# 510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
# DECISION SUMMARY
INSTRUMENT ONLY

## I Background Information:

### A 510(k) Number

K223245

### B Applicant

Copan WASP Srl

### C Proprietary and Established Names

Colibrí

### 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 |
| LON | Class II | 21 CFR 866.1645 - Fully automated short-term incubation cycle antimicrobial susceptibility system | MI - Microbiology |

## II Submission/Device Overview:

### A Purpose for Submission:

To obtain a substantial equivalence determination for the Colibrí for use with the WASPLab device.

**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 or Bruker MALDI Biotyper CA mass spectrometry systems for qualitative identification and microbial suspension 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.

**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)
bioMérieux VITEK MS
bioMérieux VITEK 2
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.]

[Refer to the K220546 Decision Summary for Special Controls for Use Statements that are only applicable to the sample preparation for antimicrobial susceptibility testing workflow.]

## IV Device/System Characteristics:

### A Device Description:

The Colibrí is an instrument designed to be used as an accessory for the downstream matrix assisted laser desorption/ionization time of flight mass spectrometry (MALDI-TOF MS) and antimicrobial susceptibility testing (AST) analyzers. The Colibrí comprises the Colibrí instrument (including on-board pipetting system, spreader, and nephelometer), software, primary tubes for microbial suspension, and daily verification kit. The Colibrí is designed to be used in conjunction with the WASPLab device for culture plate incubation, image acquisition, and image analysis.

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 system also automates the preparation of gram-negative and gram-positive bacterial suspensions at a known concentration for the bioMérieux VITEK 2 System that is used in clinical laboratories for AST analyses. Moreover, the Colibrí is 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.] Together with the WASPLab, the Colibrí automates 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. Alone, the Colibrí automatically prepares target slides for ID and microbial suspensions and purity plates for AST.

Barcode-labeled plates are loaded into the WASPLab system, where the barcode is scanned and recorded. Plates are incubated in the WASPLab system, where they are photographed periodically. Acquired images are saved onto the WASPLab Control unit and visualized by the operator through the WASPLab WebApp. Once plates exhibit adequate growth, the operator selects specific isolated colonies for picking on a digital plate image and assigns the automatic ID or AST Tasks within the WASPLab WebApp interface. The adequacy of the colonies and the number needed for the specific assigned task is verified by the operator through the WebApp interface using the digital plate image. The coordinates of each tagged colony on the acquired image are saved and communicated to the Colibrí. The operator then manually transfers the plates to the Colibrí, where colonies are automatically picked, spotted on the target slide and

overlayed with matrix (for ID) or suspended in a Primary Tube for preparation of a Secondary Tube with the final concentration specified by the IVD analyzer (for AST). Purity plates are also automatically prepared from the AST microbial suspension. The traceability of each target spot and prepared secondary tubes is maintained by application of dedicated labels.

## 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 is described in the K193138 Decision Summary (for ID) and K220546 Decision Summary (for AST). Additional quality control measures are not needed for the WASPLab.

## V Substantial Equivalence Information:

### A Predicate Device Name(s):
Colibrí System

### B Predicate 510(k) Number(s):
K220546

### C Comparison with Predicate(s):

| Device & Predicate Device(s): | DEVICE K223245 | PREDICATE K220546 |
|---|---|---|
| Device Trade Name | Colibrí | Colibrí System |
| **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 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 | 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 and with 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 System is a semi-automated preanalytical 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 |

| Device & Predicate Device(s): | DEVICE K223245 | PREDICATE K220546 |
|---|---|---|
| | 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. | suspensions for AST and purity plates are identified by barcode label. 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 the identification or processing of yeast species, molds, Nocardia, or mycobacteria. |
| Sample/Media Type | Isolated bacterial colonies from any patient source grown on solid media plates included in K193138 and K220546. | Same |
| Method of Testing | Direct testing from isolated colonies for ID purposes in conjunction with bioMérieux VITEK MS or Bruker MALDI Biotyper CA System.<br>Direct testing from isolated colonies for AST purposes in conjunction with bioMérieux VITEK 2. | Same |
| Plate Management | Barcode-labeling plates are manually loaded into the Colibrí after image acquisition | 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 |
| Image Acquisition | D 28 Camera with D 29 background and lighting | 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 | Same |

| Device & Predicate Device(s): | DEVICE K223245 | PREDICATE K220546 |
|---|---|---|
| | 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. | |
| AST Suspension Preparation | Using a pipetting system, a predefined number of morphologically similar colonies are transferred into Primary Tube containing saline solution (0.45% NaCl Saline Solution pH 4.5 to 7.0). A homogenous heavy suspension of organisms is prepared and checked by using on-board Colibrí nephelometer. In the Secondary Tube containing 3.0mL of the same saline solution, a variable aliquot of the heavy suspension is automatically transferred to obtain the final microbial concentration according to IVD package insert indications. The suspensions prepared by Colibrí must be tested in MANUAL MODE on the VITEK 2. | Same |
| 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. No changes have been made. | Same |
| **General Device Characteristic Differences** | | |
| Plate Management | Automatic plate loading for image capturing that is performed according to a set image protocol | Manual loading for image capturing and selection of plate media type by the operator |
| Plate Incubation | Automatic and managed by the WASPLab | Manual |

| Device & Predicate Device(s): | DEVICE K223245 | PREDICATE K220546 |
|---|---|---|
| Plate Image Acquisition & Colony Selection | WASPLab & WebApp | Colibrí Vision System |

## VI Standards/Guidance Documents Referenced:

*The following FDA-recognized Consensus Standards were referenced and pertain to the device and study design for the addition of the WASPLab to the Colibrí workflow:*

- IEC 62304 Medical Device Software - Software life-cycle processes (Edition 1.1 2015-06 Consolidate version)
- EN ISO 13485:2016 Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes
- Guidance for Industry and Food and Drug Administration Staff – General Principle of Software Validation (January 11, 2002)
- Guidance for Industry and Food and Drug Administration Staff – Content of Premarket Submission for Management of Cybersecurity in Medical Device (October 2, 2014)

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 and for AST can be found in the K220546 Decision Summary.

