May 4, 2023

BD Kiestra B.V.
Karin Brands
Manager Regulatory Affairs
Marconilaan 6
Drachten, Frisia 9207 JC
Netherlands

Re: K213280
Trade/Device Name: BD Kiestra Methicillin-resistant *Staphylococcus aureus* (MRSA) Application, BD Kiestra MRSA App
Regulation Number: 21 CFR 866.2190
Regulation Name: Automated Image Assessment System For Microbial Colonies On Solid Culture Media
Regulatory Class: Class II
Product Code: QQY
Dated: September 30, 2021
Received: October 1, 2021

Dear Karin Brands:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

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

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

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

Sincerely,

Ribhi Shawar -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration **Indications for Use**	Form Approved: OMB No. 0910-0120 Expiration Date: 06/30/2023 *See PRA Statement below.*

510(k) Number *(if known)*
K213280

Device Name
BD Kiestra™ Methicillin-resistant Staphylococcus aureus (MRSA) Application

Indications for Use *(Describe)*

The BD Kiestra™ Methicillin-resistant *Staphylococcus aureus* (MRSA) Application is an in-vitro diagnostic software program that requires the BD Kiestra™ Laboratory Automation Solution in order to operate.

The BD Kiestra™ Methicillin-resistant *Staphylococcus aureus* (MRSA) Application is applied to digital images of BD BBL™ CHROMagar™ MRSA II culture plates inoculated with anterior nares samples.

Algorithms are applied to digital images to provide a qualitative assessment of colony growth and colorimetric detection of target colonies for the detection of nasal colonization by MRSA and to serve as an aid in the prevention and control of MRSA infection. Applied algorithms provide the following results:

- "No growth", which will be manually released individually or as a batch (with other no growth samples) by a trained microbiologist upon review of the digital plate images.
- "Growth - other" (growth without mauve color), which digital plate images will be manually reviewed by a trained microbiologist.
- "Growth MRSA Mauve" (growth with mauve color), which digital plate images will be manually reviewed by a trained microbiologist.

The assay is not intended to guide, diagnose, or monitor treatment for MRSA infections. It is not intended to provide results of susceptibility to oxacillin/methicillin.

The BD Kiestra™ Methicillin-resistant *Staphylococcus aureus* (MRSA) Application is indicated for use in the clinical laboratory.

Type of Use *(Select one or both, as applicable)*
☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary Preparation Date: 4 May 2023

Submitted by:
BD Kiestra BV
Marconilaan 6
9207 JC Drachten
The Netherlands

Contact:
Karin Brands
Manager Regulatory Affairs
Tel: +31 646 804 924
Email: Karin.brands@bd.com

Proprietary Names:
BD Kiestra™ Methicillin-resistant *Staphylococcus aureus* (MRSA) Application

Common Names:
BD Kiestra™ MRSA App
MRSA App

Regulatory Information

Regulation section:

866.2190	Automated image assessment system for microbial colonies on solid culture media

Classification:
Class II

Panel:
Microbiology

Product Code(s):
QQY

Predicate Device

APAS Independence with IC Chromogenic MRSA BD Analysis Module; APAS Independence with IC Chromogenic MRSA TFS/S Analysis Module, Clever Culture Systems AG

Device Establishment

BD Kiestra B.V.
Marconilaan 6
9207 JC Drachten,
The Netherlands
Registration Number: 3010141591

Performance Standards

N/A

510(k) Summary
BD Kiestra™ Methicillin-resistant *Staphylococcus aureus* (MRSA) Application

Intended Use

The BD Kiestra™ Methicillin-resistant *Staphylococcus aureus* (MRSA) Application is an in-vitro diagnostic software program that requires the BD Kiestra™ Laboratory Automation Solution in order to operate.

The BD Kiestra™ Methicillin-resistant *Staphylococcus aureus* (MRSA) Application is applied to digital images of BD BBL™ CHROMagar™ MRSA II culture plates inoculated with anterior nares samples.

Algorithms are applied to digital images to provide a qualitative assessment of colony growth and colorimetric detection of target colonies to screen for nasal colonization by MRSA, and to serve as an aid in the prevention and control of MRSA infection. Applied algorithms provide the following results:

- "No growth", which will be manually released individually or as a batch (with other no growth samples) by a trained microbiologist upon review of the digital plate images.
- "Growth - other" (growth without mauve color), which digital plate images will be manually reviewed by a trained microbiologist.
- "Growth MRSA Mauve" (growth with mauve color), which digital plate images will be manually reviewed by a trained microbiologist.

