| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 49D0661011 | 07/21/2021 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Metropolitan Laboratory Services, Inc | 12011 Lee Jackson Memorial Hwy Suite 200, Fairfax, VA | |

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** | An announced on-site CLIA recertification survey was conducted at Metropolitan Laboratory Services (formerly Mira Scientific) on July 20-21, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The survey included an entrance interview on May 28, 2021 and virtual record review conducted on July 15, 2021. The laboratory was surveyed under 42 C.F.R. part 493 CLIA Regulations. The laboratory was not in compliance with the following 42 CFR part 493 CLIA Regulations: D5400 - 42 C.F.R. 493.1250 Condition: Analytic Systems and D6076 - 42 C.F.R. 493.1441 Condition: High complexity laboratory director. Metropolitan Laboratory Services (formerly Mira Scientific) is performing SARS CoV-2 (COVID-19) testing and is in compliance with the applicable COVID-19 reporting requirements. |
| **D2009** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(1)<br><br>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.<br><br>This STANDARD is not met as evidenced by:<br>***REPEAT DEFICIENCY**** Based on a review of the laboratory's proficiency testing (PT) records, the laboratory's 2019 Plan of Correction, lack of documentation, and an interview with the Laboratory Manager, the Laboratory Director (LD) and testing personnel (TP) failed to sign twenty-two (22) of forty-one (41) PT attestation statements from April 2019 to July 2021. Findings include: 1. Review of the College of American Pathologists (CAP) PT records from April 2019 until July 2021 revealed the following PT: CAP 2019 K-A Ligand, General not signed by TP and LD; CAP 2019 C-C General Chemistry/Therapeutic Drug not signed by TP and LD; CAP 2019 K-C Ligand, General not signed by TP and LD; CAP 2019 D-C Bacteriology not |

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| | signed by TP and LD; CAP 2020 FH13-B Hematology/Auto Differential not signed by TP; CAP 2020 VM-B Viral Markers not signed by TP; CAP 2020 C-B General Chemistry/Therapeutic Drug not signed by TP; CAP 2020 CGL-B Coagulation, Limited not signed by TP; CAP 2020 D-B Bacteriology not signed by TP and LD; CAP 2020 K-B Ligand, General not signed by TP; CAP 2020 CGL-C Coagulation, Limited not signed by TP and LD; CAP 2020 VM-C Viral Markers not signed by TP; CAP 2020 CM-B Clinical Microscopy not signed by TP; CAP 2020 FH13-C Hematology/Auto Differential not signed by TP and LD; CAP 2020 C-C General Chemistry/Therapeutic Drug not signed by TP and LD; CAP 2020 D-C Bacteriology not signed by TP; CAP 2020 K-C Ligand, General not signed by TP and LD; CAP 2020 G-C Syphilis Serology not signed by TP; CAP 2020 S-C Diagnostic Immunology not signed by TP; CAP 2020 COVS-B SARS CoV-2 Serology not signed by TP; CAP 2020 COV2-B SARS CoV-2 Molecular not signed TP and LD; CAP 2021 FH13-A Hematology/Auto Differential. 22 of 41 attestation statements were not signed by Laboratory Director and TP. The surveyor requested checklists and signed attestation statements for the PT events listed above. The laboratory provided no documentation for review. 2. Review of the laboratory's 2019 Plan of Correction on Form CMS-2567 (dated 4/21/19) revealed the laboratory would have a PT event form with a checklist with a "reminder for TP/LD to sign attestation page." and the "LD will review, sign, and date all PT events prior to submission while double-checking that all attestation pages are signed by TP." 3. In an exit interview with the laboratory manager, Testing Personnel (TP) A, and TP B on July 21, 2021 at approximately 12:45 PM, the above findings were confirmed. |
| **D2015** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(5)(6)<br><br>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the laboratory's policies and procedures, proficiency testing (PT) records and an interview with the Laboratory Manager, the laboratory failed to follow their established policy and maintain the instrument printouts for twelve (12) of forty-one (41) PT events from April 2019 to July 2021. Findings include: 1. Review of the laboratory's policy and procedure manual revealed a policy, "Proficiency Testing", which stated "1. All result forms along with instrument printouts and/or manual testing documentation will be retained by the Laboratory Manager for a period of 2 years." 2. Review of the laboratory's College of American Pathologists (CAP) PT records revealed the laboratory failed to maintain the instrument printouts for the following PT events: 2019 K-B Ligand, General; 2019 K-C Ligand General; 2019 D-C Bacteriology; 2020 D-B Bacteriology; 2020 CM-B Clinical Microscopy; 2020 D-C Bacteriology; 2020 COVS-B SARS Co-V-2 Serology; 2020 COV2-B SARS Co-V-2 Molecular; 2020 FH-13 Hematology Auto Differentials; 2020 VM-B Viral Markers; |