## VII Performance Characteristics (if/when applicable):

The performance of the Colibrí in combination with the WASPLab was evaluated using a total workflow validation study with downstream IVD analyzers (ID: bioMérieux VITEK MS; AST: bioMérieux VITEK 2). An image evaluation study was additionally conducted.

[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 AST workflow.]

### A Analytical Performance:

1. Precision/Reproducibility:
   Precision/Reproducibility for the bacterial ID and AST function of the Colibrí was previously evaluated in K193138 and K220546, respectively. Refer to the Decision Summaries of K193138 and K220546 for additional information.

2. Linearity:

   Not applicable.

3. Analytical Specificity/Interference:

See Section 4 below.

4. Accuracy (Instrument):

*Accuracy of ID and AST Results (WASPLab Workflow Validation)*

A workflow validation study was performed to assess the ability of the Colibrí to (1) prepare target plates and obtain accurate ID results and (2) prepare microbial suspensions and obtain accurate AST results when used in conjunction with the WASPLab. Three different Colibrí instruments interfaced with three different WASPLab instruments operated by three different operators were used to prepare suspensions from isolated colonies of representative isolates of different species of *Enterobacterales* (n=4), *Staphylococcus* (n=2), *Streptococcus* (n=1), *Enterococcus* (n=2), and non-fermenting gram-negative bacilli (n=1) grown on trypticase soy agar + 5% sheep blood or MacConkey agar. Both whole and bi-plates were tested (**Table 1**).

**Table 1.** Species tested in workflow validation study.

| Classification | Species |
|---|---|
| Gram-negative | *Escherichia coli* |
| | *Klebsiella pneumoniae* |
| | *Proteus mirabilis* |
| | *Pseudomonas aeruginosa* |
| | *Citrobacter koseri* |
| Gram-positive | *Enterococcus faecalis* |
| | *Enterococcus faecium* |
| | *Staphylococcus aureus* |
| | *Staphylococcus saprophyticus* |
| | *Streptococcus agalactiae* |

The clinical strains evaluated were "on-panel" species for the VITEK MS with "on scale" MIC values for at least 4 antibiotics representative of the major classes of drugs in VITEK 2 cards. Test strains were combined in polymicrobial mixtures and inoculated on representative culture medium (**Table 2)**. Plates were incubated in three WASPLab devices in aerobic conditions at 35±2 °C for 14 or 18 hours. In the study, one bioMérieux VITEK MS (for bacterial ID) and one bioMérieux VITEK 2 (for AST) with various AST card types containing a broad range of concentrations of specific drugs were used (VITEK cards used: GN74, *Enterobacterales* species; GN82, Non-fermenters species; G67, *Staphylococcus* species; GP67, *Enterococcus* species; ST03, *Streptococcus* species).

**Table 2**. Composition of polymicrobial mixtures.

| Mix | Composition | Agar Medium | Incubation Time |
|---|---|---|---|
| Mix 1 | *Staphylococcus aureus, Enterococcus faecalis, Streptococcus agalactiae* | Tryptic Soy Agar + 5% sheep blood | 18 h |
| Mix 2 | *Staphylococcus saprophyticus, Escherichia coli, Enterococcus faecium* | Tryptic Soy Agar + 5% sheep blood | 18 h |
| Mix 3 | *Escherichia coli, Streptococcus agalactiae, Citrobacter koseri* | Tryptic Soy Agar + 5% sheep blood // MacConkey Agar (bi-plate) | 14 h / 18 h |
| Mix 4 | *Klebsiella pneumoniae, Proteus mirabilis, Pseudomonas aeruginosa* | Tryptic Soy Agar + 5% sheep blood // MacConkey Agar (bi-plate) | 14 h / 18 h |

Three operators selected eligible colonies for ID or AST workflows from digital images in the WASPLab WebApp to be processed by the Colibrí. For bi-plates, both sides of the plate were used for colony selection; however, for each microbial suspension, the colonies were selected on the same agar side. Each plate was automatically unloaded by WASPLab and manually loaded into the Colibrí. Three Colibrí instruments were used to automatically prepare target slides and microbial suspensions. After target slides were prepared, the operator manually prepared and added calibration spots of VITEK MS-DS targets and manually overlaid matrix solution on the calibration spots according to the VITEK MS-DS instructions for use. After microbial suspensions were prepared, they were manually loaded in the VITEK 2 Cassette, associated with the appropriate AST card. After processing, plates were visually assessed to ensure the correct colonies were picked. Specific details and results are included below.

