| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 15D0662599 | 08/10/2022 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Indiana State Department Of Health Laboratories | 550 W 16th St, Indianapolis, IN | |

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 |
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| **D0000** | The Indiana State Department of Health Laboratories were surveyed under 42 CFR part 493 CLIA regulations. The following deficiencies were found during the announced routine CLIA recertification survey performed from August 9, 2022 to August 10, 2022: |
| **D5209** | PERSONNEL COMPETENCY ASSESSMENT POLICIES<br>CFR(s): 493.1235<br><br>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of laboratory personnel competency assessment records and an interview with a quality assurance (QA) specialist, the laboratory failed to establish written policies and procedures to assess technical supervisors (TS) and general supervisors (GS) for competency in 2021 and 2022. Findings Include: 1. The personnel form CMS-209 filled out by the laboratory at the time of the survey listed 6 TS, and 20 GS for the laboratory. 2. Review of the Quality Manual (ISDH-QM-1), section 6.2.12 competencies of technical personnel, revealed, that the laboratory did not establish a TS or GS competency assessment policy. 3. Interviews with QA specialist on 8/10/2022 at 9:45 am confirmed the laboratory did not establish a written policy to assess TS and GS for competency. |
| **D5401** | PROCEDURE MANUAL<br>CFR(s): 493.1251(a)<br><br>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 |

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| | examining specimens.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the laboratory Standard Operating Procedures (SOP) and an interview with the Quality Assurance (QA) specialist, the laboratory failed to follow its policy to review 21 of 28 clinical SOPs at least biennially from the last review dates. Findings Include: 1. Review of the Quality Manual (ISDH-QM-1), section 8.3.2 stated the following "Clinical SOPs are reviewed at least biennially and revised as needed by the lab supervisor. The QMs and all other SOPs are reviewed at least annually and revised as needed by the QAC." 2. On the day of survey, 08/10/2021, review of the bacteriology documents within MediaLab, the electronic document control system, revealed that 21 of 28 documents were not reviewed biennially from the last review date. 3. Interview with the QA specialist on 8/10/2022 at 3:00 pm confirmed the laboratory did not follow established written policy ISDH-QM-1 Quality Manual regarding document review. |
| **D5407** | PROCEDURE MANUAL<br>CFR(s): 493.1251(d)<br><br>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and an interview with the serology technical supervisor (TS), the laboratory failed to update procedures to reflect the change of storage time based on Abbott Alinity human immunodeficiency virus (HIV), and HCV (hepatitis C virus) transit extension validation. Findings Include: 1. Review of the verification addendum Abbott Alinity HIV HCV transit extension validation, approved by the lab director on 07/27/2021, revealed, in "purpose and principal" that the laboratory performed this validation to the objective of this stability study is to extend the FDA approved Abbott Alinity transit time of human serum specimens sent to IDOHL for Anti-HCV and HIV Ag/Ab Combo testing, from three (3) days at ambient temperatures to nine (9) days at ambient temperatures while providing quality results. "In summary", IDH-SER-36 Standard Operating Procedure (SOP) will be modified to reflect the changes validated in this document. 2. Review of the IDOH-SER-36 Abbott Alinity i SOP, version 1, effective date 5/10/2021, revealed, in Table 1. Assay and Specimen Transit & Freeze /Thaw Requirements, Transit Time by Storage Temp (from time of collection) is 3 days at room temp. 3. Interviews with Serology TS on 8/10/2022 at 11:30 am confirmed the laboratory did not update the SOP IDH-SER-36 to reflect the changes in storage time with the validation study for transit extension. |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>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. |