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| | 2021 COV2-A SARS CoV-2 Molecular; 2021 K-A Ligand, General. 12 PT events. The surveyor requested to review the instrument printouts for the above listed PT events. The laboratory provided no documentation for review. 3. In an exit interview with the laboratory manager, Testing Personnel (TP) A, and TP B on July 21, 2021 at approximately 12:45 PM, the above findings were confirmed. |
| **D5211** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(a)<br><br>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.<br><br>This STANDARD is not met as evidenced by:<br>Based on the review of the laboratory's proficiency testing (PT) records, policies and procedures, lack of documentation, and interviews, the laboratory director failed to review and sign four (4) of forty-one (41) PT result evaluations from March 2019 until July 2021. Findings include: 1. Review of the laboratory's College of American Pathologists (CAP) PT records from March 2019 until July 2021 (a total of 41 events) revealed a lack of documentation of the signature by laboratory director for the following 4 PT events: CAP 2019 Bacteriology D-C; CAP 2019 Ligand, General K-C; CAP 2020 General Chemistry/Therapeutic Drugs C-C; CAP 2020 SARS CoV-2 Molecular COV2-B. The surveyor requested documentation of the above listed PT evaluations signed by the laboratory director. The laboratory provided no documentation for review. 2. Review of the laboratory's policies and procedures revealed a policy, "Proficiency Testing", which stated "Proficiency Result Report Review: A. All proficiency testing result reports will be reviewed by the Laboratory Manager. Reports demonstrating a score of 100% for all analytes tested will be reviewed, initialed and dated by testing personnel and the Laboratory Director." 3. In an exit interview with the laboratory manager, Testing Personnel (TP) A, and TP B, on July 21, 2021 at approximately 12:45 PM, the above findings were confirmed. |
| **D5213** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(b)(1)<br><br>The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the laboratory's proficiency testing (PT) records, policies and procedures, lack of documentation and interviews, the laboratory failed to follow their established policy and verify the accuracy of eighteen (18) non-graded PT events from March 2019 until July 2021. Findings include: 1. Review of the laboratory's College of American Pathologists (CAP) PT documentation from March 2019 until July 2021, a total of forty-one events, revealed no evaluation or verification of accuracy for the following non-graded PT events: CAP 2019 FH13-B Hematology Auto Differentials; CAP 2019 D-C Bacteriology; CAP 2019 K-C Ligand-General; CAP 2020 FH-13-B Hematology Auto Differentials; CAP 2020 VM-Viral Markers; CAP 2020 C-B General Chemistry/Therapeutic Drugs; CAP 2020 CGL-B 2020 Coagulation, Limited; CAP 2020 D-B Bacteriology; CAP 2020 K-B Ligand, General; CAP 2020 CGL-C Coagulation, Limited; CAP 2020 VM-C 2020 Viral Markers; CAP 2020 CM-B 2020 |

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| | Clinical Micro; CAP 2020 FH-13-C Hematology Auto Differential; CAP 2020 C-C General Chemistry/Therapeutic Drugs; CAP 2020 D-C Bacteriology; CAP 2020 S-C Diagnostic Immunology; CAP 2020 COVS-B SARS-CoV-2 Serology; CAP 2021 FH13-B Hematology Auto Differentials. 18 ungraded events. The surveyor requested to review the evaluation or verification of accuracy for the 18 non-graded events listed above. The laboratory provided no documentation for review. 2. Review of the laboratory's policies and procedures revealed a policy, "Proficiency Testing", which stated "PROFICIENCY RESULT REPORT REVIEW: B. Results that are not graded due to lack of peer group consensus or referee's decision will be compared to the appropriate peer group results provided in the participant summary provided with the result for acceptability. Documentation of this review will be made on the result form." 3. In an exit interview with the laboratory manager, Testing Personnel (TP) A, and TP B, on July 21, 2021 at approximately 12:45 PM, the above findings were confirmed. |
