



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

I Background Information:

A 510(k) Number

K234012

B Applicant

bioMerieux Inc.

C Proprietary and Established Names

Vitek Compact Pro

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
LON	Class II	21 CFR 866.1645 - Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility System	MI - Microbiology

II Submission/Device Overview:

A Purpose for Submission:

To obtain a substantial equivalence determination for the VITEK COMPACT PRO.

B Type of Test:

In vitro diagnostic test software used for identification and antimicrobial susceptibility testing of microorganisms.

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The VITEK COMPACT PRO is intended for the automated quantitative and/or qualitative antimicrobial susceptibility testing of isolated colonies for most clinically significant aerobic Gram-negative bacilli, *Staphylococcus* spp., *Enterococcus* spp., *Streptococcus* spp., and yeast.

The VITEK COMPACT PRO is also intended for the automated identification of most clinically significant anaerobic organisms and *Corynebacterium* species, fermenting and nonfermenting Gram-negative bacilli, Gram-positive organisms, fastidious organisms, and yeasts and yeast-like organisms.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

Following VITEK 2 ID & AST Cards can only be used with the VITEK COMPACT PRO:

GN, GP, ST, YS AST cards

ANC, BCL, CBC, GN, GP, NH, YST ID cards

IV Device/System Characteristics:

A Device Description:

The VITEK COMPACT PRO is intended for laboratory use by professional users who are trained in microbiology and good laboratory practices. The VITEK COMPACT PRO instrument is an automated instrument designed for use in both clinical and industry laboratories. The instrument performs sample well filling, incubation, and optical readings. The VITEK COMPACT PRO instrument is a two-step automated instrument for:

- Hydrating reagents with sample inoculum prepared from isolated colonies
- Pre-processing cards, incubating cards, and continuous reading for growth

The VITEK 2 Systems Software receives the instrument optical readings and performs analysis to report the ID/AST results. The instrument then ejects the used reagent card into the waste area for disposal. The system includes a VITEK COMPACT PRO instrument with an internal computer, monitor, keyboard, mouse, handheld barcode scanner, and USB hub. The software provided with the internal computer includes analysis and limited data management programs. A bidirectional computer interface (BCI) may transfer results automatically to the user's laboratory information system (LIS). A Quality Control System is available to track the quality control results of the test cards. The Advanced Expert System (AES, Clinical Use) is available to provide online, systematic validation of results and interpretation of resistant phenotypes found during susceptibility testing.

The VITEK COMPACT PRO is intended for organism identification and AST results (quantitative MIC values). Then, VITEK2 Systems softwares (e.g., LIS and AES) use the organism ID and antimicrobial agent MIC values to determine the qualitative categorical interpretation based on the best phenotypic match.

B Instrument Description Information:

1. Instrument Name:

VITEK COMPACT PRO

2. Specimen Identification:

Patient information may be entered manually or downloaded from a data management system. The instrument reads the bar code information from the cards and cassettes and automatically sends the information to the system software.

3. Specimen Sampling and Handling:

Isolated colonies are inoculated into saline and then the density was manually adjusted to a 0.5 McFarland standard using a VITEK 2 DENSICHECK. Specimens and a cassette are loaded into the instrument for the autoinoculation into test cards. Then, the cassette is manually transferred into the load/unload station for incubation.

4. Calibration:

Self-calibrating.

5. Quality Control:

Quality Control (QC) testing of the VITEK COMPACT PRO should be performed as dictated by the protocol in the package insert of each AST card and antimicrobial agent. The purpose of QC testing is to monitor performance of the VITEK COMPACT PRO as well as the proficiency of the laboratory personnel who use the system. The QC testing is performed with the manufacturer recommended QC strains. The QC workflow follows the same steps as the sample workflow. The QC results are generated and displayed on the user interface indicating the expected QC MIC range, the VITEK COMPACT PRO AST interpretive criteria call, and whether the relevant antimicrobial agents for the organism have passed or failed.

During validation testing of each AST card, indicated antimicrobial agents and CLSI-recommended reference strains are summarized in **Table 1**. Purity of all the isoaltes was confirmed by purity plates, with 100% of purity plates showing monomicrobial growth. Results are summarized in **Table 2** and the quality control testing is acceptable.

