



STANDARD OPERATING PROCEDURE

Department: Microbiology

SOP No.:

Title: Identification of Microorganism by using VITEK 2 compact

Effective Date:

Supersedes: Nil

Review Date:

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1.0 Objective

To lay down a procedure for identification of Microorganism by using VITEK 2 compact. Make: bioMerieux in Microbiology laboratory.

2.0 Scope

This Standard Operating Procedure is applicable to Quality Control department.

3.0 Responsibility

Executive / Sr.Executive-QC : Responsible for following the procedure for identification of microorganism by using VITEK 2 compact.

Head-QC / Designee : Responsible for compliance of this SOP.

4.0 Abbreviations and Definitions

SOP : Standard Operating Procedure

No. : Number

QC : Quality control

5.0 Procedure

5.1 Preparation of inoculum:

5.1.1 For the sub culturing and Gram staining refer as per mentioned current version of SOP "Isolation and identification of EM isolates".

5.1.2 Select identification card based on colony morphological characters and its Gram nature, for Gram positive select GP card, for Gram negative select GN card, for Yeast select yeast identification card, for bacillus select BCL card and for Anaerobes select ANC card.

5.1.3 Under laminar Air Flow, take prescribed inoculum fluid tube (polypropylene) and dispense 3 ml of sterile saline with the help of dispenser.

5.1.4 Pickup isolated colonies from subculture tube / petriplates and suspend the colonies in a tube of normal saline.

5.1.5 Vortex tube approximately 10 to 15 seconds. Measure the turbidity of the vortexed



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solution by using densicheck.

5.2 Operation and calibration of densicheck:

- 5.2.1 Operate the Densi check by pressing the power key. Press the Read / Enter key and allows the user to manually initiate a reading. Before making a measurement on densi check (instrument provides a values in McFarland units proportional to microorganisms concentration in any suspension), the densi check instrument shall be calibrated every time before use with the densi check standards (0.5 McF, 2.0 McF & 3.0 McF)
- 5.2.2 To change the tube type (Plastic / Glass) setting in densi check instrument, press the menu key , select appropriate tube type either glass or plastic by pointing the triangle and press Enter.(for inoculum preparation select “plastic” setting and for calibration select “glass” setting)
- 5.2.3 Before using standards to calibrate the densi check instrument ensure that the glass tube setting is displayed
- 5.2.4 Place the test tube containing blank solution (normal saline) and press the ZERO/SCROLL key and the instrument will display a series of dashes followed by 0.00
- 5.2.5 Select the desired standard (0.5 McF,2.0McF&3.0 McF) and clean the outside surface with a lens tissue and gently invert the standard five to six times to ensure it is homogeneous
- 5.2.6 Insert the standard in to the instrument and rotate slowly one full rotation until the numerical value is displayed
- 5.2.7 Check that the displayed McFarland value is within the acceptable range given in the Table-1

Standard	Acceptable Range	
0.5 McF	0.44	0.56
2.0McF	1.85	2.15
3.0McF	2.79	3.21



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5.2.8 Repeat Step 5.2.5 to 5.2.7 for the remaining standards and record the results in Annexure-2.

5.2.9 Make the inoculum from the previously sub cultured well isolated colony to be identified in test tube containing the 3 to 4 ml of sterile normal saline using a sterile inoculation loop. Make inoculum up to 0.5 to 0.63 McFarland for Gram Negative Bacteria & Gram Positive cocci and for yeast, anaerobes and Gram Positive Bacilli 1.8 to 2.2 McFarland and take a reading in the calibrated densi check instrument.

5.3 Operation of VITEK 2 COMPACT:

5.3.1 Put 'ON' the ON/ OFF power switch first on the computer module prior to inoculum fluid preparation work.

5.3.2 Then put 'ON' the ON/ OFF switch of the VITEK instrument.

5.3.3 Log on the specific user 'ID' and 'Password' to enter in to the system.

5.3.4 Then enter in to V2C software with specific user 'ID' and 'Password'.

5.3.5 Click on V2C software icon.

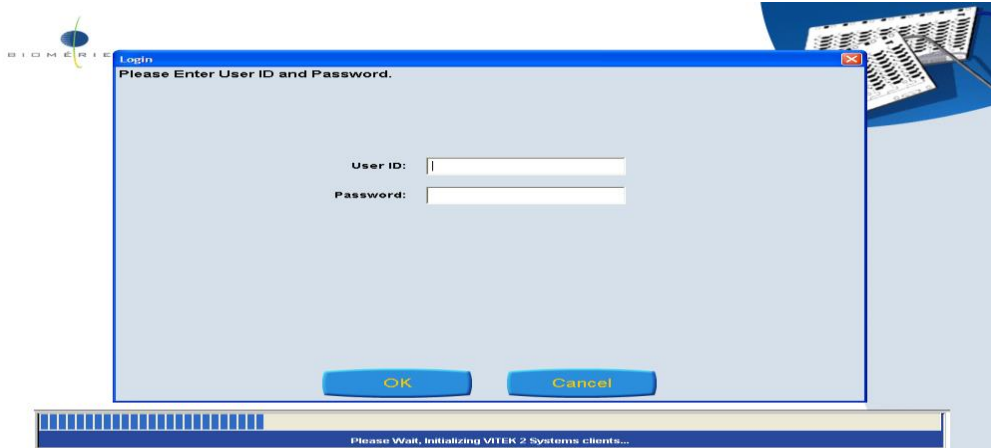


5.3.6 System will show user ID and Password



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5.3.7 To log in by entering user ID and Password system will display main menu.

