Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2198912	05/01/2023
Name of Provider or Supplier	**Street Address, City, State**	
Wiener And Daniels Dpm Pa	20 Crossroads Drive #15, Owings Mills, MD	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the policy and procedure manuals, laboratory records, and interview with the testing person (TP), the laboratory's policy and procedure manuals failed to include written instructions for all activities that the TP performs. Findings: 1. According to the TP each patient run is given an identification (ID) number (#) that includes the year, month, date, and fungal or wound. The instructions for labeling the run were not included in the procedure manual. 2. According to the TP each patient specimen is given an ID# that includes the first letter of the first name and the last name on the BioRad CFX-96 polymerase chain reaction (PCR) workload file. The

	instructions for labeling the patient specimen on the PCR file were not included in the procedure manual. 3. According to the TP the monthly quality assurance (QA) records are scanned to the technical supervisor for review. The instructions for scanning the QA records were not included in the procedure manual. 4. During the survey on 05/01 /23 at 1:15 PM, the TP confirmed that the policy and procedure manual failed to contain all the required written instructions for the laboratory staff.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on review of the patient worksheets for the BioRad CFX-96 polymerase chain reaction (PCR) analyzer and interview with the testing person (TP), the laboratory failed to ensure that reagents and standards used for the patient testing were not used after their expiration date. Findings: 1. The patient worksheets did not include the expiration dates of the PCR reagent plates and quality control (QC) used during testing. 2. During the survey on 05/01/23 at 1:15 PM, the TP confirmed that the patient worksheets and the other record systems available failed to include the expiration dates of the PCR reagents and QC materials used when performing the testing.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the procedure and interview with the testing person (TP), the laboratory failed to perform two levels of quality control (QC) each day of testing as required in paragraph (d)(3) of this section and establish an Individualized Quality Control Plan (IQCP) for the fungal and wound deoxyribonucleic acid (DNA) panel testing on the BioRad CFX-96 polymerase chain reaction (PCR) analyzer. Findings: 1. The laboratory is required to test two levels of QC materials each day of testing unless they have written an IQCP. An IQCP plan requires the laboratory to perform a risk assessment that includes an evaluation of the specimen used; environment for testing; integrity of the reagent; components of the test system; and competency of the testing personnel. The quality assessment portion of the IQCP should include a review of the QC, proficiency testing records, patient results and all other records pertaining to the fungal and wound panel testing on the PCR analyzer. 2. The laboratory's procedure manual requires the weekly testing of the QC materials. 3. During the

	survey on 05/01/23 at 1:15 PM, the TP confirmed that the laboratory failed to have an established IQCP for performing fungal and wound panel testing on the PCR analyzer on a weekly basis.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patients' final reports and interview with the testing person (TP), the laboratory failed to ensure that the final test reports listed the correct address of the laboratory where the testing was performed. Findings: 1. Review of the patients final reports showed that the billing address is listed as the laboratory address. The laboratory CLIA certificate was also registered with the billing address and not the address of the testing location. 2. During the survey on 05/01/2023 at 1:15 PM, the TP confirmed that the final test reports failed to list the correct address of the laboratory where the testing was being performed.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on review of the validation records for the BioRad CFX-96 polymerase chain reaction (PCR) analyzer and interview with the testing person (TP), the laboratory director (LD) failed to ensure that the validation records were approved by the LD, included the dates of testing, the identity of the "partner laboratory", raw data from the "partner laboratory" and investigation of the potential contamination due to poor aseptic technique in the laboratory during sample prep. Findings: 1. The validation summary for the wound and fungal pathogens using real-time reverse transcriptase quantitative were reviewed. 2. The validation records failed to include documentation of the approval (signature and date) of the LD. 3. The validation records failed to include documentation of the actual three days that the validation testing was being performed on. 4. The following statements were listed at the top of the "Clinical Correlation Study." "Five clinical samples were tested, and the results were compared to a partner laboratory." " Most of the data aligned with the partner laboratory. Sample 6 should have been completely negative. These results indicate contamination and potentially poor aseptic technique in the laboratory during sample prep." 5. The correlation data from the validation records failed to include documentation of the identity of the "partner laboratory" along with the raw showing when the testing was