Table 1. Quality Control Antimicrobial Agents and Strains Tested

AST Card	Antimicrobial Agent	Strain
GN AST card	Amoxicillin/clavulanic acid, Aztreonam, Cefazolin, Cefepime, Ceftazidime, Ceftriaxone, Ciprofloxacin, Ertapenem, ESBL, Meropenem/vaborbactam, Minocycline, Tigecycline, Tobramycin, Trimethoprim/sulfamethoxazole	<i>Escherichia coli</i> , ATCC 25922 <i>Escherichia coli</i> , ATCC 35218 <i>Klebsiella pneumoniae</i> , ATCC 700603 <i>Klebsiella pneumoniae</i> , ATCC BAA-2814 <i>Pseudomonas aeruginosa</i> ATCC 27853

AST Card	Antimicrobial Agent	Strain
GP AST card	Ampicillin, Cefoxitin Screen, Clindamycin, Daptomycin, Erythromycin, Gentamicin High Level, Linezolid, Moxifloxacin, Nitrofurantoin, Oxacillin, Streptomycin High Level, Tetracycline, Vancomycin	<i>Enterococcus faecalis</i> , ATCC 29212 <i>Enterococcus faecalis</i> , ATCC 51299 <i>Staphylococcus aureus</i> , ATCC 29213 <i>Staphylococcus aureus</i> , ATCC BAA-1026
ST AST card	Benzylpenicillin, Ceftriaxone, Clindamycin, Erythromycin, Inducible Clindamycin Resistance, Levofloxacin, Linezolid, Tetracycline, Trimethoprim/sulfamethoxazole, Vancomycin	<i>Staphylococcus aureus</i> , ATCC 29213 <i>Staphylococcus aureus</i> , ATCC BAA-977 <i>Streptococcus pneumoniae</i> , ATCC 49619
YS AST card	Caspofungin, Micafungin	<i>Candida krusei</i> , ATCC 6258 <i>Candida parapsilosis</i> , ATCC 22019

All gram-negative (GN), gram-positive (GP) and *Streptococcus* (ST) reproducibility isolates were sub-cultured twice onto trypticase soy agar and incubated appropriately at 35 ± 2 °C, for 18 – 24 hours (GN and GP) or 18 – 20 hours (ST) before testing. All yeast (YS) isolates were sub-cultured twice onto Sabouraud dextrose agar and incubated at 35 ± 2 °C for 24 hours. MIC values for each drug/organism combination were compared to the expected MIC range. Purity of all the suspensions was confirmed by purity plates. A minimum of 20 replicates of each QC strain were tested at each clinical trial site on the VITEK COMPACT PRO and the VITEK 2 60 instruments. Each quality control organism had no more than five MIC results per drug and instrument after each day's testing. Results are summarized in **Table 2** stratified by each AST card. The cumulative reporting and stratification by each card is presented for simplicity and was based on the analysis for each drug/organism combination which revealed acceptable quality control test results.

Table 2. Quality Control Results Stratified by AST Card

AST card	Number of MIC values within QC Range	
	VITEK COMPACT PRO	VITEK 2 60
GN AST card	3469/3482 (99.6%)	3480/3482 (99.9%)
GP AST card	3386/3393 (99.8%)	3384/3393 (99.7%)
ST AST card	1124/1134 (99.1%)	1123/1134 (99.0%)
YS AST card	298/300 (99.3%)	298/300 (99.3%)

V Substantial Equivalence Information:

A Predicate Device Name(s):

VITEK 2 System

B Predicate 510(k) Number(s):

N50510/S82

C Comparison with Predicate(s):**Table 3: Predicate Comparison**

Device & Predicate Device(s):	<u>K234012</u> VITEK COMPACT PRO	<u>N50510/S0082</u> VITEK 2 System
Device Trade Name	VITEK COMPACT PRO	VITEK 2 System
General Device Characteristic Similarities		
Intended Use/Indications for Use	<p>The VITEK COMPACT PRO is intended for the automated quantitative and/or qualitative antimicrobial susceptibility testing of isolated colonies for most clinically significant aerobic gram-negative bacilli, <i>Staphylococcus</i> spp., <i>Enterococcus</i> spp., <i>Streptococcus</i> spp., and yeast.</p> <p>The VITEK COMPACT PRO is also intended for the automated identification of most clinically significant anaerobic organisms and <i>Corynebacterium</i> species, fermenting and nonfermenting gram-negative bacilli, gram-positive organisms, fastidious organisms, and yeasts and yeast-like organisms.</p>	<p>The VITEK 2 is intended to be used for the automated quantitative or qualitative susceptibility testing of isolated colonies for most clinically significant aerobic gram-negative bacilli, <i>Staphylococcus</i> spp., <i>Enterococcus</i> spp., <i>Streptococcus agalactiae</i> and <i>S. pneumoniae</i>.</p>
Test Cards	VITEK 2 AST 64-well cards	Same
AST Card Inoculum	Isolated colonies prepared with a DENSICHECK densitometer and autoinoculation after loading specimens and AST card into the instrument.	Same
Filling and Sealer process	Vacuum filled and	Same