A. Bacterial Identification

A total of 292 spots from target slides prepared by Colibrí with WASPLab were analyzed to determine microbial identification performance and accuracy. The results were compared to the expected strain identity. To be acceptable, ≥95% of colonies shall be identified by VITEK MS with good confidence and matching the expected identity.

Results are shown in **Tables 3–4**. For gram-negative species, 100% agreement was observed between sample preparation using the Colibrí with WASPLab and the expected identity (**Table 3**). No significant differences were observed between species, media, or plate type. The results are acceptable. For gram-positive species, ≥95% agreement was observed between the expected identity and sample preparation using the Colibrí with WASPLab (**Table 4**). No significant differences were observed between species, media, or plate type. The results are acceptable. In summary, the data support the equivalency of the Colibrí with WASPLab for the preparation of target slides for use with downstream MS analyzers for bacterial identification.

**Table 3.** Comparison of VITEK MS results for gram-negative bacterial identification from targets by the Colibrí interfaced with WASPLab and expected strain identity.

| Expected Organism Identity | Culture Medium | Strains Tested | Colonies Picked | VITEK MS Identification Result | | | % Agreement [1] | |
|---|---|---|---|---|---|---|---|---|
| | | | | Good Confidence | Low Discrimination | No ID | Species (Single Media) | Species (Combined Media( |
| *Citrobacter koseri* | TSA | 1 | 10 | 10 | -- | -- | 100% | 100% |
| | MAC | 1 | 11 | 11 | -- | -- | 100% | |
| *Escherichia coli* | TSA | 1 | 14 | 14 | -- | -- | 100% | 100% |
| | MAC | 1 | 9 | 9 | -- | -- | 100% | |
| *Klebsiella pneumoniae* | TSA | 1 | 7 | 7 | -- | -- | 100% | 100% |
| | MAC | 1 | 9 | 9 | -- | -- | 100% | |
| *Proteus mirabiliis* | TSA | 1 | 7 | 7 | -- | -- | 100% | 100% |
| | MAC | 1 | 8 | 8 | -- | -- | 100% | |
| *Pseudomonas aeruginosa* | TSA | 1 | 8 | 8 | -- | -- | 100% | 100% |
| | MAC | 1 | 9 | 9 | -- | -- | 100% | |
| **TOTAL** | **2** | **5** | **92** | **92** | **--** | **--** | **100%** | **100%** |

All strains were incubated for 18 h
No ID: No Identification
[1] Agreement with Expected Organism Identity with Good Confidence

**Table 4.** Comparison of VITEK MS results for gram-positive bacterial identification from targets prepared manually and by the Colibrí interfaced with WASPLab.

| Expected Organism Identity | Strains Tested | Colonies Picked | VITEK MS Identification Result | | | % Agreement [1] |
|---|---|---|---|---|---|---|
| | | | Good Confidence | Low Discrimination | No ID | |
| *Enterococcus faecalis* | 1 | 40 | 39 | -- | 1 | 97.5% |
| *Enterococcus faecium* | 1 | 40 | 38 | -- | 2 | 95.0% |
| *Staphylococcus aureus* | 1 | 40 | 40 | -- | 0 | 100% |
| *Staphylococcus saprophyticus* | 1 | 40 | 40 | -- | 0 | 100% |
| *Streptococcus agalactiae* | 1 | 40 | 39 | -- | 1 | 97.5% |
| **TOTAL** | **5** | **200** | **196** | **--** | **4** | **98.0%** |

All strains were cultured on Trypticase Soy Agar + 5% Sheep Blood for 18 h
No ID: No Identification
[1] Agreement with Expected Organism Identity with Good Confidence

B. AST Results

A total of 200 microbial suspensions prepared by Colibrí with WASPLab and analyzed with the VITEK 2 were tested to evaluate AST accuracy, for a total of 1315 evaluable AST results.

The MIC results obtained using the Colibrí with WASPLab and VITEK 2 system were compared to the results from manually prepared samples and the VITEK 2 system, consistent with the VITEK 2 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 study is a method-to-method comparison, a higher EA and CA was required compared to AST devices that compare to a reference method. In this study, results were considered acceptable if the EA and CA were ≥95% with no major or very major errors for each antimicrobial agent/organism group tested. Additionally, no significant differences should be observed between the Colibrí instruments, operators, culture medium and plate type.

The results are summarized in **Table 5**. Due to the high degree of agreement between MICs determined from manual and Colibrí + WASPLab preparations (with both EA and CA ≥98% for each antimicrobial agent/organism group tested), the AST accuracy was determined to be acceptable. In addition, and since this is a method-to-method comparison, the cumulative results for all antimicrobial agents and species combined was evaluated. For all species and antimicrobial agents, 100% (1315/1315) of on-scale MIC results were in EA and 99.4% (2703/2720) were in CA with the comparator result. No very major or major errors occurred.

