Department of Health & Human Services
Centers for Medicare & Medicaid Services

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Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0709453	(X3) Date Survey Completed 07/20/2023
Name of Provider or Supplier Pa Dept Of Health Bureau Of Labs	Street Address, City, State 110 Pickering Way, Exton, PA	
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
D0000	Three Centers for Medicare & Medicaid Services (CMS) federal surveyors conducted an announced CLIA recertification survey at the PA DEPT OF HEALTH BUREAU OF LABS from July 18, 2023 to July 20, 2023. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. The following condition and standard level deficiencies were found during the announced routine CLIA recertification survey performed from July 18, 2023 to July 20, 2023.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on record review and interview with General Supervisor #12 (GS #12), the laboratory failed to retain Quality Control (QC) records for at least two years for one of one lot number of BBL Taxo P Discs. Findings include: 1. Interview with GS #12 on 07/20/2023 at 10:50 AM confirmed one box of BBL Taxo P Discs (Lot# 9365316) was available for use in the presumptive identification of pneumococci. 2. On 07/20 /2023, a review of QC records from January 2021 through the third day of the survey (07/20/2023) revealed no QC documentation for BBL Taxo P Discs (Lot# 9365316). 3. Interview with GS #12 on 07/20/2023 at 11:00 AM confirmed the above findings.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented.

	This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with laboratory staff, the laboratory failed to review and document the corrective actions taken for one of one Wisconsin State Laboratory of Hygiene (WSLH) Measles unsatisfactory score in 2021. Findings Include: 1. On the day of survey, June 18, 2023, review of the laboratory's PT records revealed, the laboratory had one of one unsatisfactory score of 66% for WSLH measles PT in 2021. 2. Review of the laboratory's corrective action sheet revealed, a corrective was not assessed or documented. 3. On June 18, 2023 around 1:00 am, laboratory staff confirmed the findings above and on July 19, 2023 around 2:21 PM, laboratory staff provided a CAs for the unsatisfactory score that was reviewed and documented on July 18, 2023. *** This deficiency was corrected onsite on July 19, 2023.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on record review, written laboratory procedures, client service manual, patient test requisition, final patient reports, and interview with Technical Supervisor #14 (TS#14), the laboratory failed to ensure specimen integrity was maintained (collection, storage, and transport conditions) per their own written procedures for one of two patients. Findings include: 1. Interview on 07/19/2023 at 09:20 AM with TS#14 confirmed the laboratory performed Bordetella testing using the Applied Biosystems ABX 7500 Multiplex Real Time (RT) Polymerase Chain Reaction (PCR) method. 2. On 07/18/2023 a review of the written laboratory procedure titled, "Multiplex Real-time DNA Detection of Bordetella pertussis, B. parapertussis, and B. holmesii Standard Operation Procedure" under section "D. Storage, Preservation, and Transport" stated, "2. Ship all swabs on a cold pack within 48 hours of collection (see Collection Guideline)". 3. On 07/18/2023 a review of the client service manual (Collection Guideline) titled, "Pertussis Testing Specimen Collection and Shipping Instructions" under section "Shipping Instructions" stated, "1. Ship the specimen as soon as possible after collection (within 48 hours)". 4. On 07/19/2023, a review of two patient requisitions and patient final test reports revealed one patient specimen was received and tested beyond 48 hours for one of two patients: a. Patient #M23000841 - Nasopharyngeal Swab collected on 12/27/2022, received in the laboratory on 01/05 /2023 (9 days after collection), and reported on 01/10/2023. 5. Interview on 07/19 /2023 at 09:45 AM with TS #14, confirmed the above findings.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the

	overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review, manufacturer's instructions, client service manual, written laboratory procedures, bacteriology worksheets, patient requisitions, final patient reports, and interviews, the laboratory failed to monitor and evaluate the overall quality of analytic systems and correct identified problems for each specialty and subspecialty of testing performed. Findings include: 1. The laboratory failed to follow these established and written procedures below (Refer to 5401): - Quality assessment (QA) procedures affecting 84 patient samples. - Identification of Neisseria meningitidis for one of one patient's test. - Identification of Vibrio for two of two patients' tests. - Detection of Shiga Toxin 1 and Shiga Toxin 2 for five of five patients' tests. 2. The laboratory failed to follow Para-Fix C&S Medium (Modified Cary Blair) manufacturer's instructions for one of one patient. Refer to D5411. 3. The laboratory failed to ensure the humidity was maintained as required by the manufacturer for the Applied Biosystem ABX 7500 analyzer, Cepheid GeneXpert analyzer, and Applied Biosystem Quant Studio Dx analyzer for six of six months. Refer to D5413. 4. The laboratory failed to ensure the Heat Block was maintained as required by the written laboratory procedure for six of six months. The laboratory failed to ensure the CO2 Incubator was maintained as required by written laboratory procedures for two of two months. Refer to D5413. 5. The laboratory failed to perform a negative and positive control material for Real-Time Polymerase Chain Reaction (RT PCR) Carbapenemase gene testing using the Cepheid GeneXpert for four of four patients. Refer to D5449. 6. The laboratory failed to perform a negative control for organism identification using the Matrix Assisted Laser Desorption/Ionization Time of Flight (MALDI-TOF) Mass Spectrometry for two of two patients. Refer to D5449. 7. The laboratory failed to check each batch for growth or no growth of Mueller Hinton Agar (MHA) plate for one of one lot number. Refer to D5471. .
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: A. Based on review of three of three Individual Quality Control Plans (IQCPs), quality control records, lack of documentation, and interview with the general supervisors (GS-8 and GS-13); the laboratory failed to follow quality assessment (QA) procedures to review IQCP annually and reduced quality control procedures, affecting 87 patients' tests. Findings include: Part a. 1. The IQCP protocols for these selected test systems were reviewed: QuantiFeron-TB Gold Plus (QFT-Plus) - Implemented 06/01/2019 Cepheid GeneXpert MTB/RIF - Implemented 10/13/2020 GeneXpert CT IQCP - Implemented January 1, 2020 2. In the QA section; under #7: The Clinical Microbiology Director, it is stated "The IQCP will be re-evaluated annually." This directive is included in each of the three protocols listed in findings #1. 3. On an interview with GS-8 on July 20, 2023 at 10:35 am, the GS stated that a review of the MTB/RIF had not been performed since its implementation. 4. On an

interview with GS-13 on July 20, 2023 at 12: 26 PM, the GS stated that a review of the CT.NG and QFT-Plus IQCPs had not been performed since their implementation. Part b. 5. Review of a Xpert CT_NG test run dated 03/18/2022 showed externals controls were not performed on the day three of three patients' test results were tested and reported. 6. In the Xpert CT_NG procedure titled "VIR_TSOP_035_V3", its is stated: "External controls NATCT-434 (Positive) and NATCT/NG (Negative) to be ran once per month in the first week of the month." 7. Review of the Xpert CT_NG quality control (QC) log documented externals controls were performed on 02/05 /2022 and 04/08/2022. 