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| Prepared by QA Committee | | |
| Issued by: Laboratory Manager | Revision Date:1/16/2024 | |
| Approved by Laboratory Director: | Next Review Date:1/16/2026 | |
| Microbiologist-in-Chief | | |

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Procedure of MALDI

VITEK MS Slide spot preparation

Safety Precautions

Wear protective gloves/protective clothing/eye protection/face protection

Before beginning to apply spots on a Vitek slide ensure slide is clean and reagents (matrix and formic acid) are at room temperature.

- 1. Label the <u>Vitek MS Worksheet</u> or <u>Vitek MS Worksheet with Controls</u> with the date and slide number
- 2. Apply a fresh isolate (24 hrs) of E. coli ATCC 8739 control in the central circle of the slide using 1ul of green loop for each acquisition group used.
- 3. Add 1ul of Matrix. Do not invert the matrix vial. Do not touch the crystals on the bottom of the vial with pipette tip
- 4. Ensure plates to be tested match the accompanying LIS label
- 5. Place one specimen barcode label on the work sheet
- 6. Apply a thin even layer of organism in each circle of the slide by using 1ul of green loop or wooden toothpick
- 7. Add 1ul of Matrix. Do not invert the matrix vial. Do not touch the crystals on the bottom of the vial with pipette tip
- 8. For Yeast, add 0.5ul of formic acid first, wait until it crystallizes, then add 1ul matrix,

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VITEK MS Prep Station

- Double click the MYLA icon or also accessible via the Internet Address (192.168.168.241) in an Internet Browser window.
- 2. Enter User name
- 3. Enter Password

Note: Check Application Login Information in Microbiology Internal Manual or bench for

posting of user name and current password

| ⊖ Dashboard × + | | | | - • × |
|---|-----------|-------------|------------------------|---|
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| Getting Started | | | | |
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| To Do 20 VIEKKIS SW VIEKKIS Z Roview 13 30 VITEKIS Z Roview 1221 VIEKKIS Z Roview 1221 VIEKKIS Z Roview 1221 | UTY | | | Fix Patient Inconsistencies 97 98 16 |

- Click Vitek Flexprep icon (if needed click Layout button on right to toggle between Vitek XL and Vitek MS.)
- 5. Scan your Slide into the Slide ID field and select OK.

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| Flex Prep RCE X + | | - 6 X |
|---|-----------|---------|
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| 🖉 VITEK 2 Systems Web 😔 Dashboard Virtu D 🔮 VITEK 🖲 MS SOFTWARE 💼 Dashboard VMS 📑 Flex Prep RCE | | |
| Sample Preparation | | ^ |
| Lab ID: Isolate: | Layout | |
| VITEK® MS | | |
| • Slide ID: DS220314768 | | |
| Preparation mode: IVD | | |
| Cancel VK | | |
| | Validate | |
| | Cancel | |

6. Select your Bench ID from the dropdown next to "isolate".

| | Sample Preparation | 🥹 c | onfiguration | | | | | | |
|---------------------------------------|--------------------|------|--------------|----------------|---------------------------|---------|----------|---------------------|---|
| * Lab ID: John | | | * Isolate: 1 | * Bench: Bench | 1 A | | | | 1 |
| | | 1 | | | Slide summary | r | | | |
| | | Spot | Accession ID | Operator | Microorganism | Bench | QC | Comment | - |
| 1 2 3 4 Microorganism Type: | P1 | A1 | John-1 | | fungi | Bench A | | | |
| O O O Dacteria | Add spot | A2 | | | | | | | |
| tungi | | A3 | | | | | | | |
| | Erase end | A4 | | | | | | | |
| | Erase spor | B1 | | | | | | | |
| | F2 | B2 | | | | | | | |
| | Skip spot | B3 | | | | | | | |
| | | B4 | | | | | | | |
| | Reagents/Comment | C1 | | | | | | | _ |
| | | C2 | | | | | | | |
| | - IV | C3 | | | | | | | |
| | Erase slide | C4 | | | | | | | |
| | F3 | D1 | | | | | | | _ |
|) : D \$987654321 | Close slide | D2 | | | | | | | |
| OT : 1003806630 XPIRY : 10/12/2019 | | D3 | | | | | | | _ |
| | | D4 | | | | | | | |
| | | E1 | | | | | | | - |
| | | | | | | | | | |
| fse 📋 ? | | | | | | VITEK | FLEXPREP | Release version 1.1 | |

7. Scan the specimen barcode on your worksheet in the Lab id# field

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- Ensure isolate number is correct automatically increases each time barcode is entered on slide
- Bacteria is the default option
- For yeast spots, choose Fungi option

Note: You may optionally duplicate the information for the next spot on the slide if you have made 2 spots for the same organism (ie. The same organism you are trying to ID with the same specimen **and** isolate number.) Select F1 or click "Add spot" to do this.