| **D5400** | ANALYTIC SYSTEMS<br>CFR(s): 493.1250<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on a laboratory tour, review of the laboratory's policies and procedures, manufacturer's operators guide, package inserts, validation/verification records, instrument calibration verification records, quality assessment documents, instrument patient records, patient test records, lack of documentation and interviews, the laboratory failed to: 1. follow their established policy for the evaluation of patient test results prior to reporting results in the laboratory information system (see D5401); 2. document the approval and review of the laboratory's instructions for use (IFUs) and operator's manuals for the laboratory's new instruments and methods prior to patient testing (see D 5407); 3. document review/evaluation of the accuracy, precision, reportable range for new instruments and methods prior to patient testing (see D5421); 4. follow their established policy for performing calibration verification procedures every six months for analytes assayed on the Abbott Architect ci4100 (see D5439); 5. identify and address analytic issues within the specialties of chemistry, hematology and microbiology (see D5791). |
| **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 examining specimens.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's policies and procedures, instrument test records, |

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| | quality control (QC) documentation, patient reports, and an interviews, the laboratory failed to follow the established policy for the evaluation of patient COVID-19 test results prior to reporting results in the laboratory's information system for 10 days in May of 2021 while reporting 56 patients. Findings include: 1. Review of the laboratory's procedure manual revealed a manufacturer's instructions for use (IFU), "BioGX Xfree COVID-19 Direct RT-PCR", which stated "Examination and Interpretation of Patient Specimen Results-...The list of expected results is outlined Table2. If the results are obtained that do not follow these guidelines, re-test the sample or re-extract and re-test the sample if using extraction. If the repeat testing yields similar results, collect a fresh sample from the patient for testing." Review of Table 2 of expected results revealed that if the patient's results were "Indeterminate" (invalid) with a negative RNase P or Internal Amplification Control (IAC) then the "Result Interpretation" is "Repeat Test*". The asterisk indicates interpretation note. The interpretation note states "Repeat the test by preparing a new test from the remaining patient sample collection and ensure the patient sample and PCR master mix is dispensed properly in the well being analyzed. Repeat testing must yield RNase P and IAC detection without N1 detection to confirm a NEGATIVE result. However, if the same result is obtained upon a repeat test, report results as INCONCLUSIVE." 2. Review of the QuantStudio7's patient test records and patient ProLis (laboratory information system) reports revealed the following the dates and samples whose printouts indicated "Indeterminate" (invalid) results with no evidence of repeat testing and were reported as NEGATIVE: 05/03/2021-Sample ID 2105030004-24; 05/05 /2021-Sample ID 2105050003-23; 05/13/2021-Sample ID 2105130006-24; 05/14 /2021-Sample IDs 2105140001-24, 2105140003-24; 2105140004-24, 2105140005-23, 2105140006-24, 2105140007-24, 2105140008-24, 2105140011, 2105140012, 2105140013, 2105140014-24; 05/15/2021-Sample IDs 2105140002-24, 2105150001-24; 05/17/2021-Sample IDs 2105170001-24, 2105170009-24, 2105170011-24, 2105170012-24, 2105170013-24, 2105170014-24; 05/18/2021-Sample IDs 2105180001, 2105180002-24, 2105180003-24, 2105180005-24, 2105180006-24, 2105180007-24; 05/19/2021-Sample IDs 2105190001-24, 2105190002-24, 2105190003-24, 2105190005-24, ID 2105190006-24, 2105190007-24, 2105190008-24; 05/20/2021-Sample IDs 2105200001-24, 2105200002-24, 2105200003-24, 2105200004-24, 2105200005-24, 2105200006-24, 2105200007-24; 05/21/2021-Sample IDs 2105210001-24, 2105210002-24, 2105210003-24, 2105210004-24, 2105210007-24, 2105210009-24, 2105210010-24, 2105210011-24, 2105210014-24, 2105210017-24, 2105210018-24, 2105210019-24, 2105210020-24, 2105210022-24, 2105210024-24. A total of 56 patients. The surveyor requested to review documentation of the repeat testing of the above listed patient samples. The laboratory provided no documentation for review. 3. In a telephone interview with a former testing personnel on July 21, 2021 at approximately 11:45 AM, the testing personnel stated they had been trained to report patient COVID-19 specimens with a negative RNase P and/or IAC as negative. 4. In an exit interview with the laboratory manager, Testing Personnel (TP) A, and TP B, on July 21, 2021 at approximately 12:45 PM, the above findings were confirmed. |