8. Further review of the QC records revealed the laboratory failed to provide any documentation QC procedures were performed in the month of March 2022. 9. The laboratory reported 87 patient during the time period of 02/05 /2022 through 04/08/2022. 10. The laboratory confirmed the findings above on July 20, 2023 around 3:00 PM. 47272 B. Based on record review, written laboratory procedure, patient bacteriology worksheet, patient final report, and interview with Technical Supervisor #14 (TS #14) the laboratory failed to follow the written procedure for the identification of Neisseria meningitidis for one of one patient. Findings include: 1. Interview on 07/20/23 at 12:10 PM with TS #14 confirmed the following: a. The laboratory performed Neisseria meningitidis testing b. The laboratory used the "Bacteriology Reference Human Worksheet" to record biochemical and serology test results 2. On 07/18/2023, a review of the written laboratory procedure titled, "Slide Agglutination for Serogrouping of Neisseria meningitidis" under section "B. Collection Procedure" stated, "2. The isolate must be pure N. meningitidis isolate confirmed with the following tests in order to proceed with the serogrouping." a. Oxidase Positive b. Catalase Positive 3. On 07/20/2023, a review of a "Bacteriology Reference Human Worksheet" for one patient# M23007176 (received into the laboratory on 01/31/2023 and reported on 02/02/2023) revealed no documentation of the Oxidase biochemical test result and the Catalase biochemical test result. 4. Interview with TS #14 on 07/20/2023 at 12:50 PM confirmed the above findings. C. Based on record review, written laboratory procedure, bacteriology worksheet, final patient reports, and interview with Technical Supervisor #14 (TS #14), the laboratory failed to follow the written procedure for the identification of Vibrio species for two of two patients. Findings include: 1. Interview on 07/20/23 at 12:05 PM with TS #14 confirmed the laboratory performed the identification of Vibrio species and used a "Bacteriology Reference Human Worksheet" to record biochemical and serology test results. 2. On 07/20/2023, a review of the written laboratory procedure titled, "ID of Vibrio species Test order: Conventional Biochemical tests and Serology" under sections: a. "Day 2" stated, "Oxidase: Positive" b. "Day 4" stated, "Record Biochemical test results" 3. On 07/20/2023, a review of the "Bacteriology Reference Human Worksheet" revealed the following for two of two patients: a. Patient #M23037196 (received into the laboratory on 07/12 /2023 and reported on 07/14/2023) revealed no documentation of the Oxidase biochemical test result. b. Patient #M23037047 (received into the laboratory on 07/03 /2023 and reported on 07/11/2023) revealed no documentation of the Oxidase biochemical test result. 4. Interview with TS #14 on 07/20/2023 at 12:35 PM confirmed the laboratory failed to document the Oxidase biochemical test results as indicated above. D. Based on record review, written laboratory procedure, patient final reports, and interview with Technical Supervisor #14 (TS #14) and Technical Supervisor #5 (TS #5), the laboratory failed to follow the written procedure for the detection of Shiga Toxin 1 and Shiga Toxin 2 using Real-Time Polymerase Chain Reaction (RT PCR) using the Applied Biosystem QuantStudio Dx for five of five patients. Findings include: 1. Interview on 07/19/2023 at 01:30 PM with TS #14, confirmed the laboratory performed Shiga Toxin 1 and Shiga Toxin 2 testing using the RT PCR Applied Biosystem QuantStudio Dx. 2. On 07/19/2023, a review of the

