	3/6	3/6	3/6	4/6	5/6
		Staphylococcus saprophyticus	3/6	4/6	3/6	3/6	3/6	4/6
		Streptococcus agalactiae	1/2	1/2	2/2	2/2	2/2	1/2
		Streptococcus pyogenes	1/2	2/2	2/2	2/2	2/2	2/2
		All Gram-positive Species	**22/32**	**22/32**	**24/32**	**24/32**	**26/32**	**28/32**

Culture Medium	Species		Number of Colonies with Expected Organism Identity [1]					
			18 hours	18 + 12 hours [2]	24 hours	24 + 12 hours [2]	48 hours	48 + 12 hours [2]
		% Agreement	**68.8**	**68.8**	**75.0**	**75.0**	**81.3**	**87.5**
	ALL	**Overall**	**38/48**	**38/48**	**40/48**	**40/48**	**42/48**	**44/48**
		% Agreement	**79.2**	**79.2**	**83.3**	**83.3**	**87.5**	**91.7**
COL	Gram-negative	*Escherichia coli*	8/8	8/8	8/8	8/8	8/8	8/8
		Klebsiella pneumoniae	4/4	4/4	4/4	4/4	4/4	4/4
		Proteus mirabilis	2/2	2/2	2/2	2/2	2/2	2/2
		Pseudomonas aeruginosa	2/2	2/2	2/2	2/2	2/2	2/2
		All Gram-negative Species	**16/16**	**16/16**	**16/16**	**16/16**	**16/16**	**16/16**
		% Agreement	**100**	**100**	**100**	**100**	**100**	**100**
	Gram-positive	*Enterococcus faecalis*	4/4	4/4	4/4	3/4	3/4	4/4
		Enterococcus faecium	4/4	4/4	4/4	4/4	4/4	4/4
		Listeria monocytogenes	2/2	2/2	2/2	2/2	2/2	2/2
		Staphylococcus aureus	6/6	6/6	5/6	6/6	5/6	6/6
		Staphylococcus epidermidis	5/6	5/6	5/6	5/6	4/6	4/6
		Staphylococcus saprophyticus	5/6	5/6	5/6	6/6	4/6	4/6
		Streptococcus agalactiae	1/2	2/2	1/2	1/2	2/2	1/2
		Streptococcus pyogenes	2/2	2/2	2/2	2/2	2/2	2/2
		All Gram-positive Species	**29/32**	**30/32**	**28/32**	**29/32**	**26/32**	**27/32**
		% Agreement	**90.6**	**90.6**	**87.5**	**90.6**	**81.3**	**84.4**
	ALL	**Overall**	**45/48**	**46/48**	**44/48**	**45/48**	**42/48**	**43/48**
		% Agreement	**93.8**	**95.8**	**91.7**	**93.8**	**87.5**	**89.6**
MAC	Gram-negative	*Escherichia coli*	11/12	12/12	12/12	10/12	12/12	12/12
		Klebsiella pneumoniae	12/12	12/12	12/12	12/12	12/12	12/12
		Proteus mirabilis	12/12	12/12	12/12	12/12	12/12	12/12
		Pseudomonas aeruginosa	12/12	12/12	12/12	12/12	12/12	12/12
		All Gram-negative Species	**47/48**	**48/48**	**48/48**	**46/48**	**48/48**	**48/48**
		% Agreement	**97.9**	**100**	**100**	**95.8**	**100**	**100**
CNA	Gram-positive	*Enterococcus faecalis*	8/8	8/8	**NA**	**NA**	8/8	6/8
		Enterococcus faecium	8/8	8/8	**NA**	**NA**	8/8	8/8
		Staphylococcus aureus	6/8	8/8	**NA**	**NA**	8/8	7/8
		Staphylococcus epidermidis	6/8	6/8	**NA**	**NA**	6/8	7/8
		Staphylococcus saprophyticus	7/8	6/8	**NA**	**NA**	4/8	5/8
		Streptococcus pyogenes	7/8	8/8	**NA**	**NA**	8/8	8/8
		All Gram-positive Species	**42/48**	**44/48**	**NA**	**NA**	**42/48**	**41/48**
		% Agreement	**87.5**	**91.7**	**NA**	**NA**	**87.5**	**85.4**
CHO [3]	Gram-negative	*Haemophilus influenzae*	16/16	16/16	**NA**	**NA**	16/16	16/16
		Neisseria gonorrhoeae	16/16	16/16	**NA**	**NA**	16/16	16/16
		Neisseria meningitidis	16/16	16/16	**NA**	**NA**	16/16	13/16
		All Gram-negative Species	**48/48**	**48/48**	**NA**	**NA**	**48/48**	**45/48**
		% Agreement	**100**	**100**	**NA**	**NA**	**100**	**93.8**
			5 days	**5 days + 12 hours** [2]	**7 days**	**7 days + 12 hours** [2]		
BGA	Gram-negative	*Haemophilus influenzae*	48/48	48/48	47/48	33/48 [4]		
		% Agreement	**100**	**100**	**97.9**	**68.8**		