| **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: |

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| | Based on a tour, interviews, review of package inserts, manufacturer's instructions for use (IFU), operator's manuals, laboratory policies, the laboratory director (LD #1-former and LD #2-current) failed to document approval and review of the Instructions For Use (IFUs) and operator's manuals/guide for the laboratory's new instruments and methods prior to testing of patients from September 2019 until July 2021. Findings include: 1. During a tour of the laboratory on 7/20/2021 at approximately 9:00 AM, the surveyor noted the following instruments in use: Abbott Architect ci4100 (serial number C402741), Sysmex XN-1000 (serial number 393986) Sysmex CA-660 (serial number 25769) and Fisher Scientific Applied Biosystems QuantStudio7 Pro (serial number 2778720020197). The surveyor requested to review the approved test procedures. The Laboratory Manager provided manufacturer operator's manuals for the Abbott Architect, Sysmex XN-1000, Sysmex CA-660 and QuantStudio7 Pro. 2. Review of the laboratory's procedure manual revealed no approved procedures for testing performed on the Abbott Architect ci4100, Sysmex XN-100, Sysmex CA-660 and Fisher Scientific Applied Biosystems QuantStudio 7 Pro and new method, BioGX Xfree COVID-19 Direct RT-PCR kit. The laboratory manager stated they were using the operator's manuals/guides and IFUs as procedures for the instruments and methods. 3. Review of the laboratory's operator manuals/guides and IFUs revealed the following operator manuals and IFU lacked the laboratory director's review and approval: Abbott Architect ci4100 (serial number C40274 installed 8/5/2019); Sysmex XN-1000 (serial number 39386 installed 7/3/2019); Sysmex CA-660 (serial number 25769 installed 9/30/2019); QuantStudio 7 Pro (serial number 2778720020197) installed 5/5/2020; BioGX Xfree COVID-19 Direct RT-PCR kit validated 11/2020. 4. In an exit interview with the laboratory manager, Testing Personnel (TP) A, and TP B, on July 21, 2021 at approximately 12:45 PM, the above findings were confirmed. |
| **D5421** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(1)<br><br>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.<br><br>This STANDARD is not met as evidenced by:<br>A. Based on a tour of the laboratory, performance verification records, lack of documentation, and interviews, the laboratory director (LD) failed to document review /evaluation of the accuracy, precision, and reportable range for patient testing of analytes prior to reporting patient results on a newly installed Abbott Architect ci4100 from August 5, 2019 to the date of the inspection on July 20, 2021. Findings include: 1. During a tour of the laboratory on July 20, 2021 at approximately 9:00 AM the surveyor observed an Abbott Architect ci4100 chemistry analyzer (serial number C402741) in use for patient testing for the following analytes: Hemoglobin A1c, C-Reactive Protein, Ferritin, Folate, Free T3, Free T4, Thyroxin (T4, total), Triiodothyronine (T3, total), Thyroid Stimulating Hormone (TSH), Uric Acid, Creatine Kinase(CK), Vitamin B12, Vitamin D 25 OH, PSA-total, PSA-free, Direct Bilirubin, Total Bilirubin, Calcium, Chloride, Cholesterol, Carbon Dioxide (CO2), Creatinine, Glucose, High Density Lipoprotein (HDL), Low Density Lipoprotein |

(LDL), Potassium, Magnesium, Phosphorus, Sodium, Triglycerides, Urea Nitrogen, Alanine Transaminase (ALT), Albumin, Total Protein, Alkaline Phosphotase, Aspartate Aminotransferase (AST), Iron, Digoxin, Syphilis-TP and T-uptake. 2. Review of all analyzer performance verification documentation records revealed the instrument was installed on 8/1/2019 with instrument verification of accuracy, precision and reportable range completed on 8/5/2019. Review of the verification documentation for the Abbott Architect analyzer revealed no LD evaluation of the verification documents prior to patient testing. The surveyor requested to review documentation the LD verified the Abbott Architect's verification documents prior to patient testing. The laboratory provided no documentation for review. 