The assay is not intended to guide, diagnose, or monitor treatment for MRSA infections. It is not intended to provide results of susceptibility to oxacillin/methicillin.

The BD Kiestra™ Methicillin-resistant *Staphylococcus aureus* (MRSA) Application is indicated for use in the clinical laboratory.

Special Conditions for Use Statement: For prescription use

Special Instrument Requirements: Integrated into the BD Kiestra™ Laboratory Automation Solution

Device Description

The BD Kiestra™ Methicillin-resistant *Staphylococcus aureus* (MRSA) Application will be optional for the BD Kiestra™ Laboratory Automation Solution and will support laboratory technologists in batching no growth on the BD BBL™ CHROMagar™ MRSA II, growth with no key colony color detected for MRSA ("Growth – other"), and growth with key colony color detected for MRSA ("Growth MRSA Mauve"). These classifications will be characterized as "no growth", "growth" and "growth with mauve color" from BD BBL™ CHROMagar™ MRSA II media, from anterior nares samples.

The technologist has the ability to create work lists in BD Synapsys™ informatics solution based on the classifications (growth, no growth or growth with mauve color). These work lists will be used for follow-up work and batching of results, at the sample level.

The BD Kiestra™ Methicillin-resistant *Staphylococcus aureus* (MRSA) Application will apply Image Algorithms to the digital images to determine if the plate contains "growth" or "no growth". At the individual plate level when the Image Algorithms detects colony growth and potential mauve color the classification will be "growth with mauve color".

When the BD Kiestra™ Methicillin-resistant *Staphylococcus aureus* (MRSA) Application is not capable of automatically generating the outputs (visual attributes: growth with or without mauve color/no

growth), the laboratory technologist will be required to read the digital image of the plate on the computer screen and decide on follow-up action as is the current standard laboratory practice.

Test Principle

The BD Kiestra™ Methicillin-resistant *Staphylococcus aureus* (MRSA) Application will be used by trained laboratory technologists. Anterior nares specimens will be inoculated manually or automated by use of the BD Kiestra™ InoqulA+™ or the BD Kiestra™ InoqulA, which are part of the BD Kiestra™ Laboratory Automation Solution, onto BD BBL™ CHROMagar™ MRSA II plates.

The BD Kiestra™ InoqulA+™ or BD Kiestra™ InoqulA system inoculates and streaks the specimen onto the BD BBL™ CHROMagar™ MRSA II plates. The plates are automatically transferred to the BD Kiestra™ ReadA™ Compact or BD Kiestra™ ReadA where they are incubated at 35°C in O_2.

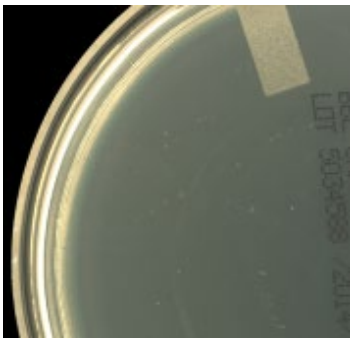
Following a short incubation period (typically 1.5 - 3.5 hours), the plate is imaged by the camera onboard the BD Kiestra™ ReadA™ Compact or BD Kiestra™ ReadA, to obtain a baseline image when no significant bacterial growth can be observed. By the 1.5 - 3.5 hours incubation time point, the plate temperature has reached the incubator temperature and condensation under the plate has dissipated, enabling a clear image of the media to serve as the reference image (T0). This T0 image is used as the baseline comparison for all subsequent images taken to ensure artifacts in the image are not considered growth and to evaluate differential contrast from growing colonies. At all timepoints, in order to maximize colony contrast to their background, the images include illumination from the top, side and bottom of the plate using black (top and side illumination) or white (bottom illumination) contrasting background.

The camera resides on the BD Kiestra™ ReadA™ Compact/BD Kiestra™ ReadA. When an image is scheduled to be taken, the plate is moved to the camera and a digital image is captured. The plate is immediately returned to its designated place, so the plate never leaves the BD Kiestra™ ReadA™ Compact/BD Kiestra™ ReadA. The plate is aligned each time an image is taken by utilizing the plate barcode for the alignment.