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| | This STANDARD is not met as evidenced by:<br>Based on a review of records, observation of the laboratory, and interview with the quality assurance (QA) director, the laboratory failed to ensure bacteriology materials had been stored as required for 17 of 17 months from 2021 and 2022. Findings include: 1. On August 9, 2022 at 09:15 am, the quality assurance director stated the MALDI Biotyper was used to perform Bacterial Identification. 2. On August 10, 2022 at 01:30 pm, seven boxes (two boxes of lot# 6030421008 and five boxes of lot# 6030422002) of In Vitro Diagnostic (IVD) and Bacterial Test Standard (BTS) were observed in the laboratory freezer with a manufacturer's storage requirement of -18 degrees Celsius or below. 3. On August 10, 2022 , a review of the policy titled, "ISDH-MOL-45 ID of Bacteria via MALDI-TOF Mass Spectrometry" revealed the IVD BTS was used in the MALDI Biotyper system quality control process to ensure reliable and accurate identification of microorganisms. 4. A review of the temperature records for 17 months (February 2021 through July 2022) revealed freezer temperatures were not documented. 5. On August 10, 2022 at 01:45 pm, the QA director confirmed freezer temperatures had not been documented until August 5, 2022. |
| **D5429** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(1)<br><br>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.<br><br>This STANDARD is not met as evidenced by:<br>A. Based on review of the FilmArray policies, lack of the BioFire FilmArray 2.0 System maintenance records and interview with the Quality Assurance (QA) director and technical supervisor (TS) #1, the laboratory failed to document maintenance for the BioFire FilmArray 2.0 System from January 2021 to August 2022 (19 of 19 months). Findings Include: 1. The ISDH-MOL-40, 13.0, B. states, "All documentation of maintenance and calibration is stored in the binder near the instrument". 2. The ISDH-ENT-19 and ISDH-MOL-40, 11.0, A. states, "The FilmArray pouch loading station, all work areas and racks should be cleaned with 10% bleach solution. Record cleaning on benched log". 3. On the day(s) of survey (08/09/2022 and 08/10/2022), review of the BioFire FilmArray 2.0 System records and lack of maintenance records revealed, the laboratory did not document maintenance for the BioFire FilmArray 2.0 System used for the Respiratory 2.1 (RP2.1) Panels and the Gastrointestinal (GI) Panels from January 2021 to August 2022 (19 of 19 months). 4. The QA director confirmed on 08/10/2022 around 12:00 PM, that maintenance has not been performed documented for the BioFire FilmArray 2.0 System. B. Based on review of the SCIEX 6500 analyzer manufacturer's instructions, lack of documentation and interview with the quality assurance (QA) specialist, the laboratory failed to follow the manufacturer's instructions for performing and documenting maintenance procedures from February 2021 through July 2022 (17 of 17 months). Findings Include: 1. On 08 /09/2022 at 02:00 pm, the quality assurance director stated, "Chemical threat testing (Cyanide, Volatile Organic Chemicals, Nerve Agents, Abrine and Ricine, and Tetramine) was performed using two SCIEX 6500 analyzers ("Scarlatti" serial number DY20691808 and "Vivaldi" serial number DY20101802)". 2. On 08/09/2022, a review of the manufacturer's maintenance instructions required the following daily |

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| | procedures: - Inspect system for leaks. - Clean curtain plate. - Clean orifice plate (front). 3. On 08/10/2022, a review of the maintenance records for 17 months revealed, daily maintenance had been performed from February 2021 through July 2022. 4. On 08/10/2022 at 9:12 am, the QA specialists confirmed the maintenance had been performed but not documented. |
| **D5435** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(b)(2)<br><br>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of maintenance records and interview with the quality assurance (QA) director, the laboratory failed to follow their centrifuge function checks protocols for three of four centrifuges used for the MALDI Biotyper from February 2021 to July 2022 (17 of 17 months). Findings include: 1. On 08/09/2022 at 09:15 am, the QA director stated the MALDI Biotyper was used to perform Bacterial Identification. 2. The ISDH-MOL-45 ID of Bacteria via MALDI-TOF Mass Spectrometry policy stated, "the laboratory used a benchtop centrifuge (at 13,000 rpm for 2 minutes) in the process for routine yeast and bacterial isolate". 3. The ISDH-QA-13 (version 2.0) Equipment Maintenance policy under the section titled, "11.2.2 Centrifuge" stated, "Centrifuges must be calibrated to the proper set rotations per minute (RPM) semi-annually". 4. On 08/10/2022, a review of centrifuge checks revealed, the laboratory could not provide documentation of centrifuges checks performed semi-annually for 17 of 17 months (February 2021 through July 2022). 5. On 08/10/2022 at 03:00 pm, the QA specialists confirmed, there were no documents to prove the centrifuge had been checked as indicated above. |
| **D5449** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(3)(ii)(g)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the BioFire FilmArray 2.0 System quality control (QC) records and interview with the Quality Assurance (QA) director and technical supervisor (TS) #1, the laboratory failed to perform a negative and positive control materials each day of patient testing for each pathogen tested on the Respiratory 2.1 (RP2.1) Panels and the Gastrointestinal (GI) Panels used on the the BioFire FilmArray 2.0 System from January 2021 to August 2022. Findings Include: 1. On the first day of survey, August |