3. In an exit interview with the laboratory manager, Testing Personnel (TP) A and TP B, on July 21, 2021 at approximately 12:45 PM, the above findings were confirmed. B. Based on a tour of the laboratory, performance verification records, lack of documentation, and interviews, the laboratory director (LD) failed to document review/evaluation of the accuracy, precision, and reportable range for patient testing of assays prior to reporting patient results on a newly installed Sysmex CA-660 coagulation analyzer from September 30, 2019 to the date of the inspection on July 20, 2021. Findings include: 1. During a tour of the laboratory on July 20, 2021 at approximately 9:00 AM the surveyor observed a Sysmex CA-660 coagulation analyzer (serial number 25769) in use for patient testing for the following assays: ProThrombin Time (PT), International Normalized Ratio (INR), Activated Partial Thromboplastin Time (aPTT), and d-Dimer. 2. Review of all analyzer performance verification documentation records revealed the instrument was installed on 9/30/2019 with instrument verification of accuracy, precision and reportable range completed on 10/1 /2019. Review of the verification documentation for the Sysmex CA-660 analyzer revealed no LD evaluation of the verification documents prior to patient testing. The surveyor requested to review documentation the LD verified the CA-660's verification documents prior to patient testing. The laboratory provided no documentation for review. 3. In an exit interview with the laboratory manager, Testing Personnel (TP) A and TP B, on July 21, 2021 at approximately 12:45 PM, the above findings were confirmed. C. Based on a tour of the laboratory, performance verification records, lack of documentation, and interviews, the laboratory director (LD) failed to document review/evaluation of the accuracy, and precision for testing of patient specimens using the new testing method, BioGX Xfree COVID-19 Direct RT-PCR on the Fisher Scientific QuantStudio7 Pro, prior to reporting patient results from November 2020 until the date of the inspection on July 20, 2021. Findings include: 1. During a tour of the laboratory on July 20, 2021 at approximately 9:00 AM the surveyor observed a QuantStudio 7 Pro analyzer (serial number 2778720020197) in use for patient testing for the presence or absence of SARS CoV-2 (COVID-19). The surveyor inquired when the instrument was installed. The laboratory manager stated they were not sure but thought it was since the last inspection. The surveyor inquired what method was being used for testing. They stated they were using the BioGX Xfree COVID-19 Direct RT-PCR on the Fisher Scientific QuantStudio7 Pro. 2. Review of all analyzer performance verification documentation records revealed the instrument was installed on 5/5/2020 with instrument verification of accuracy, and precision completed on 11/7/2020. Review of the verification documentation for the BioGX Xfree COVID-19 Direct RT-PCR on the Fisher Scientific QuantStudio7 Pro revealed no LD evaluation of the verification documents prior to patient testing. The surveyor requested to review documentation the LD verified the BioGX Xfree COVID-19 Direct RT-PCR on the Fisher Scientific QuantStudio7 Pro verification documents prior to patient testing. The laboratory provided no documentation for review. 3. In an exit interview with the laboratory manager, Testing Personnel (TP) A and TP B, on July 21, 2021 at approximately 12:45 PM, the above findings were

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| | confirmed. |
| **D5439** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(b)<br><br>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.<br><br>This STANDARD is not met as evidenced by:<br>Based on the review of the laboratory's policies and procedures, manufacturer's instructions for use (IFU), lack of documentation and interviews, the laboratory failed to follow to their established policy for performing calibration verification procedures every six months for twenty-three (23) analytes assayed on the Abbott Architect ci4100 from September 2019 until July 2021. Findings include: 1. Review of the laboratory's policy and procedures (effective 4/18/19) revealed a policy, "Calibration and Calibration Verification," which stated "9. Calibration verification will be conducted every 6 months on all on-waived testing with the exception of hematology and any analyte that uses a 6-part calibration." 