The camera produces raw data, pixel values, which are processed by the Optis Image Software resident on the BD Kiestra™ ReadA™ Compact/BD Kiestra™ ReadA. The BD Kiestra™ ReadA™ Compact/BD Kiestra™ ReadA software handles only the mechanical movements within the BD Kiestra™ ReadA™ Compact/BD Kiestra™ ReadA and interacts with the Image Software. The Image Software analyzes the plate pixel values to determine the optimal image acquisition sequence maximizing the signal to noise ratio and dynamic range. The image is further processed and corrections for chromatic aberrations and geometrical distortions are applied, which creates a high quality and normalized image.

Aside from the T0 baseline image time point (1.5 - 3.5 hours) and intermediate time point (10 - 14 hours), the imaging times are also set for at least one endpoint reading of 20 - 26 hours. Users can configure other time points in the BD Kiestra™ database manager, at the time of installation. Final incubation time is configured by the user based on the plated media formulation and the user's standard operation procedures. The BD Kiestra™ Methicillin-resistant *Staphylococcus aureus* (MRSA) Application compares each image to the corresponding baseline image for comparison for new growth and to rule out artifacts in the media such as dust or air bubbles, see **Figure 1.**

Figure 1: Baseline image showing artifacts such as ink jet printing, dust and frosted marker



The time series images are collected for each plate to allow for growth vs no growth determination and the presence of mauve colored growth by the BD Kiestra™ Methicillin-resistant *Staphylococcus aureus* (MRSA) Application.

Based on these results, growth vs no growth and mauve, the images can be sorted in order to streamline and optimize the reading workflow. Plates with no growth can be grouped in a batch list where the user can screen the proposed no growth results in a batch and report with one click. Images that show growth without any trace of mauve can be shown in a different list for single or batch evaluation, and the samples that show the presence of the mauve color will be shown in a separate list for review and further work up so that the user can prioritize those cases.

Patient demographics that are provided via the Laboratory Information System (LIS) can be used to further sort the results, through the user of user-defined expert rules.

The BD Kiestra™ Methicillin-resistant *Staphylococcus aureus* (MRSA) Application supports all features including reporting to the LIS by way of BD Synapsys™ informatics solution.

Substantial Equivalence[1]

Predicate Device Name: APAS Independence with IC Chromogenic MRSA BD Analysis Module; APAS Independence with IC Chromogenic MRSA TFS/S Analysis Module

Predicate 510(k) Number: K200839

[1] The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence as found in the Federal Food, Drug and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

Substantial Equivalence Comparison

	BD Kiestra™ Methicillin-resistant Staphylococcus aureus (MRSA) Application Subject of this 510(k)	***APAS Independence with IC Chromogenic MRSA BD Analysis Module; APAS Independence with IC Chromogenic MRSA TFS/S Analysis Module K200839*** *(Predicate Device)*
Device Trade Name	BD Kiestra™ Methicillin-resistant *Staphylococcus aureus* (MRSA) Application	APAS Independence with IC Chromogenic MRSA BD Analysis Module; APAS Independence with IC Chromogenic MRSA TFS/S Analysis Module
General Device Characteristic Similarities		
Intended Use	BD Kiestra™ Methicillin-resistant *Staphylococcus aureus* (MRSA) Application is an in vitro diagnostic system comprised of instruments (BD Kiestra™ solution) and a software application for specific indications that are used to automate imaging and interpretation of microbial colonies on plated media	The APAS Independence is *in vitro* diagnostic system comprised of an instrument and software analysis module(s) for specific indications that are used to automate imaging and interpretation of microbial colonies on plates of solid culture media.
Indications for Use	The BD Kiestra™ Methicillin-resistant *Staphylococcus aureus* (MRSA) Application is an in-vitro diagnostic software program that requires the BD Kiestra™ Laboratory Automation Solution in order to operate. The BD Kiestra™ Methicillin-resistant *Staphylococcus aureus* (MRSA) Application is applied to digital images of BD BBL CHROMagar MRSA II culture plates inoculated with anterior nares samples. Algorithms are applied to digital images to provide a qualitative assessment of colony growth and colorimetric detection of target colonies to screen for nasal colonization by MRSA and to serve as an aid in the prevention and control of MRSA infection. Applied algorithms provide the following results: • "No growth", which will be manually released individually or as a batch (with other no growth samples) by a trained microbiologist upon review of the digital plate images. • "Growth – other" (growth without mauve color), which digital plate images will be manually reviewed by a trained microbiologist. • "Growth MRSA Mauve" (growth with mauve color), which digital plate images will	The APAS Independence is an *in vitro* diagnostic system comprised of an instrument for automated imaging of agar culture plates and a software analysis module for the following use: 1. The APAS Independence, when using its IC MRSA Chromogenic BD analysis module, automates culture plate imaging and interpretation to detect the presence or absence of colonies with colors suggestive of methicillin-resistant Staphylococcus aureus (MRSA) growth on Beckton Dickson BBL™ CHROMagar™ MRSA II agar that has been inoculated with anterior nares swabs and incubated at 36°C ± 1°C for 24 hours. The APAS Independence, when using its IC MRSA Chromogenic BD analysis module, provides an aid in routine screening for colonization with MRSA. It provides one of two screening results: Presumptive MRSA or Negative. All culture plates that are identified as Presumptive MRSA by the APAS Independence, when using the IC MRSA Chromogenic BD analysis module require review by a trained microbiologist. 2. The APAS Independence, when using its IC MRSA Chromogenic TFS/S analysis module, automates culture