8. Select F12 or click validate on right side of screen.

Note: You may skip a spot if desired, select F2 or click "Skip spot" then "OK". The acquisition will continue to the next spot on the slide. If you need to edit information you must select the spot and click erase spot. You may reenter the information for that spot, then select F12.

9. Click Close slide or select F3 to send slide.

Note: ***You can rescan the slide if you want to change or add anything to it as long as you

haven't loaded it yet.***

10. Ensure no slides pending review in the instrument before loading (check clipboard).

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| Sample Preparation | Contiguration | | |
|--|---|---|---------------------------|
| Lab ID: | | D PC- vdk2see | Layout |
| A dd spot Setup operator: Commant Co | F1 VITEK© 2 PC: Cassette ID: Instruments Simulator Available Stots: 0 | VTK22460 VALID Available Slots: 60 Serial No. 4271 Available Slots: 60 | P12 Validate Cancel |
| fse E3 ? | | VITEK FLEXPREP Release version 1.1 | 14:39 |

| Button | Function |
|------------------------|--|
| F1 Add spot | Adding a Spot |
| *Erase spot | Erasing a Spot |
| F2 Skip spot | Skipping a Spot |
| *Reagents / Comment | Editing Reagent/Slide Information (if Reagent/Slide Traceability is enabled) |
| | Adding or Editing Spot Comments |
| Erase Slide | Erasing a Slide |
| F3 | Closing a Slide |

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VITEK MS Acquisition Station

- 1. Put on a new pair of gloves
- 2. DOUBLE CLICK Vitek MS Acquisition window
- 3. Enter User name/password

Note: Check Application Login Information in Microbiology Internal Manual or bench for posting of user name and current password

- 4. Click Validation Check Mark or press Enter
- 5. Click Open button on the upper right side of the computer screen
- 6. Pull out slide adaptor once the Vitek MS door is open
- 7. Remove the old slide from the adaptor
 - If slide removed has unused acquisition group(s) place on partial sorting shelf
 - If all acquisitions on slide removed have been used (all spots finished) discard slide
- 8. Put the new slides to be tested slide in the position 1,2,3,4
- 9. Scan the slide id#
- 10. Load the slide into Vitek MS machine (barcode to the left side) with one hand push down the metal bar and the other hand slide in the dented side into the machine
- 11. Press Start button to start the acquisition (if unable to select Start option, you may not have sent your slide information from the prep station, you can send it now)
- 12. Place MS worksheet on clipboard labeled as "Pending Review"

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MYLA (Result Review)

- 1. Click Dashboard-Window Internet Explorer (MYLA) window
- 2. Enter User Name
- 3. Enter Password

Note: Check Application Login Information in Microbiology Internal Manual or bench for posting of user name and current password

- 4. Click Login button or press Enter
- 5. Click Vitek MS Software icon

| Obshboard × + | | | | | - 63 × |
|--|------------------|------------|------------------------|--------------------------------|---------------------------------|
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| Getting Started | | | | | |
| ② | Dashboard | | | n n | २ @ x |
| | | | Technologist Dashboard | Manager Dashboard | Statistical Reporting Dashboard |
| Load / Unioad 🗃 | | | | | |
| | VITEKS FLEXPREP* | VitekM6_SW | 4 | | |
| To Do X ViteKMS_SW 3 33 VITEKØ 2 Review Calon Result Calon Calon Calo | IV | | | Fix Patient Inconsistencies | Fix Unknown Codes |

- 6. Dashboard window will appear
- 7. Click on Results and the dropdown menu will give us a selection. Choose "To Review" to review the acquisition
- 8. VITEK Results to Review will appear