**Table 5**. Summary of AST results, stratified by antimicrobial agent.

| Antimicrobial Agent | Organism group | Total tested | # EA | % EA | Total Evalu-able | # EA of Evalu-able | % EA of Evalu-able | # CA | % CA | # S | # R | # vmj | # maj | # min |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Amikacin | *Enterobacterales* | 80 | 80 | 100 | 80 | 80 | 100 | 80 | 100 | 80 | 0 | 0 | 0 | 0 |
| | Non-fermenters | 20 | 20 | 100 | 20 | 20 | 100 | 20 | 100 | 20 | 0 | 0 | 0 | 0 |
| Ampicillin | *Enterococcus* | 40 | 40 | 100 | 20 | 20 | 100 | 40 | 100 | 20 | 20 | 0 | 0 | 0 |
| | *Streptococcus* | 20 | 20 | 100 | 0 | 0 | N/A | 20 | 100 | 20 | 0 | 0 | 0 | 0 |
| Ampicillin / Sulbactam | *Enterobacterales* | 60 | 60 | 100 | 20 | 20 | 100 | 59 | 98.3 | 20 | 40 | 0 | 0 | 1 |
| Aztreonam | *Enterobacterales* | 80 | 80 | 100 | 40 | 40 | 100 | 80 | 100 | 20 | 60 | 0 | 0 | 0 |
| Cefazolin | *Enterobacterales* | 60 | 60 | 100 | 0 | 0 | N/A | 60 | 100 | 0 | 60 | 0 | 0 | 0 |
| Cefepime | *Enterobacterales* | 80 | 80 | 100 | 80 | 80 | 100 | 76 | 95.0 | 40 | 0 | 0 | 0 | 4 |
| | *Non-fermenters* | 20 | 20 | 100 | 20 | 20 | 100 | 20 | 100 | 20 | 0 | 0 | 0 | 0 |
| Cefotaxime | *Streptococcus* | 20 | 20 | 100 | 0 | 0 | N/A | 20 | 100 | 20 | 0 | 0 | 0 | 0 |
| Cefoxitin | *Enterobacterales* | 80 | 80 | 100 | 38 | 38 | 100 | 80 | 100 | 20 | 60 | 0 | 0 | 0 |
| Ceftazidime | *Enterobacterales* | 80 | 80 | 100 | 80 | 80 | 100 | 76 | 95.0 | 0 | 40 | 0 | 0 | 4 |
| | *Non-fermenters* | 20 | 20 | 100 | 20 | 20 | 100 | 20 | 100 | 20 | 0 | 0 | 0 | 0 |
| Ceftriaxone | *Enterobacterales* | 80 | 80 | 100 | 20 | 20 | 100 | 80 | 100 | 0 | 80 | 0 | 0 | 0 |
| | *Streptococcus* | 20 | 20 | 100 | 0 | 0 | N/A | 20 | 100 | 20 | 0 | 0 | 0 | 0 |
| Ciprofloxacin | *Non-fermenters* | 20 | 20 | 100 | 0 | 0 | N/A | 20 | 100 | 20 | 0 | 0 | 0 | 0 |
| | *Staphylococcus* | 40 | 40 | 100 | 20 | 20 | 100 | 40 | 100 | 20 | 0 | 0 | 0 | 0 |
| | *Enterococcus* | 40 | 40 | 100 | 40 | 40 | 100 | 40 | 100 | 20 | 0 | 0 | 0 | 0 |