	BD Kiestra™ Methicillin-resistant Staphylococcus aureus (MRSA) Application Subject of this 510(k)	***APAS Independence with IC Chromogenic MRSA BD Analysis Module; APAS Independence with IC Chromogenic MRSA TFS/S Analysis Module*** ***K200839*** *(Predicate Device)*
	be manually reviewed by a trained microbiologist. The assay is not intended to guide, diagnose, or monitor treatment for MRSA infections. It is not intended to provide results of susceptibility to oxacillin/methicillin. The BD Kiestra™ Methicillin-resistant *Staphylococcus aureus* (MRSA) Application is indicated for use in the clinical laboratory.	plate imaging and interpretation to detect the presence or absence of colonies with colors suggestive of methicillin-resistant Staphylococcus aureus (MRSA) growth on Thermo-Fisher Spectra™ MRSA agar that has been inoculated with anterior nares swabs and incubated at 36°C ± 1°C for 24 hours. The APAS Independence, when using its IC MRSA Chromogenic TFS/S analysis module, provides an aid in routine screening for colonization with MRSA. It provides one of three screening results: Presumptive MRSA, Presumptive non-MRSA, or Negative. All culture plates that are identified as Presumptive MRSA or Presumptive non-MRSA by the APAS Independence, when using the IC MRSA Chromogenic TFS/S analysis module, require review by a trained microbiologist.
Imaging Station	BD Kiestra™ ReadA and the BD Kiestra™ ReadA™ Compact are equipped with the imaging station using Light Emitting Diode (LED) illumination of plated media and image capture using High Speed CMOS Image Sensor camera	Light Emitting Diode (LED) illumination of culture plates and image capture using a Charged Coupled Device (CCD) camera
Controller PC	BD Kiestra™ ReadA and the BD Kiestra™ ReadA™ Compact, has its own controller PC that controls the image capturing and images storing	Control image capture, analysis, report generation and result storage
Analysis Module	On the SCU a virtual server is hosted, on which amongst others the APP (Plate Image Analyzer and Plate Algorithm libraries) are running. These services process the images and meta data for analysis. These results are sent to BD Synapsys™ informatics solution BD Synapsys™ informatics solution is installed on the BD Kiestra™ Solution to provide user configuration of image visualization and user configurable workflow rules for imaging result interpretation. Results are sent to LIS by BD Synapsys™ informatics solution after being manually reviewed and released individually or as	Installed on the APAS Controller PC to provide the configuration and instructions for image capture and analysis

	BD Kiestra™ Methicillin-resistant Staphylococcus aureus (MRSA) Application Subject of this 510(k)	***APAS Independence with IC Chromogenic MRSA BD Analysis Module; APAS Independence with IC Chromogenic MRSA TFS/S Analysis Module K200839*** *(Predicate Device)*
	a batch by a trained microbiologist upon review of the digital plate images	
Calibration	In order to keep the camera working optimally, in both the BD Kiestra™ ReadA and the BD Kiestra™ ReadA™ Compact, it is necessary for the user to occasionally calibrate the camera when alerted to do so and after cleaning. Calibration needs to be performed with BD provided calibration plates.	Performed daily using a manufacturer-provided Color Check Tool
Biological Quality Control	Performed per BD BBL™ CHROMagar™ MRSA II media package insert instructions.	Performed daily using standardized suspensions of *Staphylococcus aureus* ATCC 43300 (MRSA positive strain)
General Device Characteristics Differences		
Plate Handling	Automatic	Automated
Instrument Controller PC	Provides the user interface for the BD Kiestra™ Methicillin-resistant *Staphylococcus aureus* (MRSA) Application powered by BD Synapsys™ informatics solution	Provides the user interface for the APAS Independence and controls plate movement
Laboratory Information System (LIS) Data import	Data import through BD Synapsys™ informatics solution	Analysis result for each plate sent to the LIS. Sample ID details retrieved from the LIS
Result Reporting	Results are sent to LIS by BD Synapsys informatics solution after being manually reviewed and released individually or as a batch by a trained microbiologist upon review of the digital plate images.	Consists of software for image analysis and presentation of reports. When APAS Independence with IC MRSA Chromogenic BD analysis module completes the analysis of each plate, the APAS-generated result is sent to the LIS.