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| 🛛 Dashboard Virtu O 🛛 🔽 VITEK 2 System | ns 💟 VITEK® MS SOFTWARE 📕 Dashbo | ard VitekMS | | | |
| Presults | Slides Reports | Res | ults to Review | | Speciman Search |
| Valdate high c Reviewed | Validate 🐼 Reject 🗙 | Print 🚓 Refresh 🥌 | | | ▼ Search Criteria 9/9 |
| Accession ID | Slide ID 👽 | Organism Name | Confidence Level | Confidence Value | Instrument • |
| 3-1 | DS220314641 (A4) | | • | | VMSPRIME_ES00031 |
| 1 | DS220314641 (C3) | | A | | VMSPRIME_ES00031 |
| 62-1 | DS220314641 (D1) | | × | | VMSPRIME_ES00031 |
| 29-1 | DS220314641 (C4) | | A | | VMSPRIME_ES00031 |
| | BS220314641 (A1) | Staphylococcus epidermidis | | | 99.9 VMSPRIME_ES60031 |
| | BS220314641 (A3) | | • | | VMSPRIME_ES00031 |
| 0-1 | DS220314643 (A1) | | A | | VITEKMSACQ01 |
| -1 ****** | 💫 DS220314643 (A3) | | | | VITEKMSACQ01 |

- 9. Filter by Setup Bench by selecting the funnel next to Bench.
- 10. Results can also be filtered by Slide ID, Instrument and Review date. Click on the filter icon to add further details for filtering
- 11. Review results according to confidence level
- 12. In Confidence Level field, click the filter icon and select Red dot (low) as 1st step
- 13. Circle the lab# for further re-fire
- 14. Click the checkmarks next to the specimen you wish to reject and click "Reject x" in the action bar above the results window.
- 15. Select yellow triangle (medium) as 2nd step
- 16. View the result by clicking the **Accession ID#.** Print screen showing the possible organisms. Refer to the MS manual for commonly occurring low discrimination results. Where possible, choose the designated organism. Choose one id only by clicking the round circle on the first left row. Click the appropriate box. Return to MS review. Do this for each organism with a yellow triangle. For those with vastly different organism ID options and/ or implausible ID's, return to MS review and send to trash. For the ones sent to trash, circle the lab# for further re-fire
- 17. Meanwhile Select All as 3rd step

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- 18. Check the confidence % for all the isolates with green squares. Any that are <98% should be re-fired. Circle the lab# for refire
- 19. Print all the results by using printer icon
- 20. If \geq 98%, continue to next step.
- 21. Select all isolates \geq 98% or which have been completely reviewed. Click the green check mark (Review Selected Results icon) to complete the review.
- 22. Refiring: Take MS worksheet to the Acquisition station computer. Log on. Using the mouse, select all of the circles which have been circled and click Start.
- 23. After re-firing review the results as above. Those that are still red circles, examine the graph to access the quality of the peaks. If the peaks are good, choose other ID method. If the peaks are not good, an ID may not be acquired due to be a poor prep. It may be worthwhile doing another preparation.
- 24. For those that are yellow triangles, follow through as above
- 25. Click the Vitek MS Review to go back previous page
- 26. All the results should be reviewed and cleared from the review list
- 27. Put the Matrix and formic acid into the fridge at the end of the day. Close the system
- 28. Note: You can return to the dashboard at any time by clicking on the 'house-shaped" icon
- 29. If looking for a result by specimen, click on the binoculars in MYLA, then choose tab "Specimen" and enter LIS number (can scan barcode) and click on Search. Drag the blue slide down to view.



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Tips:

- Mucoid colonies: use sterile swab to take off the mucoid layer and then use the loop to pick the colonies.
- Extract all the Yeast with formic acid.
- Make confluent monolayer on the spot
- Try using loop first, if difficult to pick the colonies, and then use stick.

If results are not transferring, it may be due to demographic inconsistency, see Appendix A for troubleshooting.

Updating an Isolate Number

If you used the wrong isolate number when entering your slide information you can change it **before** validating the isolate.

IMPORTANT: If you update an isolate number in the VITEK® MS Software, make sure you also update it in VITEK® 2 to ensure consistency between the two systems.

- 1. In the Specimen Search screen, or from the "To Review" screen, select an Accession ID for which you want to update the isolate number
- 2. Click Update Isolate Number. The Update Isolate Number window is displayed. Note: The Previous isolate number is displayed for information.

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3. Enter the New isolate number.

IMPORTANT: You cannot choose an isolate number for which a result has already been sent to the bioMérieux middleware.

| Update isolate number | 0 |
|--|---|
| (i) Please check consistency with the other systems. | |
| Previous isolate number: 1 | |
| New isolate number: | |
| | |
| Update Cancel | |

4. Click Update. The isolate number is updated. The icon is displayed along with a tooltip indicating the initial isolate number and the new one.