5.3.8 Take a cassette along with inoculums fluid and card and put it into the VITEK 2 compact machine filler section.



Note: After preparation of inoculum within 10 minutes cassettes should be kept in VITEK loading section.



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5.3.9 Press 'start fill' button with the help of instrument monitor.



5.3.10 After completion of filling the blue light will start blinking near the filler section.



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5.3.11 Open the door of the filler section and put the cassette in 'load and unload' section and close the door.

5.3.12 After completion of bar code reading, instrument will cut the card capillary tube.

5.3.13 Then light will blink near the 'load and unload' section



5.3.14 Unload the cassette and close the door.

5.3.15 Click enter cassette manage view icon in the system software display will show.



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

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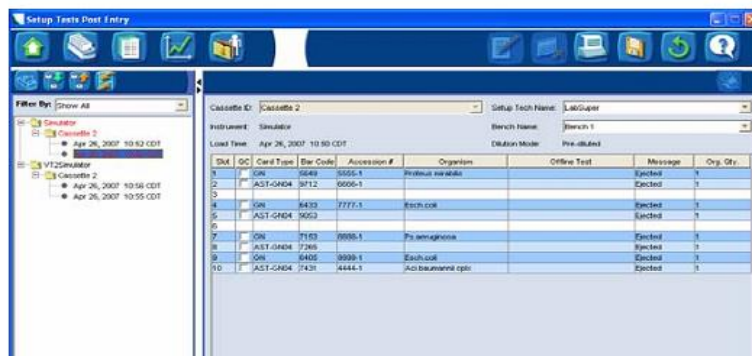
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st Cards and Cassette Information

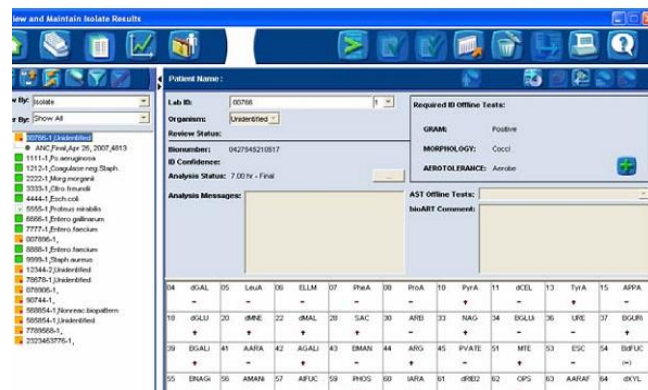
Using the Set Up Tests Post Entry Workflow

Note: While processing cards, when you log in to the system software, the Set Up Tests Post Entry view appears displaying a list of cassettes currently loaded in the selected instrument.



- 5.3.16 Enter accession number and save the information by clicking the 'save' button.
- 5.3.17 The isolates and status of the run can viewed by clicking the 'enter isolate' view.
- 5.3.18 Display will show

PART III: VIEW AND MAINTAIN RESULTS



- 5.3.19 After completion of identification the result will be displayed on the navigation



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tree and work station and card will be ejected in to waste collection bin automatically.

5.3.20 For taking the report print click the 'print' icon.

5.3.21 Storage of backup data:

5.3.22 A blank compact disk always should be inside the CD drive.

5.3.23 Every night by 1:00 am, an automatic backup will be taken.

5.3.24 Once the CD becomes full the system will give a message "Insert a new medium for backup".

5.3.25 After displaying this message, insert a new CD for backup.

5.3.26 The old CD has to be numbered serially starting from MID/CD/01 (MID: Microbial Identification system, CD: Compact Disc, 01: serial number of CD starts from 1 onwards) and store properly with department In charge.

5.3.27 **Supplemental Testing:**

Perform optional supplemental testing in case of Slash line results (i.e. two or more species shows similar biochemical characteristics in the database profile which can be differentiated by using the supplemental tests) as per manufacturer recommendation

5.4 **Cleaning of VITEK 2 Compact**

5.4.1 Clean the carousel, cassettes, optics, waste bin, Filler seal and Filler station.

5.4.2 Cleaning should be done using tissue paper/clean soft cloth with validated disinfectant except for optics. Clean optics with lence paper very carefully without using IPA & allow it to dry before using.

5.4.3 Frequency of cleaning : Once in 15 days and record the cleaning details as per the current version of specimen format given in the Annexure-1.

5.4.4 Record all the details pertaining to the Identification using Vitek 2 Compact as per SOP "Isolation and identification of EM isolates".

5.4.5 **Performance verification:**



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5.4.5.1 Check the performance of microbial identification system by evaluating / analyzing with reference & known ATCC strains of the below mentioned organisms

Staphylococcus aureus (ATCC No: 6538P), *Pseudomonas aeruginosa* (ATCC No: 9027), *Bacillus subtilis* (ATCC No: 6633), *Escherichia coli* (ATCC No: 8739) and *Candida albicans* (ATCC No: 10231)

5.4.5.2 Acceptance criteria: When challenged with above known & reference culture strains, organisms shall be identified up to species levels.

5.4.5.3 Frequency: Once in a year or in case of any major maintenance.

6.0 Forms and Records

- 6.1 Vitek 2 compact usage log : Annexure-1
- 6.2 Densicheck calibration record : Annexure-2

7.0 References

- 7.1 SOP "Isolation and identification of EM isolates".

8.0 Distribution

- 8.1 Master Copy : Documentation Cell (Quality Assurance)
- 8.2 Controlled Copies : Quality Control, Quality Assurance

9.0 History

Date	Revision Number	Reason for Revision
	00	New SOP