| Antimicrobial Agent | Organism group | Total tested | # EA | % EA | Total Evalu-able | # EA of Evalu-able | % EA of Evalu-able | # CA | % CA | # S | # R | # vmj | # maj | # min |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Clindamycin | *Staphylococcus* | 40 | 40 | 100 | 0 | 0 | N/A | 40 | 100 | 20 | 20 | 0 | 0 | 0 |
| | *Streptococcus* | 20 | 20 | 100 | 0 | 0 | N/A | 20 | 100 | 20 | 0 | 0 | 0 | 0 |
| Ertapenem | *Enterobacterales* | 80 | 80 | 100 | 0 | 0 | N/A | 80 | 100 | 60 | 20 | 0 | 0 | 0 |
| Erythromycin | *Staphylococcus* | 40 | 40 | 100 | 0 | 0 | N/A | 40 | 100 | 20 | 20 | 0 | 0 | 0 |
| | *Enterococcus* | 40 | 40 | 100 | 20 | 20 | 100 | 40 | 100 | 0 | 20 | 0 | 0 | 0 |
| | *Streptococcus* | 20 | 20 | 100 | 19 | 19 | 100 | 20 | 100 | 0 | 20 | 0 | 0 | 0 |
| Gentamicin | *Enterobacterales* | 80 | 80 | 100 | 20 | 20 | 100 | 80 | 100 | 60 | 20 | 0 | 0 | 0 |
| | *Non-fermenters* | 20 | 20 | 100 | 20 | 20 | 100 | 20 | 100 | 20 | 0 | 0 | 0 | 0 |
| | *Staphylococcus* | 40 | 40 | 100 | 0 | 0 | N/A | 40 | 100 | 20 | 20 | 0 | 0 | 0 |
| Imipenem | *Non-fermenters* | 20 | 20 | 100 | 20 | 20 | 100 | 20 | 100 | 20 | 0 | 0 | 0 | 0 |
| Levofloxacin | *Enterobacterales* | 80 | 80 | 100 | 20 | 20 | 100 | 80 | 100 | 0 | 60 | 0 | 0 | 0 |
| | *Non-fermenters* | 20 | 20 | 100 | 20 | 20 | 100 | 19 | 95.0 | 20 | 0 | 0 | 0 | 1 |
| | *Staphylococcus* | 20 | 20 | 100 | 20 | 20 | 100 | 20 | 100 | 20 | 0 | 0 | 0 | 0 |
| | *Enterococcus* | 40 | 40 | 100 | 40 | 40 | 100 | 40 | 100 | 20 | 0 | 0 | 0 | 0 |
| | *Streptococcus* | 20 | 20 | 100 | 20 | 20 | 100 | 20 | 100 | 20 | 0 | 0 | 0 | 0 |
| Linezolid | *Staphylococcus* | 40 | 40 | 100 | 40 | 40 | 100 | 40 | 100 | 40 | 0 | 0 | 0 | 0 |
| | *Enterococcus* | 40 | 40 | 100 | 40 | 40 | 100 | 40 | 100 | 40 | 0 | 0 | 0 | 0 |
| | *Streptococcus* | 20 | 20 | 100 | 0 | 0 | N/A | 20 | 100 | 20 | 0 | 0 | 0 | 0 |
| Meropenem | *Enterobacterales* | 80 | 80 | 100 | 20 | 20 | 100 | 80 | 100 | 60 | 20 | 0 | 0 | 0 |
| | *Non-fermenters* | 20 | 20 | 100 | 20 | 20 | 100 | 20 | 100 | 20 | 0 | 0 | 0 | 0 |
| Moxifloxacin | *Staphylococcus* | 40 | 40 | 100 | 0 | 0 | N/A | 40 | 100 | 40 | 0 | 0 | 0 | 0 |
| Nitrofurantoin | *Enterobacterales* | 80 | 80 | 100 | 80 | 80 | 100 | 77 | 96.3 | 0 | 40 | 0 | 0 | 3 |
| | *Staphylococcus* | 40 | 40 | 100 | 0 | 0 | N/A | 40 | 100 | 40 | 0 | 0 | 0 | 0 |
| | *Enterococcus* | 40 | 40 | 100 | 20 | 20 | 100 | 40 | 100 | 20 | 20 | 0 | 0 | 0 |
| Oxacillin | *Staphylococcus* | 40 | 40 | 100 | 20 | 20 | 100 | 40 | 100 | 0 | 40 | 0 | 0 | 0 |
| Penicillin (Benzyl-penicillin) | *Enterococcus* | 40 | 40 | 100 | 39 | 39 | 100 | 40 | 100 | 20 | 20 | 0 | 0 | 0 |
| | *Streptococcus* | 20 | 20 | 100 | 20 | 20 | 100 | 20 | 100 | 20 | 0 | 0 | 0 | 0 |
| | *Staphylococcus* | 40 | 40 | 100 | 19 | 19 | 100 | 40 | 100 | 0 | 40 | 0 | 0 | 0 |
| Piperacillin / Tazobactam | *Enterobacterales* | 80 | 80 | 100 | 40 | 40 | 100 | 76 | 95.0 | 60 | 20 | 0 | 0 | 4 |
| | *Non-fermenters* | 20 | 20 | 100 | 20 | 20 | 100 | 20 | 100 | 20 | 0 | 0 | 0 | 0 |
| Quinupristin / Dalfopristin | *Staphylococcus* | 40 | 40 | 100 | 40 | 40 | 100 | 40 | 100 | 40 | 0 | 0 | 0 | 0 |
| Tetracycline | *Enterobacterales* | 80 | 80 | 100 | 40 | 40 | 100 | 80 | 100 | 40 | 40 | 0 | 0 | 0 |
| | *Staphylococcus* | 40 | 40 | 100 | 0 | 0 | N/A | 40 | 100 | 20 | 20 | 0 | 0 | 0 |
| | *Enterococcus* | 40 | 40 | 100 | 0 | 0 | N/A | 40 | 100 | 0 | 40 | 0 | 0 | 0 |
| | *Streptococcus* | 20 | 20 | 100 | 0 | 0 | N/A | 20 | 100 | 0 | 20 | 0 | 0 | 0 |
| Tigecycline | *Enterobacterales* | 80 | 80 | 100 | 40 | 40 | 100 | 80 | 100 | 60 | 20 | 0 | 0 | 0 |
| | *Staphylococcus* | 20 | 20 | 100 | 0 | 0 | N/A | 20 | 100 | 20 | 0 | 0 | 0 | 0 |
| | *Enterococcus* | 20 | 20 | 100 | 0 | 0 | N/A | 20 | 100 | 20 | 0 | 0 | 0 | 0 |
| | *Streptococcus* | 20 | 20 | 100 | 0 | 0 | N/A | 20 | 100 | 20 | 0 | 0 | 0 | 0 |
| Tobramycin | *Enterobacterales* | 80 | 80 | 100 | 20 | 20 | 100 | 80 | 100 | 0 | 60 | 0 | 0 | 0 |
| | *Non-fermenters* | 20 | 20 | 100 | 0 | 0 | N/A | 20 | 100 | 20 | 0 | 0 | 0 | 0 |
| Trimethoprim / Sulfameth-oxazole | *Enterobacterales* | 80 | 80 | 100 | 0 | 0 | N/A | 80 | 100 | 0 | 80 | 0 | 0 | 0 |

| Antimicrobial Agent | Organism group | Total tested | # EA | % EA | Total Evalu-able | # EA of Evalu-able | % EA of Evalu-able | # CA | % CA | # S | # R | # vmj | # maj | # min |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Vancomycin | *Staphylococcus* | 40 | 40 | 100 | 20 | 20 | 100 | 40 | 100 | 40 | 0 | 0 | 0 | 0 |
| | *Enterococcus* | 40 | 40 | 100 | 40 | 40 | 100 | 40 | 100 | 40 | 0 | 0 | 0 | 0 |
| | *Streptococcus* | 20 | 20 | 100 | 20 | 20 | 100 | 20 | 100 | 20 | 0 | 0 | 0 | 0 |

EA = essential agreement; CA = category agreement; S = susceptible; R = resistant; vmj = very major error; maj = major error; min = minor error

C. Colony Picking Accuracy

After processing, plates were visually inspected to determine if the correct designated colonies had been picked. A total of 1400 colonies were designated for picking, with colonies being picked correctly 100% of the time. The results are summarized, stratified by species, in **Table 6**. The results are acceptable.