If the updated isolate number was a duplicate, the icon is removed.

Any existing interpretation remains unchanged and is still linked to the same colony. New interpretation results received for the updated isolate are linked to new isolate number (same colony).

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MALDI Organism Identification Acceptance

Bacteria/Yeast

- 1. Common isolates with ≥98% report as id by MYLA assuming that the colonial morphology or gram appearance matches the identification
- Uncommon isolates with MYLA confidence level of ≥98% report as presumptive with additional in-house testing and confirmation by PHL as necessary assuming that the colonial morphology or gram appearance matches the identification. See file "Vitek MS Uncommon bacteria to confirm at PHOL" located in the T:drive T:\microbiology\Vitek MS\
- 3. For identifications that appear as "low discrimination" by MYLA that has a list of a few isolates of the same genera, report as the complex or species based on the full list of Vitek MS organism identifications, Myla organism names and our LIS translated names: <u>VITEK-MS-V2-speciesList Created-Translated list</u>
- 4. For isolates identified as 50/50 *Klebsiella pneumoniae/variicola*, release identification as *Klebsiella variicola*.
- 5. Always report the following as presumptive with additional testing for confirmation by PHOL assuming that the colonial morphology or gram appearance matches the identification
 - Cardiobacterium hominis
 - Helicobacter pylori
 - Peptoniphilus asaccharolyticus
 - Mycoplasma species (Mycoplasma bovis, Mycoplasma hominis, Mycoplasma hyorthinis)
 - Yersinia pestis
 - Bacillus anthracis
- 6. Never to accept the following organism identifications from MYLA report Gram stain morphology only
 - Prevotella oris
 - Raoultella ornithinolytica
 - Listeria innocua
 - Listeria grayii

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- 7. For any GAS, GCS, GGS identified by MALDI, confirmation by Agglutination is needed before reporting.
- 8. For NLF *E coli* identified by MALDI, confirmation by] is needed before reporting.
 - If <u>Wellcolex Shigella Latex</u> is negative, report *E.coli*
 - If Wellcolex Shigella Latexis positive test with Remel *Shigella* serology and follow reporting algorithm in the table below:

| Wellcolex | Remel | Further Workup |
|-----------|-------|--|
| POS | POS | Release <i>Shigella species</i> with isolate comment \shcn "presumptive isolated. NOTE: Occasionally, some E. coli may identify as presumptive Shigella species using our current in-lab methodology; confirmation by Public Health Lab reference methodology to follow." Send to PHOL to confirm |
| POS | Neg | Repeat serology to confirm Repeatable, set up Vitek GNI Shigella spp ID: Release Shigella species with isolate comment \shcn |

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9. Any enteric pathogens identified by Vitek-MS require additional testing

| MS Organism Identification | Additional Testing |
|--|--|
| Salmonella species* | Perform serotying from BA subculture |
| Salmonella species not S. typhi, not S.paratyphi* | (same day if possible) |
| Salmonella paratyphi A* | |
| Salmonella typhi* | |
| | |
| NLF <i>E.coli</i> \rightarrow possible <i>Shigella species</i> * | If Wellcolex Shigella Latex positive, |
| | test with <u>Remel Shigella serology</u> . |
| | If positive for both serology tests report |
| | presumptive ID, then set up Vitek GNI |
| | (same day if possible) |
| NSF <i>E.coli</i> \rightarrow possible O157* | Subculture to BA for: |
| | Oxoid E.coli O157 Latex |
| | (same day if possible) |
| Campylobacter C. jejuni or C.coli | Gram stain if atypical colony. |
| | |
| <i>Yersinia</i> ^{1,2} (any species) | N/A |
| | |
| <i>Vibrio</i> ^{1,2} (any species) | Gram stain |
| | Subculture to BA for Oxidase(+) |
| <i>Plesiomonas</i> ^{1,2} or <i>Aeromonas</i> ^{1,2} (any species) | N/A |
| | |

¹Send presumptive identification result when additional testing is completed and send all enteric pathogens to PHL to confirm identification except *C. jejuni* or *C.coli*

²If identified by routine specimen processing, proceed to report isolate despite the fact no request for isolation was received.