[1] Expected organism identity reported with High Confidence.
[2] Incubation for the specified period at 35 ± 2°C plus 12 hours at ambient temperature.
[3] Incubated in a microaerophilic atmosphere with 5% CO_2.
[4] The potential for lower agreement after holding 7-day old cultures of *B. pertussis* at ambient temperature is noted in the device labeling for the Copan Colibrí System.

Spot Stability

The stability of target spots prepared by the Copan Colibrí System prior to and after deposition of the matrix on targets was evaluated for the bioMérieux VITEK MS and the Bruker MALDI Biotyper CA (both 48-spot reusable and 96-spot disposable targets) using a representative panel comprised of 2 species of Gram-positive and 3 of Gram-negative bacteria. Results obtained with immediate matrix deposition (Standard Deposition Mode [SDM]) were compared to those

obtained when matrix deposition was delayed for 60 minutes (Delay Deposition Mode (DDM)) on the Copan Colibrí System and when testing was delayed for 24-, 48- or 72-hours following matrix deposition (by holding the target at room temperature in ambient air or on the deck of the Colibrí Preparation Station). Results are shown for the bioMérieux VITEK MS (**Table 25**) and Bruker MALDI Biotyper CA (**Table 26**). No incorrect identification results were obtained in either mode of operation (DDM vs. SDM), with either mass analyzer, target type or testing delay. No decrease in performance was observed with the 60-minute DDM although performance was reduced when prepared targets of Gram-positive organisms were held for 72 hours prior to analysis on the VITEK MS. No decrease in performance was observed with Gram-negative species using the MALDI Biotyper CA irrespective of the mode of matrix deposition and duration of delay up to 24 hours prior to analysis. However, lower agreement with the expected results was observed with Gram-positive species using the 96-spot disposable target format than the 48-spot reusable target with both the DDM and SDM modes of operation and irrespective of a delay in analysis. The Copan Colibrí device labeling recommends that prepared targets are tested within 24 hours for the Bruker MALDI Biotyper CA and within 48 hours for the bioMérieux VITEK MS. The results are acceptable.

Table 25. Results of delays in matrix deposition and testing for the bioMérieux VITEK MS.

Species	Deposition Mode	Target Holding	N	Confidence		No ID	% agreement*
				Good	Low		
Acinetobacter baumannii	SDM (No Delay)	0h	9	9	0	0	100.0
		24h	18	18	0	0	100.0
		48h	18	18	0	0	100.0
		72h	18	18	0	0	100.0
	DDM (60-minute Delay)	0h	9	9	0	0	100.0
		24h	18	18	0	0	100.0
		48h	18	18	0	0	100.0
		72h	18	17	0	1	88.9
Escherichia coli	SDM (No Delay)	0h	9	9	0	0	100.0
		24h	18	18	0	0	100.0
		48h	18	18	0	0	100.0
		72h	18	18	0	0	100.0
	DDM (60-minute Delay)	0h	9	9	0	0	100.0
		24h	18	18	0	0	100.0
		48h	18	18	0	0	100.0
		72h	18	18	0	0	100.0
Pseudomonas aeruginosa	SDM (No Delay)	0h	9	9	0	0	100.0
		24h	18	18	0	0	100.0
		48h	18	18	0	0	100.0
		72h	18	18	0	0	100.0
	DDM (60-minute Delay)	0h	9	9	0	0	100.0
		24h	18	18	0	0	100.0
		48h	18	18	0	0	100.0
		72h	18	18	0	0	100.0
All Gram-negative	**SDM (No Delay)**	**0h**	**27**	**27**	**0**	**0**	**100.0**
		24h	**54**	**54**	**0**	**0**	**100.0**
		48h	**54**	**54**	**0**	**0**	**100.0**