Device & Predicate Device(s):	<u>K234012</u> VITEK COMPACT PRO	<u>N50510/S0082</u> VITEK 2 System
	automated heat seal	
Incubation and Reading	Automated, 35.5°C +/- 1° with automated readings every 15 minutes with 660 nm optics	Same
AST analysis	Analysis of changes in growth based turbidity	Same
Advanced Expert System	Yes	Same
Waste	Automated removal of ejected test cards to waste container at end of cycle	Same
LIS communication	Bidirectional Computer Interface (BCI)	Same
Results Reported	Identification (ID), quantitative (MIC) and/or qualitative AST results.	Same
General Device Characteristic Differences	VITEK COMPACT PRO	VITEK 2 System
Test Setup	VITEK FLEXPREP	Smart Carrier Station or VITEK FLEXPREP
Card Capacity	15 cards with licenses to expand to 30 and 60 cards	60 for VITEK 2 and 120 for VITEK 2 XL
Cards per Cassette	10	15
AST Dilution Preparation	Manual	Automated or manual

VI Standards/Guidance Documents Referenced:

- Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA
- Guidance for Content of Premarket Submissions for Device Software Functions
- Guidance for Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions
- Guidance for Electromagnetic Compatibility (EMC) of Medical Devices

The following FDA-recognized Consensus Standards were referenced and pertain to device and study design for the VITEK COMPACT PRO:

- IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests (Edition 4.1 2020-09)

- IEC 61010-1 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements (Edition 3.1 2017-01 CONSOLIDATED VERSION)
- IEC 62471 Photobiological safety of lamps and lamp systems (First edition 2006-07)

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

The reproducibility of MIC results was evaluated with VITEK COMPACT PRO. For this study, three instruments were used at three testing sites. The following VITEK AST test card panels were used during testing: Gram-Negative (GN), Gram-Positive (GP), Streptococcus (ST) and Yeast (YS). All GN, GP and ST reproducibility isolates were sub-cultured twice onto trypticase soy agar and incubated appropriately at 35 ± 2 °C, for 18 – 24 hours (GN and GP) or 18 – 20 hours (ST) before testing. All yeast isolates were sub-cultured twice onto Sabouraud dextrose agar and incubated at 35 ± 2 °C for 24 hours. Each reproducibility isolate was tested on the VITEK COMPACT PRO using the manual dilution method. The reproducibility set was tested in triplicate for three days at three clinical trial sites per instrument producing at least 54 results per antimicrobial (2 organisms \times 3 replicates \times 3 sites \times 3 days = 54). For all antimicrobials evaluated, best-case and worst-case reproducibility was $\geq 95\%$. Additionally, purity plates were analyzed for monomicrobial growth. All purity plates displayed monomicrobial growth. The list of organism groups and antimicrobial agents tested in the reproducibility study is shown in **Table 4**. Results are summarized in **Table 5** stratified by each AST card. The cumulative reporting and stratification by each card is presented for simplicity and was based on the analysis for each drug/organism combination which revealed acceptable reproducibility results.