10. Any *Streptococcus pneumoniae* identified by MALDI >98% require confirmation.

- 99.9% *S.pneumoniae* by MS that are bile soluble or optochin sensitive (only one manual confirmation test required) are confirmed and do not require further work.
- 98-99.8% *S.pneumoniae* ID by MS that are bile insoluble and optochin resistant are sent out as presumptive *S. viridans* and send to NML for confirmation.

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• Call microbiologist for isolates needing to go to NML for rpoB sequencing (contact Irene Martin at NML - Irene.martin@phac-aspc.gc.ca)

| II MALDI 77.570 | II MALDI 77.770 S.pheumoniae | | | | |
|-----------------|------------------------------|--------------------------|--------------|--|--|
| Bile solubility | Optochin | Reporting | Send to PHOL | | |
| Soluble | Sensitive | S.pneumoniae | No | | |
| Soluble | Resistant | presumptive S.pneumoniae | Yes | | |
| Insoluble | Sensitive | presumptive S.pneumoniae | Yes | | |
| Insoluble | Resistant | presumptive S.pneumoniae | Yes | | |

If MALDI 99.9% S.pneumoniae

If MALDI 98-99.8% S.pneumoniae

| Bile solubility | Optochin | Reporting | Send to PHOL |
|-----------------|-----------|-----------------------------|--------------|
| Soluble | Sensitive | presumptive S.pneumoniae | Yes |
| Soluble | Resistant | presumptive S.pneumoniae | Yes |
| Insoluble | Sensitive | presumptive S.pneumoniae | Yes |
| Insoluble | Resistant | presumptive Viridans strep. | Yes |

References: Q3232098 & Q3063546

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- 11. The following Neisseria species specimens must be confirmed by [NEISSERIA & HAEMOPHILUS (API NH)] before reporting.
 - Neisseria species Sterile sites •
 - N. gonorrhoeae ALL sites •
 - *N. meningitides* ALL sites •

If a matching ID is not obtained by API (discrepant result), report isolate as follows:

| MS ID | API ID | Site | Reporting if discrepant result | Verify in |
|-----------------|-----------------|---------------|----------------------------------|-----------|
| | | | | LIS? |
| Neisseria | N moningiti dia | Sterile sites | Neisseria, NOS further report to | YES |
| species | n.meningiliais | | follow | |
| Neisseria | N govorrhogge | Sterile sites | Neisseria, NOS further report to | YES |
| species | N.gonornoeue | | follow | |
| N. gonorrhoeae | Non- | Sterile sites | Neisseria, NOS further report to | YES |
| | N.gonorrhoeae | | follow | |
| | Non- | Non-Sterile | Neisseria gonorrhoeae (do not | NO |
| | N.gonorrhoeae | sites | release) | |
| N. meningitidis | Non- | All sites | Neisseria, NOS further report to | YES |
| | N.meningitidis | | follow | |

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Successful Vitek MS identification Tips

The following tips will help achieve successful identification for spots made and create and efficient workflow.

- 1. <u>Less is more</u>: ensure a **uniformly thin** layer is applied for successfully readings.
- 2. <u>Cover entire spot</u>: having the laser read protein rather than a blank area will shorten the time required reading each spot.
- 3. <u>BA is preferable</u>: use a colony from blood agar where possible to spot rather than pigmented colonies (e.g. MAC)
- 4. <u>Avoid agar:</u> Avoid picking up agar when sampling growth for identification as this can lead to misidentification.
- 5. <u>Avoid specimen:</u> Avoid picking up the inoculated specimen when sampling growth for identification as this can lead to misidentification.
- 6. <u>Use film growth for BC</u>: an early film growth may be used for sterile sites such a blood but be careful to avoid picking up blood by sampling the film away from the primary inoculum
- 7. <u>Do NOT refire red spots</u>: for any red spots, do not re-fire. Alternatively, re-spot and consider using formic acid.
- 8. <u>Consider FA for mucoid colonies</u>: For mucoid colonies not achieving a successful ID, consider using formic acid.

