| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 21D1020567 | 10/08/2021 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Chop A Division Of Rcca- Md | 9715 Medical Center Dr Ste 221, Rockville, 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 |
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| **D2007** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(1)<br><br>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods<br><br>This STANDARD is not met as evidenced by:<br>Based on proficiency testing (PT) record review and interview with the technical consultant (TC), the laboratory did not ensure that all the testing personnel who tested patient samples performed the PT. Findings: 1. The laboratory currently has 4 testing personnel listed on the "Laboratory Personnel Report (CMS-209)." 2. A review of PT attestation worksheets from 2019 through 2020 showed that 2 of 4 testing personnel did not perform PT for 6 of 6 PT events in hematology and coagulation; and 3. One of 4 testing personnel performed the chemistry PT for 8 of 8 PT events. 4. During an interview on 10/8/2021 at 10:00 AM, the TC confirmed that PT samples were not tested each year by all the staff who perform patient testing to ensure accurate and reliable patient test results. |
| **D3031** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(3)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on laboratory record review and electronic communication with the technical consultant (TC), the laboratory failed to retain all analytic systems records for at least |

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| | 2 years. Findings: 1. In emails sent to the TC on 4/28/2021, 7/26/2021, 9/10/2021, 9/21/2021, 9/24/2021, and 9/29/2021 the surveyor requested documents needed to complete a remote survey of the laboratory. 2. Record review showed that the laboratory did not submit a procedure for performing quality assessment reviews. 3. Record review showed that the laboratory did not submit calibration records for the Medica EasyRA chemistry analyzer. In an email on 10/1/2021 the TC stated, "EasyRA requires calibration current,etc for tests to be performed HOWEVER, was unable to locate Cal Verificaton reports to send to you." 4. The laboratory's "Quality Control" procedure manual instructs the testing person to document corrective actions performed for failed quality control. The laboratory's "Quality Assessment Review" forms refer to an "Action Log" where it notes if "Any required Corrective Action (is) properly documented." 5. Record review showed that the laboratory did not submit "Action Logs" with the remote survey documents. During a phone interview on 9/30/2021 at 9:30 AM the TC stated that the laboratory did not document any corrective actions performed on an action log. 6. The laboratory was requested to send hematology quality control records and Levy-Jennings control graphs from the Medonic hematology analyzer for October and November of 2019 and 2020. In an email on 6/29/2021 the TC stated, "November 2020 review was done 'on analyzer' on visit in December 2020 because I couldn't get the stupid printer to work. I was able to retrieve Level 2 and 3 for November to send here, but Level 1 was overwritten and unavailable." 7. During a phone interview on 10/8/2021 at 10:00 AM, the TC confirmed that the laboratory did not retain all analytic system records for at least 2 years. |
| **D3037** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(4)<br><br>Proficiency testing records. Retain all proficiency testing records for at least 2 years.<br><br>This STANDARD is not met as evidenced by:<br>Based on proficiency testing (PT) record review and electronic communication with the technical consultant (TC), the laboratory did not ensure that a copy of all PT documents was maintained by the laboratory for a minimum of two years from the date of the PT testing event. Findings: 1. A review of PT records from 3 hematology PT events in 2019 showed that the attestation statement, PT program results form, and instrument printouts for event 1 of 2019 was not present at the time of the survey. 2. In an email from 6/29/2021 the TC stated, "They're using 2 companies for Proficiency testing and somehow 2019 was not renewed in time to get Event 1 from AAB Proficiency. We ordered an off-schedule MLE to do for a first event scenario, and then continued rest of year with proper AAB Testing.....however, I was not able to locate actual worksheets for MLE off-schedule results." 3. A review of chemistry PT records from 2019 showed that the attestation statement for 1 of 5 PT events was not present at the time of the survey. 4. During an interview on 10/8/2021 at 10:00 AM, the TC confirmed that the laboratory did not retain all PT records for at least 2 years. |