**Table 6.** Summary of colony picking verification results.

| Test Strains | Total no. of colonies | Visual Picking Verification | | |
|---|---|---|---|---|
| | | No colony was picked | Wrong colony was picked | Designated colony was picked |
| *Citrobacter koseri* | 120 | 0/0 | 0/0 | 120/120 (100%) |
| *Enterococcus faecalis* | 160 | 0/0 | 0/0 | 160/160 (100%) |
| *Enterococcus faecium* | 160 | 0/0 | 0/0 | 160/160 (100%) |
| *Escherichia coli* | 120 | 0/0 | 0/0 | 120/120 (100%) |
| *Klebsiella pneumoniae* | 120 | 0/0 | 0/0 | 120/120 (100%) |
| *Proteus mirabilis* | 120 | 0/0 | 0/0 | 120/120 (100%) |
| *Pseudomonas aeruginosa* | 120 | 0/0 | 0/0 | 120/120 (100%) |
| *Staphylococcus aureus* | 160 | 0/0 | 0/0 | 160/160 (100%) |
| *Streptococcus agalactiae* | 160 | 0/0 | 0/0 | 160/160 (100%) |
| *Streptococcus pyogenes* | 160 | 0/0 | 0/0 | 160/160 (100%) |
| Total gram-positive | 800 | 0/0 | 0/0 | 800/800 (100%) |
| Total gram-negative | 600 | 0/0 | 0/0 | 600/600 (100%) |
| **TOTAL** | **1400** | **0/0** | **0/0** | **1400/1400 (100%)** |

5. Carry-Over:

Not applicable.

## B Other Supportive Instrument Performance Characteristics Data:

*Digital Image Quality*

A study was performed to compare direct visual assessment of culture plates to assessment of the corresponding digital images obtained using the WASPLab and WebApp interface. Representative organisms were suspended in saline and mixed in different ratios prior to inoculation onto appropriate culture media using both whole and bi-plates. After incubation, each

plate was imaged using three different WASPLab instruments. The plates and images were evaluated using a questionnaire in a blinded fashion by three microbiologists of differing levels of experience over 5 days. The questionnaire included questions intended to evaluate growth, semi-quantitation of colonies, differentiation of media types and differentiation of colony types (i.e., morphology, color, presence of hemolysis, etc.). A total of 480 whole plates (4 media types x 4 mixtures x 3 replicates x 1 incubation time x 5 days = 240 plates; 2 media types x 4 mixtures x 3 replicates x 2 incubation times x 5 days = 240 plates) and 160 bi-plates (1 media type x 4 mixtures x 4 replicates x 2 incubation times x 5 days = 160 plates) were prepared and analyzed.

The culture media and organism combinations evaluated are listed in **Tables 7-9.**

**Table 7.** Culture media used for evaluation of digital image quality.

| Culture Medium | Abbreviation | Incubation Time | Temperature | Atmosphere |
|---|---|---|---|---|
| Tryptic Soy Agar + 5% Sheep Blood | TSA | 14-24 hours | 35 ± 2°C | Aerobic |
| Columbia Agar + 5% Sheep Blood | COL | 24 hours | 35 ± 2°C | 5% $CO_2$ |
| Chocolate Agar | CHO | 24 hours | 35 ± 2°C | 5% $CO_2$ |
| MacConkey Agar | MAC | 14-24 hours | 35 ± 2°C | Aerobic |
| Colistin-Nalidixic Acid Columbia Agar with 5% Defibrinated Sheep Blood | CNA | 24 hours | 35 ± 2°C | Aerobic |
| Bordet-Gengou Agar | BGA | 5 days | 35 ± 2°C | Aerobic |
| Tryptic Soy Agar +5% sheep blood// MacConkey Agar (bi-plate) | TSA/MAC | 14-24 hours | 35 ± 2°C | Aerobic |

**Table 8.** Organism mixtures used for evaluation of digital image quality of whole plates.

| Final Mixtures (whole plates) | | **MIX 1: *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Bordetella pertussis*** | | | |
|---|---|---|---|---|---|
| | | $10^7$ CFU/mL | $10^6$ CFU/mL | $10^4$ CFU/mL | $10^3$ CFU/mL |
| **MIX 2: *Streptococcus oralis, Staphylococcus epidermidis, Neisseria sicca*** | $10^7$ CFU/mL | | | | X |
| | $10^6$ CFU/mL | | | X | |
| | $10^4$ CFU/mL | | X | | |
| | $10^3$ CFU/mL | X | | | |

X: Final mixture tested (prepared by combining equal volumes of MIX 1 and MIX 2)