Analytical Performance

Digital Quality Image Study

An internal digital image quality study was performed using simulated surveillance samples including MRSA, non-MRSA, and saline controls to show equivalency between a microbiologist interpreting a digital image and interpreting a plate manually (direct in hand).

Samples were plated on BD BBL™ CHROMagar™ MRSAII agar, incubated, and imaged using the BD Kiestra™ Laboratory Automation Solution. Digital images of the plates were acquired using the BD Kiestra™ ReadA Compact with 5 MP camera. Following image collection, three trained clinical microbiologists evaluated plates manually and from the digital image. Samples were randomized and readers did not have access to the direct plate when reading digital images. Results were categorized as

mauve growth, non-mauve growth, or no growth. Manual plate results were compared to the digital image results to calculate overall percent agreement. Further stratification is provided by microbiologist.

Tables 1 - 5 summarize the study results.

Table 1: Spread of Results between Manual Plate Reading and Digital Image Reading

		MANUAL PLATE			
		No Growth	Non-Mauve Growth	Mauve Growth	Total
DIGITAL IMAGE	No Growth	148	2	1	151
	Non- Mauve Growth	8	169	1	178
	Mauve Growth	3	1	188	192
	Total	159	172	190	521
Percent Agreement		148/159 (93.1%)	169/172 (98.3%)	188/190 (98.9%)	

Table 2: Microbiologist Manual Plate Reading Result (Percent Agreement) with Digital Image Reading Result

	No. of Results	***Percent Agreement[1]***		
		No Growth	*Non-Mauve Growth*	*Mauve Growth*
Microbiologist 1	174	48/51 (94.1%)	56/58 (96.6%)	64/65 (98.5%)
Microbiologist 2	172	49/55 (89.1%)	55/55 (100%)	61/62 (98.4%)
Microbiologist 3	175	51/53 (96.2%)	58/59 (98.3%)	63/63 (100%)
Combined	521	148/159 (93.1%)	169/172 (98.3%)	188/190 (98.9%)

[1] Percent agreement determined by dividing number of digital image results by the number of the manual plate read results from the same microbiologist for each designation.

Table 3: Microbiologist 1 Manual Plate Reading Result with Digital Image Reading Result

Microbiologist 1		***Manual Plate***			
		No Growth	***Non-Mauve Growth***	***Mauve Growth***	***Total***
Digital Image	***No Growth***	***48***	***2***	***0***	***59***
	Non-Mauve Growth	***3***	***56***	***1***	***60***
	Mauve Growth	***0***	***0***	***64***	***64***
	Total	***51***	***58***	***65***	***174***
No Growth Agreement:		***94.1% (48/51)***			
Non-Mauve growth Agreement:		***96.6% (56/58)***			
Mauve growth Agreement:		***98.5% (64/65)***			

Table 4: Microbiologist 2 Manual Plate Reading Result with Digital Image Reading Result

Microbiologist 2		*Manual Plate*			
		No Growth	*Non-Mauve Growth*	*Mauve Growth*	*Total*
Digital Image	*No Growth*	*49*	*0*	*1*	*50*
	Non-Mauve Growth	*4*	*55*	*0*	*59*
	Mauve Growth	*2*	*0*	*61*	*63*
	Total	*55*	*55*	*62*	*172*
No Growth Agreement:		*89.1% (49/55)*			
Non-Mauve growth Agreement:		*100.0% (55/55)*			
Mauve growth Agreement:		*98.4% (61/62)*			

Table 5: Microbiologist 3 Manual Plate Reading Result with Digital Image Reading Result

Microbiologist 3		*Manual Plate*			
		No Growth	*Non-Mauve Growth*	*Mauve Growth*	*Total*
Digital Image	*No Growth*	*52*	*0*	*0*	*52*
	Non-Mauve Growth	*1*	*58*	*0*	*59*
	Mauve Growth	*1*	*1*	*63*	*65*
	Total	*53*	*59*	*63*	*175*
No Growth Agreement:		*96.2% (51/53)*			
Non-Mauve growth Agreement:		*98.3% (58/59)*			
Mauve growth Agreement:		*100.0% (63/63)*			

Digital Image Reproducibility

Results from the internal digital image quality study (Table 6 – 10) were used to evaluate reproducibility among a panel of microbiologists for the digital image read. Analysis was performed by comparing the microbiologist's interpretation to the final digital image result (determined by 2/3 majority microbiologist result) to calculate percent agreement.

