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| VITEK MS Operating Procedure | | | | | | | | | | |
| **Purpose** | This procedure provides instruction for utilizing the **VITEK MS.** The VITEK MS is a qualitative *in vitro* diagnostic device that allows for rapid identification of microorganisms from clinical cultures. This system in conjunction with other clinical and laboratory findings aids in the diagnosis of bacterial and yeast infections in patients. | | | | | | | | | |
| **Policy Statements** | * The Procedure applies to staff responsible for the operation and maintenance of VITEK MS instrument. * The VITEK MS Instrument Manual is maintained electronically as the primary reference. * Customer service can be reached at 1-800-682-2666. The customer number for Children’s Hospitals and Clinics Microbiology Laboratory is: 1009474. The serial number is: 51079. * Procedures for Instrument start-up and shutdown are done only with bioMérieux phone technical support, phone customer service listed above. * VITEK 2 is the designated backup if there are any problems with the VITEK MS instrument or when use of the instrument is down for an extended period of time. | | | | | | | | | |
| **Principle** | From the VITEK MS Clinical Workflow User Manual (bioMérieux): The VITEK MS is a mass spectrometer system based on MALDI-TOF (MALDI: Matrix-assisted laser desorption/ionization; TOF: Time-of-Flight) technology. A portion of a colony from an agar plate is applied to a spot on a VITEK MS-DS target slide. A matrix solution is applied to the spot on the VITEK MS-DS target slide. The VITEK MS-DS target slide is dried and then loaded into the VITEK MS. The sample is submitted to multiple laser shots inside the VITEK MS mass spectrometer. The matrix absorbs the laser light and vaporizes, along with the sample, in the process gaining an electrical charge (ionization). Electric fields then guide the ions into the vacuum tube which separates them according to ‘weight’ (mass, the smaller molecules flying faster than the larger ones), and their time of flight, and displays the results as a series of lines or peaks (spectrum) which correspond to different fragments that have broken away from the original molecules in the sample. By analyzing the pattern of fragments it is possible to deduce the structure of the molecules. The sample spectra are compared to a database of spectra developed from a number of organisms. The sample spectra is interpreted to provide organism identification results associated with a confidence level. | | | | | | | | | |
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| **Materials** | **Reagents/ Supplies** | | | | | **Equipment** | | | | |
|  | * VITEK MS-DS target slide, bioM, product/part number (P/N)-410893 * VITEK MS-CHCA matrix (yellow cap),bioM, P/N-411071 * VITEK MS-FA formic acid (red cap),bioM, P/N-411072 * 1 µl calibrated sterile loops, BD, P/N-220215 * Precision pipettors (deliver 1.0 and 0.5 µl), VWR, P/N-89079-960 * Sterile colorless pipette tips without filters, Cardinal Heath, P/N-CHTA104R * Powder-free gloves * Micro tube rack * *E.coli* ATTC 8739 (calibration organism, 18-24 hours old) * *E.cloacae* ATCC 13048 (QC organism) * *C. glabrata* ATCC MYA-2950 (QC organism) * Columbia Agar with 5% Sheep Blood (SB), BBL, P/N-4321263 * Chocolate II Agar (CHOC), BBL, P/N-4321267 * MacConkey II Agar (MAC), BBL, P/N-4321270 * Sabouraud Dextrose Agar, Emmons; (SAB), BBL, P/N-4321849 * CDC anaerobic blood agar, BBL, P/N-4321734 | | | | | * VITEK MS Instrument, bioM, P/N-410895 * VITEK-MS Target Slide, bioM, P/N-410893 * VITEK MS Prep Station (physical and virtual) * VITEK MS Acquisition Station * Smart Carrier Docking Station (SCS), bioM, P/N-27210 | | | | |