	written laboratory procedure titled, "Detection of Shiga Toxin 1 and Shiga Toxin 2 from Isolate and Stool Culture/GN Broth by a Real-Time PCR using Applied Biosystems's QuantStudio DX Standard Operation Procedure" under section "D. Limits of Acceptable Performance of the Quality Controls" stated the following: a. "Control Name" 1. "Inhibition Control (bicoid alone)". b. "Acceptable Ranges" for "Shigabicoid". 1. "27-30". c. "E. Actions Taken if Control Results are Unacceptable". 1. "If the expected results for the controls are not achieved, record the control results and consult with the. Section Supervisor to determine corrective action to be taken. Record any action taken and file.". 3. On 07/19/2023, a review of the 07/11/2023 "Results Table (By Well)" revealed the results for "Run #: 2051" as follows: a. Well - "H11". b. Sample - "BICOID CTRL". c. Target - "SHIG Bicoid". d. Result (Ct) - 23.31. 4. On 07/19/2023, a review of corrective action records revealed no evidence of action taken for the unacceptable Shigbicoid result of 23.31 (acceptable range 27 - 30) for five of five patients (reported on 07/11/2023): a. Patient #M23036708. b. Patient #M23036709. c. Patient #M23036710. d. Patient #M23036978. e. Patient #M23036961. 5. Interview on 07/19/2023 at 02:35 PM with TS #5 confirmed the above findings.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on record review, manufacturer's instructions, patient requisition, patient final report, and interview with Technical Supervisor #14 (TS#14), the laboratory failed to follow Para-Fix C&S Medium (Modified Cary Blair) manufacturer's instructions for one of one patient. Findings include: 1. Interview on 07/19/2023 at 10:20 AM with TS#14 confirmed the laboratory performed Fecal Culture and Enteric Pathogen testing from stool samples shipped to the laboratory in Para-Fix C&S Medium (Modified Cary Blair). 2. On 07/19/2023, a review of the Para-Fix C&S Medium (Modified Cary Blair) manufacturer's instructions under section "COLLECTION, STORAGE and TRANSPORT" stated, "7. Proper specimen collection from the patient is critical for successful isolation and identification of enteric organisms. If immediate transportation to a laboratory is not possible refrigerate at 2-8C for up to 96 hours." 3. On 07/19/2023, a review of one patient requisition and the final patient report revealed the following for one of one patient: a. Stool specimen was collected on 06/28 /2023, received into the laboratory 9 days later on 07/07/2023, and reported on 07/11 /2023. 4. Interview on 07/19/2023 at 10:55 AM with TS #14, confirmed the above findings.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity.

(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
A. Based on record review, manufacturer's instructions, and interview with the Quality Officer and Technical Supervisor #14 (TS#14), the laboratory failed to ensure the humidity was maintained as required by the manufacturer for the Applied Biosystem ABX 7500 analyzer, Cepheid GeneXpert analyzer, and Applied Biosystem Quant Studio Dx analyzer for six of six months. Findings include: 1. Interview with TS#14 on 07/18/2023 at 09:50 AM confirmed the laboratory performed the following: a. Bordetella testing using the Applied Biosystem ABX 7500 analyzer. b. Chlamydia trachomatis, Neisseria gonorrhoeae, and Carbapenemase gene testing using the Cepheid GeneXpert analyzer. c. Shiga Toxin 1 and Shiga Toxin 2 testing using the Applied Biosystem QuantStudio Dx. 2. On 07/19/2023, a review of the manufacturer's environmental conditions for the following: a. Applied Biosystem ABX 7500 "Environmental Requirements Checklist" under section "Temperature and Humidity Requirements" stated, "Humidity: 20 to 80% relative humidity, noncondensing". b. Cepheid GeneXpert "ENVIRONMENTAL REQUIREMENTS" under section "Ambient Humidity: 10%-95% RH, non-condensing" c. Applied Biosystem QuantStudio Dx "Environmental requirements" under section "Operating conditions" stated, "Humidity 15-80% relative humidity (noncondensing) 3. On 07/19/2023, a review of laboratory records revealed no humidity readings for six of six months between 01/11/2023 through 06/20/2023. 4. Interview with the Quality Officer on 07 /19/2023 at 01:45 PM confirmed the above findings. B. Based on record review, written laboratory procedure, and interview with Technical Supervisor #14 (TS#14) and General Supervisor #7 (GS #7), the laboratory failed to ensure the Heat Block was maintained as required by the written laboratory procedure for six of six months. Findings include: 1. Interview with TS#14 on 07/20/2023 at 10:45 AM confirmed the laboratory performed the Slide Agglutination testing for Serogrouping of Haemophilus influenzae. 