**Table 9.** Organism mixtures used for evaluation of digital image quality of bi-plates.

| Final Mixtures (bi-plates) | | **MIX 1: *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Staphylococcus epidermidis*** | | | |
|---|---|---|---|---|---|
| | | $10^7$ CFU/mL | $10^6$ CFU/mL | $10^4$ CFU/mL | $10^3$ CFU/mL |
| **MIX 2: *Klebsiella pneumoniae, Enterococcus faecalis, Escherichia coli*** | $10^7$ CFU/mL | | | | X |
| | $10^6$ CFU/mL | | | X | |
| | $10^4$ CFU/mL | | X | | |
| | $10^3$ CFU/mL | X | | | |

X: Final mixture tested (prepared by combining equal volumes of MIX 1 and MIX 2)

Operators read each plate by direct visual inspection once and by inspection of the digital images (three images acquired on three different WASPLab devices) and answered the provided questionnaire to assess the quality of digital images in comparison to conventional visual inspection of plates. Percent agreement of results obtained by direct visual inspection were compared to results obtained by inspection of the digital image. The questionnaire answers were evaluated according to operator, WASPLab system, testing day, media type and (when applicable) incubation time. Percent agreement was determined with an acceptance criterion of ≥95% agreement deemed acceptable.

Summaries of the results observed on each type of medium are provided in **Tables 10-11**. No significant differences in agreement were observed between operator, WASPLab system, testing day, incubation time, or medium type.

**Table 10.** Summary of agreement between assessment of direct plates versus digital images of whole plates, stratified by medium type.

| SUMMARY OF RESULTS FOR DIGITAL IMAGE EVALUATION OF WHOLE PLATES | | | | | | | |
|---|---|---|---|---|---|---|---|
| | **Characteristics of microbial growth** | **MEDIUM TYPE** | | | | | |
| | | **TSA** | **COL** | **CHO** | **CAN** | **BGA** | **MAC** |
| GENERAL INFO | Presence of microbial growth | 1080/1080 (100%) | 540/540 (100%) | 540/540 (100%) | 540/540 (100%) | 540/540 (100%) | 1080/1080 (100%) |
| | Semi-quantitative estimation of microbial load | 1071/1080 (99.2%) | 536/540 (99.3%) | 540/540 (100%) | 525/540 (97.2%) | 497/513 [1] (96.9%) | 1079/1080 (100%) |
| | Evaluation of colonies isolation | 1080/1080 (100%) | 540/540 (100%) | 540/540 (100%) | 540/540 (100%) | 540/540 (100%) | 1080/1080 (100%) |
| | Estimation of the no. of different isolates | 1077/1080 (99.7%) | 540/540 (100%) | 539/540 (99.8%) | 540/540 (100%) | 538/540 (99.6%) | 1080/1080 (100%) |
| | Type of plate: Opaque/ Transparent | 1080/1080 (100%) | 540/540 (100%) | 540/540 (100%) | 540/540 (100%) | 540/540 (100%) | 1080/1080 (100%) |
| OPAQUE PLATE | Estimation of the no. isolates showing alpha (α)-hemolysis | 1080/1080 (100%) | 540/540 (100%) | 540/540 (100%) | 540/540 (100%) | 540/540 (100%) | N/A |
| | Estimation of the no. isolates showing beta (β)-hemolysis | 1077/1080 (99.7%) | 540/540 (100%) | N/A | 540/540 (100%) | 535/540 (99.1%) | N/A |
| | Estimation of the no. isolates showing gamma (γ)-hemolysis | 1077/1080 (99.7%) | 540/540 (100%) | N/A | 537/540 (99.4%) | 535/540 (99.1%) | N/A |
| | Estimation of the no. of flat isolates with irregular shape and metallic reflections | 1079/1080 (99.9%) | 540/540 (100%) | 540/540 (100%) | 540/540 (100%) | 539/540 (99.8%) | N/A |
| | Estimation of the no. of round isolates with regular shape | 1077/1080 (99.7%) | 540/540 (100%) | 539/540 (99.8%) | 540/540 (100%) | 534/540 (98.9%) | N/A |
| TRANSPARENT PLATE | Estimation of the no. of isolates with irregular shape | N/A | N/A | N/A | N/A | N/A | 1080/1080 (100%) |
| | Estimation of the no. of isolates un- colored or tending to pink | N/A | N/A | N/A | N/A | N/A | 1080/1080 (100%) |
| | Estimation of the no. of red isolates | N/A | N/A | N/A | N/A | N/A | 1080/1080 (100%) |
| | Estimation of the no. of mucoid isolates | N/A | N/A | N/A | N/A | N/A | 1080/1080 (100%) |
| | Estimation of the no. of swarming isolates | N/A | N/A | N/A | N/A | N/A | 1080/1080 (100%) |

| SUMMARY OF RESULTS FOR DIGITAL IMAGE EVALUATION OF WHOLE PLATES | | | | | | | |
|---|---|---|---|---|---|---|---|
| | **Characteristics of microbial growth** | **MEDIUM TYPE** | | | | | |
| | | **TSA** | **COL** | **CHO** | **CAN** | **BGA** | **MAC** |
| | Visibility of color variation of the medium | N/A | N/A | N/A | N/A | N/A | 1080/1080 (100%) |
| **TOTAL** | | **99.8%** | **99.9%** | **99.9%** | **99.6%** | **99.3%** | **100%** |

[1] Semi-quantitative growth estimates were only made for plates exhibiting growth

**Table 11.** Summary of agreement between assessment of direct plates versus digital images of bi-plates, stratified by medium type.