| **Storage** | Storage conditions are listed on each product. The CHCA matrix and formic acid (FA) are to be stored at 2-8°C when not in use. Unopened vials are accepted for use up until the manufacturer’s listed expiration date. In-use CHCA matrix vials have an expiration date of one week from the day that it is opened. In-use formic acid (FA) vials are allowed for use for two weeks from the date it is opened. Documentation of the date opened and the new expiration date should be written on all matrix and formic acid vials once they are utilized. All other supplies utilized for the VITEK MS are to be stored at room temperature. | | | | | | | | | |
| Sample | **18-72 hour growth on appropriate media:** | | | | | | | | |
|  | * Columbia blood agar * Chocolate agar * MacConkey agar * Sabouraud Dextrose Agar (Emmons) * Campy CVA agar * CDC Anaerobic blood agar | | | | | | | | |
| **Special Safety Precautions** | * Microbiologists/virologists are subject to occupational risks associated with specimen handling. * All specimens, microbial cultures and inoculated products should be considered infectious and handled appropriately. Aseptic technique and usual precautions for handling the bacterial group studied should be observed throughout this procedure. * The VITEK MS system is not for use directly with clinical specimens or with mixed cultures. * Do not re-use VITEK MS-DS target slides that have been fully used (3 acquisition groups). * Before use, check that the packaging and components are intact. * Any organisms that are potentially highly infectious should be setup in the BSL-2 hood. * Refer to the safety policies located in the safety section of the *Microbiology Procedure Manual*and the *Virology Procedure Manual***:** * [*Biohazard Containment*](http://khan.childrensmn.org/Manuals/Lab/SOP/MCVI/Safety/209727.pdf) * [*Safety in the Microbiology/Virology Laboratory*](http://khan.childrensmn.org/Manuals/Lab/SOP/MCVI/Safety/209731.pdf) * [*Biohazardous Spills*](http://khan.childrensmn.org/Manuals/Lab/SOP/MCVI/Safety/209733.pdf) | | | | | | | | | |
| **Preventative Maintenance** | For all Preventative Maintenance measures, refer to the VITEK MS Preventative Maintenance Procedure.   |  |  | | --- | --- | | **Daily Maintenance** | **Weekly Maintenance** | | * Record Room Temperature (18-26˚C) by checking Isensix (‘Micro room temp’) * Check printer paper supply * Subculture *E.coli* ATTC 8739 organism * See Desk 3 subculture schedule * Refer to protocol “LyfoCults Plus *E.coli* ATTC 8739” for monthly subculturing (found on Desk 3). | * Check desiccant   + If desiccant is not a deep rich orange color but rather displays a pale or yellow look, change desiccant using a fresh batch. See VITEK MS Preventative Maintenance Procedure for further instruction. |   Preventative Maintenance is to be documented on the VITEK MS Instrument Preventive Maintenance/Quality Control form. | | | | | | | | | |
| **Quality Control** | 1. The calibration organism is run on the center spot of each acquisition group that is utilized.    * *E.coli* ATTC 8739   **\*Calibration Failure**: If the calibration fails, an error is reported.   * + Verify that the calibration organism and matrix have been deposited.   + Repeat the acquisition group by clicking on all spots that have been setup.   + If calibration fails again, set up the isolates onto a new acquisition group and repeat. Consider using a new vial of VITEK MS-CHCA matrix.   + If calibration fails again (using a new vial of VITEK MS-CHCA matrix), contact bioMérieux Customer Support.  1. Quality Control (QC) is to be run once during day shift hours for each day that VITEK MS is in use.    * Bacterial QC: *E.cloacae* ATCC 13048    * Yeast QC: *C. glabrata* ATCC MYA-2950    * Negative QC: Matrix only with no organism      1. QC is performed after each laser “fine tuning”, or any Preventative Maintenance (PM), repair or replacement of critical components, major maintenance/service before patient results can be accepted.     Documentation of QC results is to be logged on the VITEK MS Instrument Preventative Maintenance Checklist/Quality Control form. Additionally, print all 3 QC results, staple together and initial the front page before storing them in the VITEK MS Maintenance/QC binder.  **\*QC Failure**: If the bacterial and/or yeast QC spots fail, do not accept patient results until QC is repeated and passes.   * Repeat the acquisition group by clicking on all spots that have been setup. * If QC passes after re-shooting, accept the run. * If QC does NOT pass after re-shooting 1-2 more times, do not accept patient results. Repeat setup of patient isolates and QC on a new acquisition group. * If the negative control provides identification, visually check the surface of the VITEK MS-DS target slide to ensure it is clean and repeat testing on a new acquisition group. | | | | | | | | | |