	performed and the identity of the specimens tested. 6. The "Clinical Correlation Study" portion of the validation study listed 38 different "Targets" on the worksheet. The following "Targets" had an asterisk in the "expected" column for "Sample 1" blaNDM, C.koseri, CXT-M-Group 1, and M.morganii; "Sample 2" blaNDM, C. freundii, CXT-M-Group 1, M.morganii, and S.saprophyticu, and Sul; "Sample 3" P. aeruginosa; and "Sample 4" A.baumannii and CXT-M-Group 1. The "Determined" column had a numerical value listed. The "Match" column for each organism listed "TRUE." 7. The records failed to include a documented investigation of the fact that the summary indicated that "These results indicate contamination and potentially poor aseptic technique in the laboratory during sample prep." The records failed to address the fact that the "Expected" value was not numerical and therefore did not match the "Determined" value. 8. The current TP stated that the validation had been performed once and then a second time as part of the new TP training. It could not be determined if the validation records that were reviewed were the initial or repeated validation. 9. During the survey on 05/01/2023 at 1:15 PM the TP confirmed that the validation records failed to include dates of testing and an investigation of failures. The LD failed to ensure that the validation records included dates of testing, an investigation into the comment, "contamination and potentially poor aseptic technique in the laboratory during sample prep" to ensure accurate and reliable patient test results.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the policy and procedure manuals and interview with the testing person (TP), the laboratory director (LD) failed to ensure that the established quality control (QC) procedures included an Individualized Quality Control Plan (IQCP) to monitor the QC on a weekly basis. Findings: 1. The procedure manuals that were reviewed did not include a defined IQCP to reduce the frequency of testing QC materials to a weekly basis. Cross refer to Tag D5445 for findings. 2. During the survey on 05/01/23 at 1:15 PM, the TP confirmed that the QC policy and procedure manual failed to contain an approved IQCP.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the policy and procedure manuals and interview with the testing person (TP), the laboratory director (LD) failed to ensure that the established quality assurance (QA) procedures were maintained to monitor the overall operation of the laboratory were maintained. Findings: 1. The cover sheet on the QA policy requires the signature of the technical supervisor (TS). The TS listed on the "Laboratory Personnel Report (CLIA)" form was not the TS who signed the QA procedure. At the

	time of the survey the current TS had not signed the QA procedure. 2. The "Quality Control" section states "8.3.1. All quality control documentation will be audited monthly by the laboratory director or designee and documented with a signature and date it was reviewed on the form." According to the TP the monthly QA records are scanned to the TS for review each month. At the time of the survey there were no documents showing that QC had been reviewed and approved since the laboratory opened in October 2022 through May 2023. 3. The "Review Schedule" section of the QA procedures does not identify who is to perform the review and how the documents are to be sent to the appropriate person. 4. According to the TP the laboratory receives additional blind samples from Microbio for the BioRad CFX-96 polymerase chain reaction (PCR) analyzer. These additional blind samples were not part of the written QA procedure. 5. During the survey on 05/01/23 at 1:15 PM, the TP confirmed that the policy and procedure manual failed to contain all the required written instructions for the laboratory staff.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of the quality assurance (QA) procedures, laboratory training records, and interview with the testing person (TP), the laboratory director (LD) failed to ensure that all the laboratory personnel received the appropriate initial training for the fungal and wound deoxyribonucleic acid (DNA) panel testing on the BioRad CFX-96 polymerase chain reaction (PCR) analyzer. Findings 1. The QA procedures were reviewed. Section "15. Competency" states: "15.4. Competency assessment will be assesses by the laboratory director or qualified designee" and "16. Competency Assessment Documentation" states: "16.2 Testing personnel competency documentation must be filled out" "16.3 Technical supervisor competency must be filled out for Technical Supervisors" "16.4 General supervisor competency must be filled out for General Supervisors." 2. At the time of the survey the current TP confirmed that there was no documentation available documenting the initial training of the previous TP, the current TP, technical supervisor, and general supervisor. 3. During the survey on 05/01/2023 at 1:15 PM the TP confirmed that the laboratory records failed to include initial training for the current TP, Technical supervisor and general supervisor. The LD failed to ensure that all the laboratory personnel's initial training was performed and documented.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

	This STANDARD is not met as evidenced by: Based on review of "Installation Checklist" from Precision Microbio for the BioRad CFX-96 polymerase chain reaction (PCR) analyzer, quality assurance (QA) procedures, and interview with the testing person (TP), the technical supervisor (TS) failed to ensure that the "Installation Checklist" was completed, and the TP competency records included initial training of the TP. Findings: 1. The "Installation Checklist" provided by Precision Microbio required the documentation of the client, physical address, date of installation, laboratory director, CLIA#, technical supervisor (filled out by QA), name of technician, technical contact info, and installation by. 2. At the time of the survey only the client, name of technician, and technician contact info had been completed on the "Installation Checklist." The current TP stated that they had documented the information on the worksheet and that the worksheet had not been completed by the person who performed the installation. 3. The TP also stated that the TS reviewed the patient worksheets and quality control results for an additional two weeks after the initial training to ensure that the TP had a working knowledge of the testing process. 3. The QA procedures require the documentation of the initial competency assessment for the testing personnel. At the time of the survey the laboratory records failed to include documentation of the initial competency of the current TP. 4. During the survey on 05/01/2023 at 1:15 PM the TP confirmed that the "Installation Checklist" provided by Precision Microbio had not been completed as required and the initial competency assessment was not available for the current TP.