| SUMMARY OF RESULTS FOR DIGITAL IMAGE EVALUATION OF BI-PLATES | | | |
|---|---|---|---|
| | **Characteristics of microbial growth** | **MEDIUM TYPE** | |
| | | **TSA** | **MAC** |
| GENERAL INFO | Presence of microbial growth | 1440/1440 (100%) | 1440/1440 (100%) |
| | Semi-quantitative estimation of microbial load | 1438/1440 (99.9%) | 1438/1440 (99.9%) |
| | Evaluation of colonies isolation | 1440/1440 (100%) | 1440/1440 (100%) |
| | Estimation of the no. of different isolates | 1439/1440 (99.9%) | 1440/1440 (100%) |
| OPAQUE PLATE | Estimation of the no. isolates showing alpha (α)-hemolysis | 1440/1440 (100%) | N/A |
| | Estimation of the no. isolates showing beta (β)-hemolysis | 1439/1440 (99.9%) | N/A |
| | Estimation of the no. isolates showing gamma (γ)-hemolysis | 1440/1440 (100%) | N/A |
| | Estimation of the no. of flat isolates with irregular shape and metallic reflections | 1440/1440 (100%) | N/A |
| | Estimation of the no. of round isolates with regular shape | 1439/1440 (99.9%) | N/A |
| TRANSPARENT PLATE | Estimation of the no. of isolates with irregular shape | N/A | 1440/1440 (100%) |
| | Estimation of the no. of isolates un-colored or tending to pink | N/A | 1440/1440 (100%) |
| | Estimation of the no. of red isolates | N/A | 1440/1440 (100%) |
| | Estimation of the no. of mucoid isolates | N/A | 1440/1440 (100%) |
| | Estimation of the no. of swarming isolates | N/A | 1440/1440 (100%) |
| | Visibility of color variation of the medium | N/A | 1440/1440 (100%) |
| TOTAL | | 100% | 100% |

The presence of microbial growth was detected by direct visualization versus digital image reads, and results are summarized in **Table 10** (whole-plates) and **Table 11** (bi-plates): *"Presence of microbial growth.*" A semi-quantitative assessment of the number of colonies present on each plate was also performed: "*Semi-quantitative estimation of microbial load."* Growth scores were used to characterize growth as follows based on a four-quadrant plate streaking method: 1+ is few colonies growth, present in the 1st quadrant only; 2+ is moderate growth, present up to the 2nd quadrant; 3+ is numerous growth, present up to the 3rd quadrant; and 4+ is heavy growth, present up to the 4th quadrant. For each culture medium, there was ≥95% positive agreement

between analysis of digital images and direct visualization of the culture plates for detection and semi-quantitative estimation of growth. There were no instances in which growth was detected by direct evaluation of the plate, but no growth was recorded upon analysis of the corresponding digital image. The results are acceptable.

Results from comparison of colony characteristics observed by direct visualization and digital image visualization are summarized in **Table 10** (whole-plates) and **Table 11** (bi-plates): *"Estimation of the no. of different isolates."* For each culture medium, ≥ 99% of plates exhibited the same number of isolates or more based analysis of digital images when compared to direct visualization. The results are acceptable.

Results from comparison of isolates on each plate exhibiting hemolysis by direct visualization and digital image visualization are summarized in **Table 10** (whole-plates) and **Table 11** (bi-plates) in the following categories: "*Estimation of the no. isolates showing alpha (α)-hemolysis*", "*Estimation of the no. isolates showing beta (β)-hemolysis*", and "*Estimation of the no. isolates showing gamma (γ)-hemolysis*". Only nine α-hemolytic colonies were observed on Bordet-Gengou Agar (BGA), and all nine were correctly identified via direct assessment and assessment of digital images. Over all media and plates combined, there was 100% agreement regarding the number of isolates that exhibited α-hemolysis as determined by analysis of the digital images when compared with direct visualization of the culture plates. These results are acceptable. No β-hemolytic colonies were observed on Chocolate Agar. Across all other media and plates combined, the percent agreement between image and direct evaluation of β-hemolysis was ≥99%. The results are acceptable. No γ-hemolytic colonies were observed on Chocolate Agar. However, for the other culture media and plate types, the percent agreement between image and direct evaluation of γ-hemolysis was ≥99%. The results are acceptable.

Results from comparison of observation of flat, irregular colonies with metallic reflections by direct visualization and digital image visualization are summarized in **Table 10** (whole-plates) and **Table 11** (bi-plates): "*Estimation of the no. of flat isolates with irregular shape and metallic reflections*." No flat, irregular colonies with metallic reflections were observed on CNA or CHO agar. Of the remaining media and plate types, the percent agreement between image and direct evaluation was ≥99%. The results are acceptable.

Results from comparison of observation of round, regular colonies by direct visualization and digital image visualization are summarized in **Table 10** (whole-plates) and **Table 11** (bi-plates): "*Estimation of the no. of round isolates with regular shape."* Percent agreement was ≥99% for all plate and media types. The results are acceptable.

There was 100% agreement between evaluation of digital images and direct visualization of plates for identification of specific colony characteristics on MacConkey Agar (**Table 10** for whole plates and **Table 11** for bi-plates, *"Transparent Plate"*). The results are acceptable.

Based on the high agreement between direct assessment of plates and assessment of digital images acquired by the WASPLab, the image quality evaluation study results are acceptable.

## 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.