| **Target**  **Slide**  **Set-Up Procedure** | 1. Assemble required materials:    * VITEK MS-DS target slide    * VITEK MS-CHCA matrix (yellow cap)    * VITEK MS-FA formic acid (red cap)    * 1 µl sterile loops    * Precision pipettor (1 µl and 0.5 µl)    * Sterile clear tips without filters    * Micro tube rack    * Powder-free gloves    * *E.coli* ATCC 8739 (for calibration)    * Quality control organisms (if necessary): *E.cloacae* ATCC 13048 & *C. glabrata* ATCC MYA-2950    * Patient test isolates from validated medium    * VITEK MS Target Slide Worksheet 2. Wearing powder-free gloves, obtain VITEK MS-DS target slide onto flat counter top. Avoid touching spots on the slide. Handle the slide by the end of the slide (**Figure 1**). 3. Document tech ID, target slide barcode and the date on the top of the VITEK MS Target Slide Worksheet. While setting up a slide, document patient accession and isolate numbers in the appropriate spots being tested. 4. Using a 1 µl loop, obtain a suitable colony of *E.coli* ATCC 8739 and apply it to the middle calibration spot of the acquisition group being utilized. Flip the loop to ensure even spreading of a thin layer of organism on the spot.   Target Slide Barcode  (end of slide)  Calibration Spot  (3 per slide)  Sample Spot (48 per slide)  Acquisition Group  (3 per slide)  Figure 1.   1. Open the VITEK MS-CHCA matrix and place in the micro tube rack.   **\*DO NOT vortex or mix the matrix.**   1. Using a pipettor, add 1 µl of VITEK MS-CHCA matrix onto the calibration spot. Recap the vial to ensure the matrix does not evaporate/precipitate. 2. Begin testing patient test isolates. Apply each patient to the target slide. Using a loop, apply a suitable bacterial or yeast colony (approximately 3mm) to individual sample spots (**Figure 2**). If a colony has a mucoid appearance, use a sterile swab to take off the top layer, and then utilize a loop.   Heavy Light Good Good  Figure 2.   1. Flip the loop to ensure a thin layer is spread on the spot (**Figure 3**).    * **For Yeast isolates only:**      1. Open the VITEK MS-FA vial and place in the micro tube rack.      2. Apply 0.5 µl of VITEK MS-FA formic acid to the spot.      3. Allow to dry for approximately 3-5 minutes.      4. Proceed to step 8. 2. Using a pipettor, add 1 µl of VITEK MS-CHCA matrix to each spot. Make no more than two spotsbefore adding matrix (to ensure bacterial spots do not dry out). Recap the matrix vial each time. 3. Repeat steps 6-8 for each additional patient isolate. 4. Allow all organism sample spots to dry completely (approximately 3-5 minutes). 5. Confirm crystal formation on all spots with the presence of a yellow film (**Figure 3**).   Figure 3.   1. Place VITEK MS-CHCA matrix and formic acid into the refrigerator after setup is complete. | | | | | | | | | |
| **Prep Station**  **Procedure** | 1. Double-click the VITEK MS Prep Station icon using the physical or a virtual workstation. 2. Log in to the Prep Station software using a technologist specific user name created in MYLA and click the green check button. 3. Scan (or type) the VITEK MS-DS target slide barcode (**Figure 4**).   Figure 4.   1. Scan or type the patient’s Sunquest accession number into Lab ID and enter the isolate number. 2. Confirm that the correct option is chosen for each organism by selecting either Bacteria or Fungi (**Figure 5**).   Figure 5.   1. Click Validate (or press F4 or Enter twice). 2. Repeat steps 4-6 until all organisms to be tested are validated onto the target slide. 