2. On 07/18/2023, a review of the written laboratory procedure titled, "Slide Agglutination for Serogrouping of Haemophilus influenzae" under sections: a. "VI. Instrumentation and Equipment Required" stated, "D. Heat Block 55-65C". b. "XI. Test Procedure" stated, "A. Mark a clean unfrosted slide with 8 rectangular sections using a china marker. Slides should be placed on a heating block and allowed to heat up prior to marking." 3. On 07/20/2023, a review of laboratory records revealed no Heat Block temperature readings for six of six months between 01/11/2023 through 06/20/2023. 4. Interview with GS #7 on 07/20/2023 at 11:05 AM confirmed the above findings. C. Based on record review, written laboratory procedures, and interview with the Quality Manager and Technical Supervisor #14 (TS#14), the laboratory failed to ensure the CO2 Incubator was maintained as required by written laboratory procedures for two of two months. Findings include: 1. Interview with TS#14 on 07/19/2023 at 03:34 PM confirmed the laboratory used the Isotemp Fisher Scientific CO2 incubator labeled, "28G CO2 Incubat T(Rm 137 Bacti)P147" for the incubation of isolates at temperatures between 35-37C for the following: a. Identification of Neisseria meningitidis b. Identification of Neisseria gonorrhoeae c. Serogrouping of Haemophilus influenzae 2. On 07/18 /2023 review of written laboratory procedures confirmed the incubation temperature between 35-37C for the following: a. "ID of Neisseria meningitis" under section "Day 1: Isolate the slant" stated "Sub onto CAP (incubate 35-37C in CO2 incubator)" b. . "ID of Neisseria gonorrhoeae" under section "Day 1: Isolate in Jembec media (CAP + antibiotic)" stated "Sub onto CAP (incubate 35-37C in CO2 incubator)" c. "Slide Agglutination for Serogrouping of Haemophilus influenzae" under section "D.

	Storage, Preservation, and Transport" stated, "store isolates in the CO2 incubator at 35-37C prior to testing" 3. On 07/20/2023, a review of laboratory records between 06 /01/2023 through the second day of the survey (07/19/2023) revealed an acceptable CO2 incubator range of 35 - 39C. a. Specific days incubator temperatures warmer than 37C include: 1. June 2023 - Days 14, 15,16,17,18,19,20,21,22,23,24,25,26,27,28,29,30 2. July 2023 - Days 1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16,17,18,19 4. Interview with the Quality Manager on 07/20/2023 at 01:50 PM confirmed the above findings.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: A. Based on record review, final patient reports, and interview with Technical Supervisor #14 (TS #14) and Technical Supervisor #5 (TS #5), the laboratory failed to perform a negative and positive control material for Real-Time Polymerase Chain Reaction (RT PCR) Carbapenemase gene testing using the Cepheid GeneXpert for four of four patients. Findings include: 1. Interview on 07/19/2023 at 01:00 PM with TS #14 confirmed the laboratory performed RT PCR testing in the detection and differentiation of the most prevalent Carbapenemase gene families (KPC, NDM, VIM, OXA-48, and IMP) using the Cepheid GeneXpert and Xpert Carb-R cartridge. 2. On 07/19/2023, a review of Quality Control records from 06/23/2023 through 06/30 /2023 revealed no documentation of a negative and positive control for four of four days of patient testing as follows: a. Patient #M23034337 - Specimen collected 06/12 /2023, received in the laboratory 06/21/2034, and reported 06/23/2023. b. Patient #M23034162 - Specimen collected 06/15/2023, received in the laboratory 06/20/2034, and reported 06/23/2023. c. Patient #M23035520 - Specimen collected 06/21/2023, received in the laboratory 06/28/2034, and reported 06/30/2023. d. Patient #M23035185 - Specimen collected 06/15/2023, received in the laboratory 06/27/2023, and reported 06/30/2023. 