Table 6: Reproducibility of Digital Image Reading Results

		Manual			
		No Growth	*Non-Mauve Growth*	*Mauve Growth*	*Total*
Digital Image	*No Growth*	150	2	1	153
	Non-Mauve Growth	0	175	0	175
	Mauve Growth	1	1	188	190
	Total	151	178	189	518
Percent Agreement		150/153 (98.0%)	175/175 (100%)	188/190 (98.9%)	

Table 7: Microbiologist Reproducibility (Percent Agreement) with Digital Image Reading Result

	No. of Results[1]	*Percent Agreement*[2]		
		No Growth	*Non-Mauve Growth*	*Mauve Growth*
Microbiologist 1	*173*	*50/51 (98.0%)*	*58/58 (100%)*	*63/64 (98.4%)*
Microbiologist 2	*171*	*49/51 (96.1%)*	*58/58 (100%)*	*61/62 (98.4%)*
Microbiologist 3	*174*	*51/51 (100%)*	*59/59 (100%)*	*64/64 (100%)*
Combined	*518*	*150/153 (98.0%)*	*175/175 (100%)*	*188/190 (98.9%)*

[1] Three results were excluded from the reproducibility analysis since results from at least one microbiologist was determined to be invalid.
[2] Percent agreement determined by dividing number of individual microbiologist digital read results by the number of panel digital image microbiologist results for each designation (i.e., "no growth", "non-mauve growth", "mauve growth").

Table 8: Microbiologist 1 Reproducibility of Digital Image Reading Result

Microbiologist 1		*Manual Read*			
		No Growth	*Non-Mauve Growth*	*Mauve Growth*	*Total*
Digital Image	*No Growth*	*50*	*1*	*0*	*51*
	Non-Mauve Growth	*0*	*58*	*0*	*58*
	Mauve Growth	*0*	*1*	*63*	*64*
	Total	*50*	*60*	*63*	*173*
No Growth Agreement:		*98.0% (50/51)*			
Non-Mauve Growth Agreement:		*100% (58/58)*			
Mauve Growth Agreement:		*98.4% (63/64)*			

Table 9: Microbiologist 2 Reproducibility of Digital Image Reading Result

Microbiologist 2		*Manual Read*			
		No Growth	*Non-Mauve Growth*	*Mauve Growth*	*Total*
Digital Image	*No Growth*	*49*	*1*	*1*	*51*
	Non-Mauve Growth	*0*	*58*	*0*	*58*
	Mauve Growth	*1*	*0*	*61*	*62*
	Total	*50*	*59*	*62*	*171*
No Growth Agreement:		*96.1% (49/51)*			
Non-Mauve Growth Agreement:		*100% (58/58)*			
Mauve Growth Agreement:		*98.4% (61/62)*			

Table 10: Microbiologist 3 Reproducibility of Digital Image Reading Result

Microbiologist 3		*Manual Read*			
		No Growth	*Non-Mauve Growth*	*Mauve Growth*	*Total*
Digital Image	**No Growth**	*51*	*0*	*0*	*51*
	Non-Mauve Growth	*0*	*59*	*0*	*59*
	Mauve Growth	*0*	*0*	*64*	*64*
	Total	*51*	*59*	*64*	*174*
No Growth Agreement:		*100.0% (51/51)*			
Non-Mauve Growth Agreement:		*100.0% (59/59)*			
Mauve Growth Agreement:		*100.0% (64/64)*			

Reproducibility

An internal reproducibility study was conducted with seeded samples representing MRSA positive (mauve) and MRSA negative (non-mauve) isolates. Seeded samples were created with saline using 18–24-hour bacterial strains on TSAII obtained from clinical and ATCC® strains. The Reproducibility Study was conducted at two internal sites at the BD Sparks, MD location with two different automated systems. A panel of 7 simulated clinical nares samples (5 mauve and 2 non-mauve) as well as saline control samples (expected no growth) were evaluated including the following:

Mauve
Staphylococcus aureus methicillin resistant (Collection: POS 9246, Source: clinical)
Staphylococcus aureus methicillin resistant (Collection: POS 3890, Source: ATCC® 43300™)
Staphylococcus aureus methicillin resistant (Collection: POS 8161, Source: clinical)
Staphylococcus aureus methicillin resistant (Collection: POS 8214, Source: clinical)
Staphylococcus aureus methicillin resistant (Collection: POS 10575, Source: clinical)

Non-Mauve
Staphylococcus haemolyticus (Collection: POS 3441, Source: clinical)
Staphylococcus haemolyticus (Collection: POS 8113, Source: clinical)

The samples were plated on BD BBL™ CHROMagar™ MRSAII media. Four dilutions were prepared for each strain in saline at dilutions of 1×10^2, 1×10^3, $1–5 \times 10^4$, and 0 CFU/mL (saline). The following table shows the results per site and organism:

Seeded organism	Dilution	Site 1001 Growth	Site 1001 Color	Site 4002 Growth	Site 4002 Color	Combined Growth (95% CI)	Combined Color (95% CI)
N/A (Saline)	**0**	99.6% (1029/1033)	99.6% (1029/1033)	99.7% (1053/1056)	99.7% (1053/1056)	99.7% (2082/2089) (99.3%, 99.8%)	99.7% (2082/2089) (99.3%, 99.8%)
MRSA STAAUE POS 10575	**10^2**	100.0% (55/55)	100.0% (55/55)	100.0% (45/45)	100.0% (45/45)	100.0% (100/100) (96.3%, 100.0%)	100.0% (100/100) (96.3%, 100.0%)
	10^3	100.0% (45/45)	100.0% (45/45)	100.0% (45/45)	100.0% (45/45)	100.0% (90/90) (95.9%, 100.0%)	100.0% (90/90) (95.9%, 100.0%)
	10^4	100.0% (75/75)	100.0% (75/75)	100.0% (73/73)	100.0% (73/73)	100.0% (148/148) (97.5%, 100.0%)	100.0% (148/148) (97.5%, 100.0%)
MRSA STAAUE ATCC 43300	**10^2**	100.0% (35/35)	100.0% (35/35)	100.0% (45/45)	100.0% (45/45)	100.0% (80/80) (95.4%, 100.0%)	100.0% (80/80) (95.4%, 100.0%)
	10^3	100.0% (59/59)	100.0% (59/59)	100.0% (60/60)	100.0% (60/60)	100.0% (119/119) (96.9%, 100.0%)	100.0% (119/119) (96.9%, 100.0%)
	10^4	100.0% (60/60)	100.0% (60/60)	100.0% (55/55)	100.0% (55/55)	100.0% (115/115) (96.8%, 100.0%)	100.0% (115/115) (96.8%, 100.0%)
MRSA STAAUE POS 8161	**10^2**	100.0% (60/60)	100.0% (60/60)	100.0% (59/59)	100.0% (59/59)	100.0% (119/119) (96.9%, 100.0%)	100.0% (119/119) (96.9%, 100.0%)
	10^3	100.0% (45/45)	100.0% (45/45)	100.0% (45/45)	100.0% (45/45)	100.0% (90/90) (95.9%, 100.0%)	100.0% (90/90) (95.9%, 100.0%)
	10^4	100.0% (75/75)	100.0% (75/75)	100.0% (90/90)	100.0% (90/90)	100.0% (165/165) (97.7%, 100.0%)	100.0% (165/165) (97.7%, 100.0%)
MRSA STAAUE POS 8214	**10^2**	100.0% (50/50)	100.0% (50/50)	100.0% (35/35)	100.0% (35/35)	100.0% 85/85) (95.7%, 100.0%)	100.0% (85/85) (95.7%, 100.0%)