3. To verify that the data are correct, click each spot to confirm the accession and isolate numbers.  |  |  | | --- | --- | | **Additional Action Buttons** | | | New Slide (F5) | Creates a new slide | | Erase Spot (F6) | Erases one spot at a time | | Add Spot | Add an additional spot for an isolate |  1. Once all spots have been checked, click Send Slide (F8).   **\*No changes can be made to the slide after the slide is sent!**   1. Perform the acquisition within 48 hours of sample prep. The slide should be kept at room temperature during this period. | | | | | | | | | |
| **Acquisition Station Procedure** | 1. Double-click the VITEK MS Acquisition icon. 2. Log in to the Acquisition software using the general laboratory user name (Vitekms) and password (Vitekms1) and click the green check button. The acquisition screen will display. 3. Wearing powder free gloves, confirm that all target slides are completely dry.   **\*DO NOT put wet samples into the VITEK MS; moisture within the vacuum system may damage the instrument.**   1. Click the **Open** button on the Acquisition screen (**Figure 6**).   Figure 6.     1. After approximately 1-2 minutes the instrument vents to a pressure of about +3 mbar and the door will open. 2. Remove the adapter from the VITEK MS and remove any previously used slides. 3. Begin to load the target slide(s) to be tested in the adapter starting with numbered position 1 (**Figure 7**).    1. The top of the adapter has angled corners.    2. Barcodes are positioned on the left side of the adapter.   Angled corner  1  2  3  4  Positions  Barcodes on left  Figure 7.   1. In the Acquisition Station, Scan/Enter the barcodes on the target slides starting with position 1.    1. Verify that all barcodes are entered into the software correctly. 2. Load the slides into the VITEK MS carrier within 5 minutes of the door opening. The door will automatically close after 5 minutes.    1. Place adapter into carrier face up with the angled corners to the front (**Figure 8**).    2. Slide the adapter into the carrier until it will go no further.    3. The back edge of the adapter should be flush with the carrier.   Angled Corners  Figure 8.   1. Click the **Start** button. 2. The run will begin shortly. A calibration check will start each acquisition group being utilized. An internal check will end the testing portion of each acquisition group. If both checks pass, all results will transfer into MYLA. Refer to the Quality Control section if this procedure if a failure as occurred. 3. Refer to the VITEK MS/MYLA Reporting Procedure & Scheme for instruction on resulting. | | | | | | | | | |
| **Alternate Method** | In the case of instrument failure, use backup identification as required: VITEK 2, Microscan NC32 & PC20, or API. | | | | | | | | | |
| **References** | VITEK MS Clinical Workflow User Manual, 2013.  VITEK MS Customer Training Course manual, 2016.  VITEK MS “The Basics” manual, 2014.   1. Employee must read the procedure and training documentation. 2. Employee will observe trainer performing the procedure. 3. Employee will demonstrate the ability to perform procedure, record results and document corrective action after instruction by the trainer. | | | | | | | | | |
| **Training Plan/ Competency Assessment** |
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| **Authorization** |  | | | **Signature** | | | | | **Date** | |
| **Technical Director** | | | Dr. Phillip Heaton | | | | | 10/07/16 | |
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|  | | | **Issue date for training** | | | | | 10/10/16 | |
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| **Historical**  **Record** | **Version** | **Written/Revised by:** | | | **Effective Date:** | | **Summary of Revisions** | | | |
| 1 | Andrew Fangel/  Dr. Phillip Heaton | | | 10/07/16 | | Initial Version | | | |
| 2 | Susan DeMeyere | | | 10/17/17 | | Remove running patient samples in duplicate. | | | |
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