3. Interview on 07/19/2023 at 01:50 PM with TS #5 confirmed the above findings. B. Based on record review, written laboratory procedure, final patient reports, and interview with Technical Supervisor #14 (TS #14), the laboratory failed to perform a negative control for organism identification using the Matrix Assisted Laser Desorption/Ionization Time of Flight (MALDI-TOF) Mass Spectrometry for two of two patients. Findings include: 1. Interview on 07/19 /2023 at 11:30 AM with TS #14 confirmed the laboratory performed organism identification using the (MALDI-TOF) Mass Spectrometry. 2. On 07/19/2023, a review of the written laboratory procedure titled, "Organism Identification using the Matrix Assisted Laser Desorption/Ionization Time of Flight (MALDI-TOF) Mass Spectrometry Standard Operation Procedure" under section "A. Controls Required" stated the following: a. "2. Matrix HCCA Blank control 1. "It is performed after target cleaning." 2. "The first run using the target will have one spot with matrix only labeled "Blank" 3. "The results are recorded on the "MALDI-TOF Target Cleaning and Blank/Matrix Record"" 3. On 07/19/2023, a review of the 04/26/2023 "Run Results Report" revealed no documentation of the Blank Control for two of two patients reported on 04/26/2023: a. Patient #M23025761 - Specimen collected 04/17

	/2023, received in the laboratory on 04/20/2023, and reported on 04/26/2023 b. Patient #M23025824 - Specimen collected 04/19/2023, received in the laboratory on 04/21/2023, and reported on 04/26/2023 4. Interview on 07/19/2023 at 12:31 PM with TS #14 confirmed the above findings.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review, written laboratory procedures, final patient reports, interview with Testing Person #10 (TP #10), and Technical Supervisor #14 (TS #14), the laboratory failed to check each batch for growth of Mueller Hinton Agar (MHA) plate for one of one lot number. Findings include: 1. Interview on 07/20/2023 at 11:35 AM with TS #14 confirmed the laboratory performed Modified Carbapenem Inactivation Method (mCIM) procedure inoculating the MHA plate with test disks. 2. On 07/20 /2023, a review of the laboratory procedure titled, "Modified Carbapenem Inactivation (mCIM) Standard Operating Procedure" under section "C. Preparation and inoculation of MHA plate(s) with E. coli 25922 indicator strain and test disks" stated the following: a. "1. A maximum of 4 MEM disks may be placed on a 90 mm diameter MHA plate and a maximum of 8 MEM disks on a 150 mm diameter plate for the mCIM.". 3. On 07/20/2023 Quality Control (QC) records revealed no evidence the laboratory checked MHA Lot#60285 for growth or no growth before use. MHA Lot#60285 used for patient testing from 03/24/2023 to 06/30/2023: a. Patient #M23022559 tested on 04/05/2023 b. Patient #M23024105 tested on 04/12/2023 c. Patient #M23024451 tested on 04/13/2023 d. Patient #M23024848 tested on 04/14 /2023 e. Patient #M23024956 tested on 04/18/2023 f. Patient #M23025875 tested on 04/21/2023 g. Patient #M23026145 tested on 04/25/2023 h. Patient #M23026471 tested on 04/26/2023 i. Patient #M23027125 tested on 05/02/2023 j. Patient #M23028188 tested on 05/05/2023 k. Patient #M23028569 tested on 05/10/2023 l. Patient #M23029313 tested on 05/16/2023 m. Patient #M23030294 tested on 05/19 /2023 n. Patient #M23031589 tested on 05/31/2023 o. Patient #M23032434 tested on 06/06/2023 p. Patient #M23033242 tested on 06/09/2023 q. Patient #M23034162 tested on 06/20/2023 r. Patient #M23034337 tested on 06/21/2023 s. Patient #M23034840 tested on 06/22/2023 t. Patient #M23035185 tested on 06/27/2023 u. Patient #M23035520 tested on 06/28/2023 4. Interview with TP #10 on 07/20/2023 at 11:55 AM confirmed the above findings.
D5503	BACTERIOLOGY CFR(s): 493.1261(a)(2) (a) The laboratory must check the following for positive and negative reactivity using control organisms: (a)(2) Each week of use for gram stains.