| **D5221** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(d)<br><br>All proficiency testing evaluation and verification activities must be documented.<br><br>This STANDARD is not met as evidenced by: |

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| | Based on proficiency testing (PT) record review and interview with the technical consultant (TC), the laboratory failed to document all corrective actions taken to prevent recurrence of the proficiency testing (PT) failures. Findings: 1. Chemistry PT records were reviewed for 2019 through 2021. 2. For the 1st event of 2019 the laboratory scored: sodium (Na): 0%, carbon dioxide (CO2): 60%, chloride (Cl): 60%, and total iron binding capacity (TIBC) (iron based calculation): 60%. On the "Performance Review and Corrective Action Documentation" form provided by the PT provider the corrective action was documented as "Tech to rerun specimens to evaluate cause of failures." There were no instrument printouts present, showing that the PT had been rerun and no documentation that a root cause analysis had been performed to determine the cause of the PT failures. 3. For the 3rd event of 2019 the laboratory scored: Na: 60% and Calcium (Ca): 60%. The laboratory's corrective actions included halting testing for Na, replacing the electrode on the analyzer for Na, rerunning PT samples, and reviewing quality control (QC) and patients. The laboratory also stated that it would "Order 2 remedial sets for corrective action to submit to regulatory agencies." The corrective actions documented did not address the failed PT for Ca. 4. For the 1st event of 2020 the laboratory scored: Cl: 60%, albumin (Alb): 80%, creatinine: 80%, and phosphorus: 80%. Corrective actions stated, "Please repeat ..." next to each of the failed analytes but there were no instrument printouts present, showing that the PT had been rerun and no documentation that a root cause analysis had been performed to determine the cause of the PT failures. 5. For the 1st event of 2021 the laboratory scored: Na: 40%, Cl: 80%, CO2: 80%, total protein (TP): 80%, and TIBC (measured): 80%. Corrective actions stated to "Repeat Assays noted" and "QC checked and acceptable for day of testing." There were no instrument printouts present, showing that the PT had been rerun and no documentation that a root cause analysis had been performed to determine the cause of the PT failures. 6. For the 2nd event of 2021 the laboratory scored: alanine aminotransferase: 0%, Alb: 40%, alkaline phosphatase: 60%, aspartate aminotransferase: 20%, Ca: 40%, lactate dehydrogenase: 60%, and TP: 40%. Corrective actions stated, "Unacceptable analytes to be investigated. All errant samples to be repeated." There were no instrument printouts present, showing that the PT had been rerun and no documentation that a root cause analysis had been performed to determine the cause of the PT failures. 7. During an interview on 10/8/2021 at 10:00 AM, the TC confirmed that the laboratory failed to document all corrective actions taken to prevent recurrence of the proficiency testing (PT) failures. |
| **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 record review and phone interview with the technical consultant (TC), the laboratory failed to follow written procedures for performing proficiency testing (D5401, part I); failed to follow written procedures for performing daily maintenance on the Medica EasyRA chemistry analyzer as recommended by the manufacturer (D5401, part II); failed to follow written procedures for documenting corrective |

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| | actions when chemistry quality control (QC) does not meet the laboratory's criteria for acceptability (D5401, part III); failed to follow written procedures for not reporting patient results if QC does not meet the laboratory's criteria for acceptability (D5401, part IV); failed to ensure that daily maintenance was performed on the Medica EasyRA chemistry analyzer as recommended by the manufacturer (D5429); failed to ensure that calibrations for the Medica EasyRA chemistry analyzer were verified at least once every 6 months (D5439); failed to document corrective action procedures when chemistry QC did not meet the laboratory's criteria for acceptability (D5783); and