Seeded organism	Dilution	Site 1001 Growth	Site 1001 Color	Site 4002 Growth	Site 4002 Color	Combined Growth (95% CI)	Combined Color (95% CI)
	10^3	100.0% (59/59)	100.0% (59/59)	100.0% (59/59)	100.0% (59/59)	100.0% (118/118) (96.8%, 100.0%)	100.0% (118/118) (96.8%, 100.0%)
	10^4	100.0% (45/45)	100.0% (45/45)	100.0% (45/45)	100.0% (45/45)	100.0% (90/90) (95.9%, 100.0%)	100.0% (90/90) (95.9%, 100.0%)
MRSA STAAUE POS 9246	**10^2**	100.0% (40/40)	100.0% (40/40)	100.0% (45/45)	100.0% (45/45)	100.0% (85/85) (95.7%, 100.0%)	100.0% (85/85) (95.7%, 100.0%)
	10^3	100.0% (45/45)	100.0% (45/45)	100.0% (45/45)	100.0% (45/45)	100.0% (90/90) (95.9%, 100.0%)	100.0% (90/90) (95.9%, 100.0%)
	10^4	100.0% (45/45)	100.0% (45/45)	100.0% (45/45)	100.0% (45/45)	100.0% (90/90) (95.9%, 100.0%)	100.0% (90/90) (95.9%, 100.0%)
***S. haemolyticus* STAHAE POS 3441**	**10^2**	100.0% (25/25)	100.0% (25/25)	100.0% (30/30)	100.0% (30/30)	100.0% (55/55) (93.5%, 100.0%)	100.0% (55/55) (93.5%, 100.0%)
	10^3	88.9% (40/45)	88.9% (40/45)	100.0% (45/45)	100.0% (45/45)	94.4% (85/90) (87.6%, 97.6%)	94.4% (85/90) (87.6%, 97.6%)
	10^4	100.0% (45/45)	100.0% (45/45)	100.0% (45/45)	100.0% (45/45)	100.0% (90/90) (95.9%, 100.0%)	100.0% (90/90) (95.9%, 100.0%)
***S. haemolyticus* STAHAE POS 8113**	**10^2**	100.0% (40/40)	100.0% (40/40)	97.8% (40/40)	97.8% (40/40)	100.0% (80/80) (95.4%, 100.0%)	100.0% (80/80) (95.4%, 100.0%)
	10^3	100.0% (45/45)	100.0% (45/45)	100.0% (45/45)	100.0% (45/45)	100.0% (90/90) (95.9%, 100.0%)	100.0% (90/90) (95.9%, 100.0%)
	10^4	100.0% (45/45)	100.0% (45/45)	100.0% (45/45)	100.0% (45/45)	100.0% (90/90) (95.9%, 100.0%)	100.0% (90/90) (95.9%, 100.0%)

Average Mauve CFU Diameter When First Detected

To determine the average CFU diameter of a mauve colony when first detected, an unlocked version of the application (Not available for commercial use) was used to process digital images of plates with MRSA isolates in 1-hour increments starting at hour 2 and ending at hour 22. These images were then evaluated by 3 microbiologists to measure the diameter of the mauve colonies at first detection by the application. A total of 857 CFUs were evaluated throughout the full 22-hour incubation time.

Testing included:

- 3 MRSA isolates × 5 replicates per dilution × 2 dilutions
- 1 media type (BD BBL™ CHROMagar™ MRSAII media) evaluated
- total of 30 plates evaluated using images collected every hour from 2–22 hours of incubation (30 plates × 21 images per plate = approximately 630 images)

The following table shows the average mauve CFU diameter when first detected:

Strain name	Reference Number	BD Test Media	Tracked CFU count	Average Mauve CFU Diameter (mm) When First Detected	Mauve CFU Diameter When First Detected Standard Deviation (mm)
MRSA 1	ATCC® 43300™	CHROM MRSAII	277	0.42	0.12
MRSA 2	ATCC® 33591™	CHROM MRSAII	236	0.38	0.10
MRSA 3	POS3679*	CHROM MRSAII	344	0.39	0.09

*Internal reference number

Clinical Performance Studies

Approximately 1,800 clinical anterior nares specimens were plated, incubated, and imaged on the BD Kiestra™ Laboratory Automation Solution at three clinical sites. To establish performance of the MRSA app, the images were manually read by trained microbiologists at those sites for the following requirements:

- "No growth"
- "Growth - other" (growth without mauve color)
- "Growth MRSA Mauve"

Clinical anterior nares specimens were plated and incubated in air (O_2) for 24 hours on BD BBL™ CHROMagar™ MRSA II media. The Percent Agreement for each interpretation are listed in the following table:

		Microbiologist Interpretation of Digital Image			
		No Growth	Non-Mauve Growth	Mauve Growth	Grand Total
BD Kiestra™ MRSA App	No Growth	773	9	1	784
	Non-Mauve Growth	237	207	5	456
	Mauve Growth	13	29	319	369
	Grand Total	1023	245	325	1593
	No Growth Percent Agreement 75.6% (773/1023) Non-Mauve Percent Agreement: 84.5% (207/245) Mauve Percent Agreement: 98.2% (319/325)				