	This STANDARD is not met as evidenced by: Based on record review, written laboratory procedure, and interview with Technical Supervisor #14 (TS #14), the laboratory failed to perform Gram Stain quality control slides weekly for eight of eight months. Findings include: 1. Interview with TS #14 on 07/20/2023 at 09:45 AM confirmed the laboratory performed Gram Stains in the laboratory. 2. On 07/18/2023, a review of the written laboratory procedure, titled "Culture Gram Stain" under section, "B. Frequency of Performing Controls" stated, "Control slides are prepared & stained weekly". 3. Record review from 08/10/2022 through 03/17/2023 revealed control slides not performed weekly for eight of eight months: a. Control slides not performed between 08/17/2022 through 09/01/2022 b. Control slides not performed between 09/01/2022 through 10/07/2022 c. Control slides not performed between 10/07/2022 through 10/26/2022 d. Control slides not performed between 10/26/2022 through 11/09/2022 e. Control slides not performed between 11/09/2022 through 11/29/2022 f. Control slides not performed between 12 /06/2022 through 12/29/2022 g. Control slides not performed between 01/04/2023 through 01/17/2023 h. Control slides not performed between 01/17/2023 through 02 /02/2023 i. Control slides not performed between 02/02/2023 through 02/22/2023 j. Control slides not performed between 03/01/2023 through 03/17/2023 4. Interview with TS #14 on 07/20/2023 at 10:05 AM confirmed the above findings.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory records and interview with the laboratory director (LD) and laboratory personnel from the quality department, the LD failed provide overall management and direction in accordance with 42 CFR 493.1445 from July 2021 to July 2023. Finding Includes: The LD failed to ensure that the quality assessment programs established assured the quality of laboratory services provided and to identify failures in quality as they occur - Refer to D6094.
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: A. Based on review of three of three Individual Quality Control Plans (IQCPs), quality control records, lack of documentation, and interview with the general supervisors (GS-8 and GS-13); the laboratory director (LD) failed to ensure the quality assessment (QA) procedures are maintained to assure the quality of laboratory services. Findings include: 1. The LD failed to ensure three of three reduced quality control plans (IQCP) were re-assessed annually. See D5401, Part a. 2. The LD failed to ensure the reduced QC procedures are followed in accordance to their individual IQCP. See D5401, Part b. 38555 B. Based on review of the Preanalytic, Analytic and

	Postanalytic Quality assessment (QA) policies, interview with the Laboratory director (LD) and personnel from the quality department, the LD failed to ensure QA programs were established and maintained to assure the quality of laboratory services provided July 2021 to July 2023. Findings Include: 1. On the date of survey, July 18, 2023, review of the QA manual revealed the laboratory had a Preanalytic, Analytic and Postanalytic QA policies. 2. Review of the procedures revealed, the LD failed to establish in the procedures that mechanism were in place to assess the laboratory for its Preanalytic, Analytic and Postanalytic Quality assessment (QA) processes to assure the quality of laboratory services provided July 2021 to July 2023. 3. The laborator'ys corrective action from the June 30, 2021 stated, "The BOL will develop a policy concerning analytic quality assessment and will implement it and the existing policies on pre-analytic and post-analytic quality assessment. The BOL will document the communication of the policies to laboratory staff. Quality problems and quality assessment activities will be discussed at monthly meetings attended by the laboratory director, supervisors, and quality officer. The BOL will keep records of these meetings. 4. On the day of survey the laboratory was unable to provide QA meetings performed each month from July 2021 to July 2023. 5. The laboratory director and personnel from the quality department confirmed the findings above July 20, 2023 around 3:30 pm. **** Repeat deficiency from the June 30, 2021 survey.
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 testing personnel (TP) training records and interview with laboratory staff, the technical supervisors (TS) failed to sign off on TP training performed from October 2022 to July 2023. Findings Include: 1. On the day of survey, July 19, 2023 review of a sampling of TP training records revealed, the following training documents were not signed (8 out of 22) by a TS from October 2022 to July 2023: Media Folder - 3 of 3 TP training records. Bacteriology folder - 2 of 2 TP training records. Mycobacteriology folder - 3 of 3 TP training records. 2. The laboratory confirmed the findings above on July 20, 2023 around 3:00 PM.