failed to 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 (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>I. Based on procedure manual and proficiency testing (PT) record review and interview with the technical consultant (TC), the laboratory did not follow written procedures for performing PT. Findings: 1. The laboratory's PT procedure states that "Specimens must be rotated among all testing personnel." The laboratory did not ensure that all the testing personnel who tested patient samples performed the PT. Cross refer to D2007; and 2. The PT procedure states, "Staff must retain all documents including test records, result form, attestation sheet and PT evaluation form." The laboratory did not ensure that a copy of all PT documents was maintained by the laboratory for a minimum of two years from the date of the PT testing event. Cross refer to D3037; and 3. The PT procedure states, "PT failures (individual scores or overall event) must be investigated." The laboratory failed to document all corrective actions taken to prevent recurrence of the proficiency testing (PT) failures. Cross refer to D5221 4. During a phone call on 10/8/2021 at 10:00 AM, the TC confirmed that the laboratory did not follow written procedures for performing PT. II. Based on procedure manual and chemistry instrument maintenance record review and phone interview with the technical consultant (TC), the laboratory did not follow written procedures for performing daily maintenance on the Medica EasyRA chemistry analyzer as recommended by the manufacturer. Findings: 1. The laboratory's "Medica EasyRA" "Maintenance" procedure states, "Maintenance is performed according to manufacturer's recommendations." 2. The laboratory uses a Medica EasyRA chemistry analyzer to perform chemistry testing. The analyzer's "Daily Cleaning and Inspection" log records the date daily maintenance is performed and the initials of the testing person (TP) who performed the maintenance. Required maintenance includes: "Probe Clean," "ISE Clean," "Dilutor Pump Check," "Probe Check," "Waste/Diluent Check," and "Pump Tube Check." 3. A review of "Daily Cleaning and Inspection" logs from October and November of 2019 and 2020 showed that in October, 2019 daily maintenance was documented on 6 days. On 2 of 6 days the TP documented performing 2 of the 6 required maintenance duties ("Probe Clean" and "ISE Clean"). 4. In November, 2019 daily maintenance was documented on 15 days. On 8 of 15 days the TP documented performing 2 of the 6 required maintenance duties ("Probe Clean" and "ISE Clean"). 5. In October, 2020 daily maintenance was |

documented on 17 days. On 11 of 17 days the TP documented performing 2 of the 6 required maintenance duties ("Probe Clean" and "ISE Clean"). 6. In November, 2020 daily maintenance was documented on 12 days. On 5 of 12 days the TP documented performing 2 of the 6 required maintenance duties ("Probe Clean" and "ISE Clean"). 7. During a phone interview on 9/30/2021 at 9:30 AM, the TC stated that the laboratory staff declined to use a "print out list" to document maintenance "off line" and confirmed that the laboratory did not follow written procedures for performing required daily maintenance on the chemistry analyzer as recommended by the manufacturer. III. Based on quality control (QC) record and procedure manual review and phone interview and email communication with the technical consultant (TC), the laboratory failed to follow written procedures for documenting corrective actions when chemistry QC does not meet the laboratory's criteria for acceptability. Findings: 1. The laboratory's chemistry "Quality Control" procedure states that "QC will be performed each day of patient testing using a minimum of 2 levels of QC for each analyte tested" and that "Unacceptable QC may be repeated two times to allow for insufficient warm-up or missing before undertaking further actions such as obtaining new QC vials, or checking for any analyzer malfunctions which may be affecting performance and require service. Document any activity." 2. A review of QC run on the Medica EasyRA chemistry analyzer in November, 2019 showed the following for "Level A" QC, lot # 19140: a. Alkaline Phosphatase (Alkp): The QC was out of the laboratory's acceptable range on 11/7/2019. The QC was repeated 1 time but the QC was still not acceptable. QC was out of range and repeated 3 times on 11/8/2019, out of range and repeated 1 time on 11/20/2019, and out of range and repeated 2 times on 11/27/2019. b. Sodium (Na): The QC was out of the laboratory's acceptable range on 11/19/2019. The QC was repeated 1 time but the QC was still not acceptable. QC was out of range and repeated 1 time on 11/20/2019. 