2. Review of the manufacturer's IFUs for the analytes assayed on the Abbott Architect revealed the following analytes which use less than 6-part calibration: Alkaline Phosphotase, Alanine Transaminase (ALT), Amylase, Creatine Kinase (CK), Chloride, Direct Low Density Lipoprotein (LDL), Iron, Potassium, Lactate Dehydrogenase (LDH), Lipase, Sodium, High Density Lipoprotein (HDL), Ferritin, Free Prostatic Specific Antigen (PSA), PSA-total, Free T3, Free T4, Thyroxin (T4, total), Triiodothyronine (T3, total), Thyroid Stimulating Hormone (TSH), and T-uptake. Review of the calibration verification documents for the Abbott Architect revealed the laboratory performed calibration verification for the above listed analytes upon installation of the instrument on 8/5 /2019. The surveyor requested to review additional calibration verification documentation for calendar year 2020 and 2021. The laboratory provided no documentation for review. 3. In an exit interview with the laboratory manager, Testing Personnel (TP) A and TP B, on July 21, 2021 at approximately 12:45 PM, the above findings were confirmed. |
| **D5791** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(a)(c) |

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| | (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.<br><br>This STANDARD is not met as evidenced by:<br>** Repeat Deficiency** Based on the review of the laboratory's "Quality Assessment (QA) Plan", policies and procedures, instrument validation/verification records, quality control (QC) records, calibration verification records, patient records, and interviews, the laboratory failed to follow their established Quality Assurance (QA) plan and identify and address analytic issues within the specialties of diagnostic immunology, chemistry, hematology, and microbiology (Cross Reference D 5401, 5407, 5421 and 5439) from March 2019 to January 2021. Findings include: 1. Review of the laboratory's "Quality Assessment (QA)", policies and procedures, instrument validation/verification records, quality control (QC) records, calibration verification records, patient records revealed the following analytic issues: -No documentation of testing personnel following their established policy for the performance and reporting of invalid SARS CoV-2 (COVID-19) testing for ten (10) days in May 2021 (see D5401); -No documentation of the laboratory director approving instrument procedures prior to patient testing (see D5407); -No documentation of the laboratory director approving the verification of performance characteristics for Abbott Architect ci4000, Sysmex XN-1000 and Sysmex CA-660 prior to analyzing patient specimens (see D5421); -No documentation of the laboratory following their established policy and performing calibration verification procedures for analytes with less than six (6) point calibrations September 2019 until July 2021 (see D5439). 2. Review of the "QA Plan" revealed the following statement, "Plan Implementation: The QA plan will be implemented by: Performing at least 4 QA reviews annually, 1 from each phase of the laboratory testing-general, pre-analytic, analytic and post analytic. Analytic: -Procedure Manual-The lab will have written policies and procedures for all activities and test procedures performed in the lab. The procedure manual is accessible to lab staff reviewed annually and approved by the Lab Director. -Verification of Performance Specifications-Before a new test is introduced into the lab, manufacturer stated claims for performance specifications of accuracy, precision, reportable range and reference range will be verified. -Calibration and Calibration Verification-Calibration and Calibration Verification procedures will be performed following manufacturer instructions to ensure method accuracy..." 3. Review of the available Quality Assessment documentation revealed a lack of documentation of the "4 QA reviews" performed annually from March 2019 until January 2021. The surveyor requested to review documentation of the "4 QA reviews" from March 2019 until January 2021. The laboratory provided no documentation for review. In an interview with the Laboratory Manager on July 2021 at approximately 10:00 AM, the laboratory manager stated they began performing QA reviews beginning in January 2021. The laboratory manager provided evidence of reviews from January 2021 until the date of the survey. 4. In an exit interview with the laboratory manager, Testing Personnel (TP) A, and TP B, on July 21, 2021 at approximately 12:45 PM, the above findings were confirmed. |
| **D6076** | LABORATORY DIRECTOR<br>CFR(s): 493.1441<br><br>The laboratory must have a director who meets the qualification requirements of 493. |