Table 4. List of Organism group and Antimicrobial Agents for Reproducibility Testing

AST card	Organism group	Antimicrobial Agents
GN AST card	Enterobacterales, <i>Acinetobacter</i> spp., and/or <i>Pseudomonas aeruginosa</i>	Amoxicillin/clavulanic acid, Aztreonam, Ceftazidime, Ciprofloxacin, Ceftriaxone, Ertapenem, Cefepime, Minocycline, Trimethoprim/sulfamethoxazole, Tigecycline, and Tobramycin
GP AST card	<i>Enterococcus</i> spp. and/or <i>Staphylococcus</i> spp.	Ampicillin, Clindamycin, Daptomycin, Erythromycin, Nitrofurantoin, Linezolid, Moxifloxacin, Oxacillin, Quinupristin/dalfopristin, Tetracycline, and Vancomycin
ST AST card	<i>Streptococcus</i> spp.	Ceftriaxone, Erythromycin, Clindamycin, Levofloxacin, Benzylpenicillin, Linezolid, Trimethoprim/sulfamethoxazole, Tetracycline, and Vancomycin
YS AST card	<i>Candida</i> spp.	Fluconazole and Micafungin

Table 5. Reproducibility Results Stratified by AST card

AST card	Antimicrobial Agents	Best case (%)	Worst case (%)
GN AST card	Site 1	564/567 (99.5%)	561/567 (98.9%)
	Site 2	564/567 (99.5%)	560/567 (98.8%)
	Site 3	566/567 (99.8%)	560/567 (98.8%)
GN AST card total		1694/1701(99.6%)	1681/1701 (98.8%)
GP AST card	Site 1	732/738 (99.2%)	724/738 (98.1%)
	Site 2	731/738 (99.1%)	728/738 (98.6%)
	Site 3	734/738 (99.5%)	713/738 (96.6%)
GP AST card total		2197/2214 (99.2%)	2165/2214 (97.8%)
ST AST card	Site 1	627/630 (99.5%)	626/630 (99.4%)
	Site 2	622/630 (98.7%)	617/630 (97.9%)
	Site 3	630/630 (100%)	630/630 (100%)
ST AST card total		1879/1890 (99.4%)	1873/1890 (99.1%)
YS AST card	Site 1	112/117 (95.7%)	112/117 (95.7%)
	Site 2	116/117 (99.1%)	116/117 (99.1%)
	Site 3	116/117 (99.1%)	116/117 (99.1%)
YS AST card total		345/351 (98.3%)	345/351 (98.3%)

2. Linearity:

Not applicable.

3. Analytical Specificity/Interference:

Not applicable.

4. Accuracy (Instrument):

The accuracy of MICs obtained by the VITEK COMPACT Pro was evaluated testing representative strains of clinically relevant microorganisms with the VITEK AST cards. The test cards were categorized as each product class of gram-negative (GN), gram-positive (GP), Streptococcus (ST) and yeast (YS) with the list of indicated organisms per antimicrobial. All GN, GP and ST challenge isolates were sub-cultured twice onto trypticase soy agar and incubated appropriately at 35 ± 2 °C, for 18 – 24 hours (GN and GP) or 18 – 20 hours (ST) before testing. All yeast isolates were sub-cultured twice onto Sabouraud dextrose agar and incubated at 35 ± 2 °C for 24 hours. Three different VITEK COMPACT PRO and VITEK 2 60 instruments operated by three different operators were used to test isolated colonies of representative isolates of different species of *Enterobacteriales*, *Acinetobacter* spp., *Pseudomonas aeruginosa*, *Staphylococcus* spp., *Streptococcus* spp., *Enterococcus* spp., and *Candida* spp.. **Table 6** shows the test antimicrobial agents and organism groups used for the AST challenge study.

Table 6. List of Organism group and Antimicrobial Agents for Challenge Study

AST card	Organism group	Antimicrobial Agents
GN AST card	Enterobacteriales, <i>Acinetobacter</i> spp.,	Amoxicillin/clavulanic acid, Aztreonam, Ceftazidime, Ciprofloxacin, Ceftriaxone, Cefazolin, Cefepime, ESBL Screen, Ertapenem,

AST card	Organism group	Antimicrobial Agents
	and <i>Pseudomonas aeruginosa</i>	Meropenem/vaborbactam, Minocycline, Trimethoprim/sulfamethoxazole, Tigecycline, Tobramycin
GP AST card	<i>Enterococcus</i> spp., <i>Staphylococcus</i> spp, and <i>Streptococcus</i> spp.	Ampicillin, Cefoxitin Screen, Clindamycin, Daptomycin, Erythromycin, Gentamicin High Level Screen, Linezolid, Moxifloxacin, Nitrofurantoin, Oxacillin, Streptomycin High Level Screen, Tetracycline, Vancomycin
ST AST card	<i>Streptococcus</i> spp.	Benzylpenicillin, Ceftriaxone, Clindamycin, Erythromycin, Inducible Clindamycin Resistance Screen, Levofloxacin, Linezolid, Tetracycline, Trimethoprim/sulfamethoxazole, Vancomycin
YS AST card	<i>Candida</i> spp.	Caspofungin, Micafungin