Vitek MS Etiquette

Setting up runs:

- Remember to record the slide # on the MALDI worksheet
- Match the isolate # with the number on the MALDI worksheet
 - Do not use the same isolate number twice once it has already been **transferred**
- Perform smaller batches and more frequent loads
- Use different prep stations when batching slides
- Leave a MALDI worksheet by the Vitek MS if slide is in progress

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Analyzing runs:

- Review your MALDI results soon after it's completed its run
 - Do not leave for extended periods of time without reviewing in MYLA
 - If you will be gone for an extended period, find a technologist willing to review for you
- Remember to remove your MALDI worksheet when finished with Vitek MS
- Trash all unwanted IDs after each run
- Trash finished worksheets when complete
- Place finished worksheets in the save basket when complete
- Place worksheet for "partially" used MS slides in the "Partial" basket near the machine that was used

Finished runs:

- Notify the following bench when your run is complete (re-fires completed)
- Ensure the colonial morphology is described for the isolate put into the Vitek MS
 o T:test → J: Morph → pick
- For transferred isolates that are not being reported, switch to as corresponding letter (1=A, 2=B..) and **verify isolate.**
- Ensure the MALDI ID correspond/match the morphology/gram stain of the sample

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Vitek MS Quality Control

Each Vitek MS requires a positive and negative control QC performed upon receipt and new lot as well as once daily for each microorganism type. One bacterial and one yeast isolate will be used for positive quality control. A spot with matrix alone will be used for the negative control.

The following quality control strains are to be used on each day of testing with the expected results below. Results will be documented in MicQC.

| VITEK MS DAILY QUALITY CONTROL | | | |
|--------------------------------|-------------------------------------|--|--|
| QC ORGANISMS | EXPECTED RESULTS | | |
| Enterobacter aerogenes 13048 | Enterobacter aerogenes ² | | |
| Candida glabrata MYA-2950 | Candida glabrata ² | | |
| No organisms (matrix only) | No ID ¹ | | |

¹If the negative control gives an identification result, visually check the surface of the MS slide to ensure it is clean and repeat negative control

² Repeated low confidence identification following proper procedures and technique may indicate calibration may be required.

If unexpected results are achieved follow <u>Out of Range Results procedure</u> in the Quality Control Manual.

Vitek MS Maintenance

Routine maintenance is required as scheduled below. All results are documented in the LIS.

Weekly Maintenance

Desiccant Check

Check colour of desiccant is orange. If desiccant is changing colour to pink, change the desiccant.

Area Cleaning

Clean dusk from Vitek MS area including acquisition station and monitor.

Vitek MS Verification and Fine-tuning

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When verification/fine-tuning is being performed ensure to place signs on BOTH Vitek MS Machines.

For machine undergoing Verification/Fine-tuned post with sign:

MONITORING OF THIS INSTRUMENT WILL BE PERFORMED FIRST THING THIS MORNING PLEASE LOAD SLIDES IN MACHINE #1 / #2, UNTIL FURTHER NOTICE

For the machine not undergoing Verification/ Fine-tuning post with sign:

THE OTHER MALDI MACHINE IS BEING MONITORED THIS MORNING. PLEASE ENSURE: BLOOD CULTURES & INFECTION CONTROL HAVE FIRST PRIORITY FOR LOADING

Document verification and fine tuning in SoftMic weekly.

Verification:

The calibration status of all instruments are continuously monitored by technical support. A technical support representative will contact the laboratory when an instrument is drifting and verification is required.

To perform verification:

- 1) Prepare **two** complete acquisition groups (32 spots plus the control spots) of a new Vitek MS slide from a fresh *E. coli* ATCC 8739 plate.
- 2) Scan the slide and enter "Ecoli8739" into each of the 32 positions on the slide at the Prep Station
- Load the slide into position 1 (first slot left hand side) in the VITEK MS instrument to be verified (i.e. Instrument 1 or 2). The slide should be placed in the instrument for 8:00am-8:15am maximum in order to respect the arranged schedule
- 4) Start the run, complete the form for the Vitek MS in question located in T:\microbiology\Vitek MS and email to bioMérieux to assess the spots remotely
- 5) If the quality of the spots indicates that a fine tuning is required (determined by bioMérieux technical support), the technical support person will proceed to fine tune the instrument using the same slide

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- 6) If the original spots are not of sufficient quality to allow tuning, bioMérieux will be a request the preparation of two further acquisition groups (i.e. 32 spots plus controls)
- 7) If the verification values are good (as deemed by technical support personnel), technical support will notify us that there is no need to fine tune the instrument.
- 8) To prevent unnecessary spot failures due to instrument drift, monitoring could be scheduled every two weeks, depending on the rate of instrument use.
- 9) Biomérieux hotline team will reply to us through email when the verification/fine-tuning is finalized and to mention:
 - Verification or Fine-tuning needed
 - System ready to go

*Note: If at any time the control fails or the instrument seems to be having an inordinate amount of unidentified isolates, and unscheduled verification may be necessary.