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| | 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.<br><br>This CONDITION is not met as evidenced by:<br>Based on a tour of the laboratory, review of the laboratory's policies and procedures, instrument and method validation records, manufacturer's operator's guide, package inserts, patient test records, calibration verification records, the Centers for Medicare and Medicaid Services Laboratory Personnel Report form, laboratory personnel files, proficiency testing (PT) records, and interviews, the laboratory director failed to ensure: 1. an approved plan of correction was followed when proficiency testing results were found to be unacceptable or unsatisfactory (see D6092); 2. the established quality assessment plan identified and addressed issues in the analytic systems of Microbiology, Diagnostic Immunology, Chemistry, and Hematology (Cross Reference D6094); and 3. that training and competency assessments for testing personnel were reviewed and approved prior to patient testing (see D6102). |
| **D6092** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(4)(iv)<br><br>The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's proficiency testing records (PT), lack of documentation and interview, the laboratory director failed to ensure documentation of the evaluation and corrective actions taken for PT events scored as less than eighty percent (unsatisfactory) for eight (8) of forty-one (41) PT events from 2019 to the date of the survey, July 21, 2021. The findings include: 1. Review of the laboratory's policy and procedure manual revealed a policy "Proficiency Testing" which stated, "PROFICIENCY RESULT REVIEW, C. Results that are flagged as unacceptable or that display a significant bias from the group mean will be considered deficiencies and will be investigated." 2. Review of the laboratory's College of American Pathologists records from 2019 until July 21, 2021 revealed the following PT events with scores less than 80% (unsatisfactory) events: CAP 2019 D-B Bacteriology=79%; CAP 2019 C-B General Chemistry/Therapeutic Drug, Valproic Acid=60%; CAP 2019 C-C General Chemistry/Therapeutic Drug, Iron=40%; CAP 2019 C-C General Chemistry /Therapeutic Drug, Magnesium=40%; CAP 2020 FH-13-B Hematology Auto Differentials=60%; CAP 2020 C-C General Chemistry/Therapeutic Drug, Total Bilirubin=60%; CAP 2020 K-C Ligand General, Triiodothyronine=0%; CAP 2020 CGL-C Coagulation, Limited=50%. A total of 8 events. The surveyor requested to review documentation of the evaluation and corrective actions taken for the PT events listed above. The laboratory provided no documentation for review. 3. In an exit interview with the laboratory manager, Testing Personnel (TP) A and TP B on July 21, 2021 at approximately 12:45 PM, the above findings were confirmed. |
| **D6094** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5)<br><br>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. |

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| | This STANDARD is not met as evidenced by:<br>Based on the review of Quality Assurance (QA) plan, laboratory's policies and procedures, manufacturer's operating guides, package inserts, instrument and method validation records, calibration verification records, and interviews, the laboratory director failed to ensure the established quality assurance plan identified and addressed issues in the analytic systems of diagnostic immunology, chemistry, hematology and microbiology. (Cross Reference D5791.) |
| **D6102** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(12)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), available testing personnel (TP) files, lack of documentation, and interviews, the laboratory director (LD) failed to ensure that training and competency assessments were reviewed and approved for two (2) of 2 TP prior to testing and reporting patient results in the specialties of Diagnostic Immunology, Chemistry and Hematology. Findings include: 1. Review of the laboratory's CLIA CMS-209 Form revealed 2 testing personnel identified as performing testing in the specialties of diagnostic immunology, chemistry and hematology. 2. Review of the testing personnel's (TP A and TP B) initial competency assessment records revealed no evidence of the laboratory director's review and approval of the training and competency assessments. (See attached Personnel Code sheet.) The training and initial competency assessments were signed on June 3, 2021 by the laboratory manager. 3. In an exit interview with the laboratory manager, Testing Personnel (TP) A and TP B, on July 21, 2021 at approximately 12:45 PM, the above findings were confirmed. |