The MIC results obtained using the VITEK COMPACT PRO were compared to the MIC results obtained using the VITEK 2. Essential Agreement (EA) was defined as MIC results obtained from the VITEK COMPACT PRO that were within one doubling dilution of the MIC results obtained from the VITEK 2. Category Agreement (CA) was defined as MIC interpretations (S/SDD/I/R) that were the same between the VITEK COMPACT PRO and VITEK 2. Very major errors were defined as false susceptible results from the VITEK COMPACT PRO, major errors were defined as false resistance results from the VITEK COMPACT PRO, and minor errors were defined as results with minor discrepancies (i.e., an intermediate result reported as either resistant or susceptible, or vice versa). Since this is a method-to-method comparison, results were considered acceptable if the EA was $\geq 95\%$.

Overall performance of AST card results was $>95\%$ for GN AST card (n=625 including screening results), GP AST card (n=554 including screening results), ST AST card (n=437 including screening results), and YS AST card (n=89 results), which is acceptable.

For all species and antimicrobial agents in GN AST card, 576/583 (98.8%) of MIC results were within one doubling dilution of the comparator result and 567/576 (97.3%) of SIR categorizations were in agreement. For each microorganism and antimicrobial agent, essential agreement was $>95\%$ except ceftriaxone (91.3% EA). One very major error (false susceptible) occurred with Cefepime. One major error (false resistance) occurred with Meropenem/vaborbactam and Trimethoprim/sulfamethoxazole each. All purity plates (100%) exhibited monomicrobial growth.

For all species and antimicrobial agents in GP AST card, 427/429 (99.5%) of MIC results were within one doubling dilution of the comparator result and 418/429 (97.4%) of SIR categorizations were in agreement. For each microorganism and antimicrobial agent, essential agreement was $>95\%$. Two very major errors (false susceptible) occurred with Daptomycin. Two major errors (false resistance) occurred with Ampicillin. All purity plates (100%) exhibited monomicrobial growth.

For all species and antimicrobial agents in ST AST card, 387/393 (98.5%) of MIC results were within one doubling dilution of the comparator result and 388/393 (98.7%) of SIR

categorizations were in agreement. For each microorganism and antimicrobial agent, essential agreement was >95%. One very major error (false susceptible) occurred with Ceftriaxone, Clindamycin, and Tetracycline. One major error (false resistance) occurred with Tetracycline. All purity plates (100%) exhibited monomicrobial growth.

For all species and antimicrobial agents in YS AST card, 89/89 (100%) of MIC results were within one doubling dilution of the comparator result and 89/89 (100%) of SIR categorizations were in agreement. For each microorganism and antimicrobial agent, essential agreement was >95%. No very major error (false susceptible) and major error (false resistance) occurred. All purity plates (100%) exhibited monomicrobial growth.

Given a large volume of data, **Table 7** summarizes the results stratified by AST card only. The cumulative reporting and stratification by each AST card is presented for simplicity and was based on the analysis for each drug/organism combination which revealed acceptable high degree of agreement between VITEK COMPACT PRO and VITEK 2 instruments.

Table 7. Summary of AST Results, Stratified by AST Card

AST card	Organism group	Total tested	# EA	% EA	Total Eval.	# EA Eval.	% EA Eval.	# CA	% CA	# S	# R	# vmj	# maj	# min
GN AST	Enterobacterales <i>Acinetobacter</i> spp. <i>Pseudomonas aeruginosa</i>	583	576	98.8%	232	225	97.0%	567	97.3%	302	229	1	2	13
GP AST	<i>Staphylococcus</i> spp. <i>Enterococcus</i> spp. <i>Streptococcus</i> spp.	429	427	99.5%	192	190	99.0%	418	97.4%	272	130	2	2	7
ST AST	<i>Streptococcus</i> spp.	393	387	98.5%	244	238	97.5%	388	98.7%	122	260	3	1	1
YS AST	<i>Candida</i> spp.	89	89	100%	72	72	100%	89	100%	81	8	0	0	0

5. Carry-Over:

Not applicable.

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.