Fine-tuning:

- 1) Prepare a new Vitek MS slide with two full acquisition groups of E. coli 8739
- 2) This time, do not enter scan the slide or enter the spots at the Prep Station
- 3) Merely load the slide into the instrument to be fine tuned notify the technical support person that it has been loaded
- 4) Do NOT start the run
- 5) Technical support will fine tune the instrument remotely and will contact us when it is complete and ready for use
- 6) Fine-tuning date must be documented.

<u>Monthly Maintenance</u> *Adapter Cleaning* Clean adapter with kimwipe.

O ring and Seal Check

Open the door and check the condition of both the O-ring and sealing face of the front door. Wipe away moderate soiling with a clean kimwipe. If badly contaminated, use a alcohol to help clean the door seal.

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Front door (open position)

Yearly Maintenance

Yearly Maintenance is performed by Vitek MS technical staff. A PM visit must be arranged annually.

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Related Documents:

| Document name | Document code |
|--|------------------|
| Vitek MS Worksheet | |
| Vitek MS Worksheet with Controls | |
| VITEK-MS-V2-speciesList Created-Translated list | Policy: #MI\MSID |
| International Journal of Systematic and Evolutionary | |
| <u>Microbiology</u> | |
| (For Official/approved organism name changes) | |
| https://lpsn.dsmz.de/ | |
| (User friendly website to review name changes) | |

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Record of Edited Revisions

Manual Section Name: Vitek MS MALDI-TOF Manual

| Page Number / Item | Date of Revision | Signature of |
|---|--------------------------|-----------------|
| | | Approval |
| Updated workflow | November 04, 2013 | Dr. T. Mazzulli |
| Updated MALDI acceptance guide | November 19, 2013 | Dr. T. Mazzulli |
| Monitoring and Fine tuning procedure added | December 16, 2013 | Dr. T. Mazzulli |
| If $= 98\%$, write the result on the MS worksheet. Put a | December 16, 2013 | Dr. T. Mazzulli |
| checkmark if 99.9%. Update some process | | |
| Annual Review Date | March 31, 2014 | Dr. T. Mazzulli |
| Fix hyperlink in TOC: MALDI Organism Identification | June 06, 2014 | Dr. T. Mazzulli |
| Acceptance. Modified header | | |
| Removed duplicate steps 31- 63 from Myla | June 10, 2015 | Dr. T. Mazzulli |
| Added Vitek MS etiquette section | | |
| To Vitek MS monitoring and fine tuning added | | |
| "Monitoring" paragraph at top of section, and "Note" | | |
| with 4 bullets | | |
| -Updated monitoring procedure to verification procedure. | July 16, 2015 | Dr. T. Mazzulli |
| -#3 verification: verification slide to be put at 8am | | |
| #4 added link to email to hotline for | | |
| verification/finetuning | | |
| -Removed testing with strep isolate if maldi has an | | |
| inordinate amount of unidentified isolates. Added point | | |
| #10 hotline team reply via email | | |
| Beginning of Section: Vitek MS Verification and Fine- | September 17, 2015 | Dr. T. Mazzulli |
| tuning added instructions for posting signage on both | | |
| Vitek MS Machines. | | |
| Under Organism acceptance added: For Beta hemolytic | October 01, 2015 | Dr. T. Mazzulli |
| strep: GAS, GCS, GGS identified by MALDI, | | |
| confirmation by <u>Streptococcus Latex Agglutination</u> is | | |
| needed before reporting. | | |
| | | |
| Under verifications: Added separate email templates for | October 7, 2015 | Dr. T. Mazzulli |
| Vitek MS 1 and Vitek MS 2 | | |
| MS organism ID acceptance added #7 criteria for | November 30, 2015 | Dr. T. Mazzulli |
| Streptococcus pneumoniae | | |
| Added to organism ID list: always send for confirmation | February 22, 2016 | Dr. T. Mazzulli |
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| as per Biomerieux recall Feb 22 nd 2016 for: | | Approvar |
| Yersinia pestis, Bacillus anthrasis | | |
| Added to Maldi Etiquette: | April 12, 2016 | Dr. T. Mazzulli |
| • Place finished worksheets in the save basket | | |
| when complete | | |
| • Place worksheet for "partially" used MS slides in | | |
| the "Partial" basket near the machine that was | | |
| used | | |
| Removed monitoring values for indication of fine tuning. | May 16, 2016 | Dr. T. Mazzulli |
| Document verification and fine tuning in SoftMic | | |
| weekly. | | |
| Added Maintenance section with weekly and monthly | | |
| and yearly maintenance required. | | |
| Annual Review | June 10, 2016 | Dr. T. Mazzulli |
| Added Related Documents table with link to Vitek myla | | |
| ID table and MS worksheet | | |
| Removed Total Peaks Value communicated and | December 6, 2016 | Dr. T. Mazzulli |
| documentation needed. (due to Myla upgrade, no longer | | |
| required) | | |
| Maldi verification spots increased from 16 to 32 spots | March 13, 2017 | Dr. T. Mazzulli |
| with controls. | | |
| Updated requirements on confirming ID of <i>S.pneumoniae</i> | April 6, 2017 | Dr. T. Mazzulli |
| to include performing optochin. | | 5 5 1 1 |
| Annual Review | June 10, 2017 | Dr. T. Mazzulli |
| Addition of daily QC section including yeast control. | July 4, 2017 | Dr. T. Mazzulli |
| Addition of expanded Neisseria acceptance rules based | August 15, 2017 | Dr. T. Mazzulli |
| on species and sites. | | |
| Added enteric media additional testing | | |
| Expanded procedure for NLF <i>E.coli</i> . | A 11.0 C 0010 | |
| Annual Review | April 26, 2018 | Dr. T. Mazzulli |
| Updated link to location verification email to technical | | |
| support. | | |
| Added section : 11ps for successful identification | A | D. T. M |
| Annual Keview | April 25, 2019 | Dr. I. Mazzulli Dr. T. $M_{2} =11$ |
| Addition of MALDI mold procedure and QC organism | January 00, 2020 | Dr. I. Mazzulli Dr. T. Mazzulli |
| salely recautions added to VITEK MS Slide spot | redruary 21, 2020 | Dr. 1. Mazzulli |
| preparation & VITEK MS Slide spot preparation for | | |