		72h	**54**	**54**	**0**	**0**	**100.0**
	DDM (60-minute Delay)	**0h**	**27**	**27**	**0**	**0**	**100.0**
		24h	**54**	**54**	**0**	**0**	**100.0**
		48h	**54**	**54**	**0**	**0**	**100.0**
		72h	**54**	**53**	**0**	**1**	**98.1**
Enterococcus faecium	SDM (No Delay)	0h	9	9	0	0	100.0
		24h	18	18	0	0	100.0
		48h	18	18	0	0	100.0
		72h	18	12	0	6	66.7
	DDM (60-minute Delay)	0h	9	9	0	0	100.0
		24h	18	18	0	0	100.0
		48h	18	18	0	0	100.0
		72h	18	10	0	8	55.6
Staphylococcus aureus	SDM (No Delay)	0h	10	10	0	0	100.0
		24h	20	20	0	0	100.0
		48h	20	20	0	0	100.0
		72h	20	18	0	2	90.0
	DDM (60-minute Delay)	0h	10	10	0	0	100.0
		24h	20	20	0	0	100.0
		48h	20	20	0	0	100.0
		72h	20	18	0	2	90.0
All Gram-positive	**SDM (No Delay)**	**0h**	**19**	**19**	**0**	**0**	**100.0**
		24h	**38**	**38**	**0**	**0**	**100.0**
		48h	**38**	**38**	**0**	**0**	**100.0**
		72h	**38**	**30**	**0**	**8**	**78.9**
	DDM (60-minute Delay)	**0h**	**19**	**19**	**0**	**0**	**100.0**
		24h	**38**	**38**	**0**	**0**	**100.0**
		48h	**38**	**38**	**0**	**0**	**100.0**
		72h	**38**	**28**	**0**	**10**	**73.7**

Table 26. Results of delay in matrix deposition for 60 minutes and testing for 24 hours for the Bruker MALDI Biotyper CA.

Species	**Deposition Mode**	**Target Holding**	**48-spot Reusable Target**					**96-spot Disposable Target**				
			N	**Confidence**		**No ID**	**% agreement***	**N**	**Confidence**		**No ID**	**% agreement***
				High	**Low**				**High**	**Low**		
Acinetobacter baumannii	SDM (No Delay)	0h	9	9	0	0	100.0	19	19	0	0	100.0
		24h	18	18	0	0	100.0	38	38	0	0	100.0
	DDM (60-minute Delay)	0h	9	9	0	0	100.0	19	19	0	0	100.0
		24h	18	18	0	0	100.0	37	36	0	1	97.3
Escherichia coli	SDM (No Delay)	0h	9	9	0	0	100.0	18	18	0	0	100.0
		24h	18	18	0	0	100.0	36	36	0	0	100.0
	DDM (60-minute Delay)	0h	9	9	0	0	100.0	16	16	0	0	100.0
		24h	18	18	0	0	100.0	36	36	0	0	100.0
Pseudomonas	SDM	0h	9	9	0	0	100.0	19	19	0	0	100.0

aeruginosa	(No Delay)	24h	18	18	0	0	100.0	38	38	0	0	100.0
	DDM (60-minute Delay)	0h	9	9	0	0	100.0	19	19	0	0	100.0
		24h	18	18	0	0	100.0	38	38	0	0	100.0
All Gram-negative	**SDM (No Delay)**	**0h**	**27**	**27**	**0**	**0**	**100.0**	**56**	**56**	**0**	**0**	**100.0**
		24h	**54**	**54**	**0**	**0**	**100.0**	**112**	**112**	**0**	**0**	**100.0**
	DDM (60-minute Delay)	**0h**	**27**	**27**	**0**	**0**	**100.0**	**54**	**54**	**0**	**0**	**100.0**
		24h	**54**	**54**	**0**	**0**	**100.0**	**111**	**110**	**0**	**1**	**99.1**
Enterococcus faecium	SDM (No Delay)	0h	9	9	0	0	100.0	19	18	1	0	94.7
		24h	18	18	0	0	100.0	38	37	1	0	97.3
	DDM (60-minute Delay)	0h	9	9	0	0	100.0	19	18	1	0	94.7
		24h	18	18	0	0	100.0	38	37	1	0	97.3
Staphylococcus aureus	SDM (No Delay)	0h	10	9	1	0	90.0	19	14	5	0	73.7
		24h	20	20	0	0	100.0	38	30	8	0	78.9
	DDM (60-minute Delay)	0h	10	9	1	0	90.0	19	14	5	0	73.7
		24h	20	17	3	0	85.0	39	31	8	0	79.5
All Gram-positive	**SDM (No Delay)**	0h	**19**	**18**	**1**	**0**	**94.7**	**38**	**32**	**6**	**0**	**84.2**
		24h	**38**	**38**	**0**	**0**	**100.0**	**76**	**67**	**9**	**0**	**88.2**
	DDM (60-minute Delay)	0h	**19**	**18**	**1**	**0**	**94.7**	**38**	**32**	**6**	**0**	**84.2**
		24h	**38**	**35**	**3**	**0**	**92.1**	**77**	**68**	**9**	**0**	**88.3**

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.