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| | 9, 2022 review of BioFire FilmArray 2.0 System RP2.1 panel QC records revealed, each day of patient testing, the laboratory did not perform positive and negative QC for each pathogen on the RP2.1 panel from October 2021 to March 2022 (5 of 5 months). 2. On the second day of survey, August 10, 2022, review of BioFire FilmArray 2.0 System GI panel QC records revealed, each day of patient testing, the laboratory did not perform positive and negative QC for each pathogen on the GI panel from January 21, 2021 to August 10, 2022 (19 of 19 months). 3. From October 2021 to March 2022 - 46 patient RP2.1 panels were analyzed on the BioFire FilmArray 2.0 System. 4. From January 21, 2021 to August 10, 2022 - 15 patient GI panels were analyzed on the BioFire FilmArray 2.0 System. 5. The laboratory confirmed on 08/10/2022 around 4:00 PM, that negative and positive control materials were not performed each day of patient testing for each pathogen tested on the RP2.1 and GI Panels used on the the BioFire FilmArray 2.0 System. |
| **D5775** | COMPARISON OF TEST RESULTS<br>CFR(s): 493.1281(a)(c)<br><br>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.<br><br>This STANDARD is not met as evidenced by:<br>A. Based on a review of chemical threat testing records, lack of documentation and interview with the quality assurance (QA) director and testing personnel (TP) #7, the laboratory failed to evaluate and defined the relationship between test results using 2 of 2 Agilent analyzers and 2 of 2 SCIEX 6500 analyzers used to perform chemical threat testing twice a year from 2021 to 2022. Findings include: 1. On August 9, 2022 at 01:55 pm, TP #7 stated: "Chemical threat testing (lead, urine metals, and blood metals) was performed using two Agilent analyzers ("Lahaina" serial number SG19485075 and "Maia" serial number SP18071056)" and at 02:00 pm, the QAdirector stated: "Chemical threat testing (Cyanide, Volatile Organic Chemicals, Nerve Agents, Abrine and Ricine, and Tetramine) was performed using two SCIEX 6500 analyzers ("Scarlatti" serial number DY20691808 and "Vivaldi" serial number DY20101802)". 2. On August 9, 2022, the laboratory was unable to provide documentation evaluating the relationship between 2 of 2 Agilent analyzers and 2 of 2 SCIEX 6500 analyzers used to perform chemical threat testing twice a year from 2021 to 2022. 3. The QA director confirmed the findings above on August 9, 2022 at 02:15 pm. 42173 B. Based on observation, lack of documentation, and interview with the Biothreat lab technical supervisor (TS), the laboratory failed to perform and document comparison of test results for two of two 7500 Fast DX Real-time PCR polymerase chain reaction instruments used in the Biothreat laboratory twice a year. Findings include: 1. A tour of the Biothreat laboratory on August 10, 2022, at 10:30 am, revealed there were two 7500 Fast DX Real-time PCR instruments used in the laboratory. 2. There were no documents available for comparison of test results between two 7500 Fast DX Real-time PCR instruments used in the Biothreat laboratory for 2021 and 2022. 3. During the interview on August 10, 2022, at 10:35 am, the Biothreat lab TS confirmed that the laboratory didn't perform a comparison of test results between the two instruments. |