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| mold cultures | | |
| Annual Review | May 10, 2020 | Dr. T. Mazzulli |

Full document review included in all updates. Bi-annual review conducted when no revision had been made within 2 years.

| Page Number / Item | Date of Revision | Edited by: |
|--|-------------------|----------------|
| Minor formatting change | April 11, 2021 | Jessica Bourke |
| Added note for kleb pneumo/variicola 50/50 | May 18, 2021 | Wayne Chiu |
| References for ID name changes added | June 23, 2021 | Jessica Bourke |
| Clarified S. pneumo confirmation chart | July 6, 2021 | Wayne Chiu |
| Removed username/password | Aug 18, 2021 | Wayne Chiu |
| Included Prevotella oris to list of "never report from | Sep 17, 2021 | Wayne Chiu |
| MALDI" | Sep 17, 2021 | wayne Chiu |
| Included Raoultella ornithinolytica to list of "never report | Dec 24, 2021 | Wayne Chiu |
| from MALDI" | Dec 24, 2021 | wayne eniu |
| Removed username/password information from VITEK | | |
| MS Prep Station, VITEK MS Acquisition Station and | February 25, 2022 | Oliver Li |
| MYLA applications | | |
| Removed Appendix A, move to BC manual | June 6, 2022 | Wayne Chiu |
| Removed Haemophilus haemolyticus from limitation list | | |
| Updated MALDI spot preparation instructions | November 1, 2022 | Wayne Chiu |
| | | |
| Updated send to PHOL for MALDI ID S. pneumoniae | November 23, 2022 | |
| Updated SOP to reflect changes to Software Update to | | |
| VITEK MS v3.2 in sections: VITEK MS Prep Station, | June 8, 2023 | Oin Liu |
| MYLA (Result Review) | June 0, 2025 | |
| Added section: Updating an Isolate Number | | |
| Minor formatting | July 21, 2023 | Qin Liu |
| Added/Updated tips for Successful Vitek MS identification | | |
| (page 19): | | |
| Avoid agar | November 1, 2023 | Qin Liu |
| Avoid specimen | | |
| • Updated the tip for use film growth for BC : avoid | | |

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| picking up blood by sampling the film away from | | |
| the primary inoculum. | | |

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