3. A review of QC run on the Medica EasyRA chemistry analyzer in November, 2019 showed the following for "Level B" QC lot # 19141: a. Alkp: The QC was out of the laboratory's acceptable range and repeated 1 time on 11/7/2019 and 11/20/2019. QC was out of range and repeated 3 times on 11/8/2019. b. Potassium: The QC was out of the laboratory's acceptable range on 11/13/2019. The QC was repeated 1 time but QC was still not acceptable. QC was out of range and repeated 1 time on 11/18/2019, 11/20/2019, and 11/25/2019, repeated 2 times on 11/8/2019 and 11/27/2019, and repeated 5 times on 11/19/2019. c. Na: The QC was out of range and repeated 1 time on 11/18/2019, 11/19/2019, 11/20 /2019, and 11/25/2019. QC was out of range and repeated 2 times on 11/27/2019. d. Total Iron Binding Capacity (TIBC): The QC was out of the laboratory's acceptable range on 11/27/2019. The QC was repeated 2 times but QC was still not acceptable. 4. A review of remote survey documents submitted to the surveyor by the TC showed that there was no documentation of corrective actions taken for unacceptable chemistry QC. There was no way to determine if patients were tested when QC failed to meet the laboratory's criteria for acceptability. 5. During a phone interview on 9/30 /2021 at 9:30 AM the TC stated that the laboratory did not document any corrective actions performed on an action log and confirmed that the laboratory failed to document corrective action procedures when chemistry QC did not meet the laboratory's criteria for acceptability. IV. Based on quality control (QC) record and procedure manual review and phone interview and email communication with the technical consultant (TC), the laboratory failed to follow written procedures for not reporting patient results if QC does not meet the laboratory's criteria for acceptability. Findings: 1. The laboratory's chemistry "Quality Control" procedure states that "No patient results will be reported until both levels of either control provide acceptable results for each test performed." 2. A review of QC run on the Medica EasyRA chemistry analyzer in November, 2019 showed the following for "Level A" QC, lot # 19140: a. Alkaline Phosphatase: The QC was out of the laboratory's acceptable range

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| | on 11/7/2019. The QC was repeated 1 time but the QC was still not acceptable. b. Sodium: The QC was out of the laboratory's acceptable range on 11/19/2019. The QC was repeated 1 time but the QC was still not acceptable. 3. A review of QC run on the Medica EasyRA chemistry analyzer in November, 2019 showed the following for "Level B" QC lot # 19141: a. Potassium: The QC was out of the laboratory's acceptable range on 11/13/2019. The QC was repeated 1 time but QC was still not acceptable. b. Total Iron Binding Capacity: The QC was out of the laboratory's acceptable range on 11/27/2019. The QC was repeated 2 times but QC was still not acceptable. 4. During a phone interview on 9/30/2021 at 9:30 AM the TC stated that the laboratory did not document any corrective actions performed on an action log. There is no way to determine if patient results were reported when chemistry QC did not meet the laboratory's criteria for acceptability. |
| **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>Based on chemistry instrument maintenance record review and phone interview with the technical consultant, the laboratory did not ensure that daily maintenance was performed on the Medica EasyRA chemistry analyzer as recommended by the manufacturer. Cross-refer to D5401, part II |
| **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>Note: This is a repeat deficiency. The laboratory was cited during the re-certification |

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| | survey on 10/23/2018 for not performing and documenting calibration verification. The plan of correction stated that this would be corrected. Based on calibration record review and electronic communication with the technical consultant, the laboratory failed to ensure that calibrations for the Medica EasyRA chemistry analyzer were verified at least once every 6 months. Cross-refer to D3031 |
| **D5783** | CORRECTIVE ACTIONS<br>CFR(s): 493.1282(b)(2)<br><br>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.<br><br>This STANDARD is not met as evidenced by:<br>Based on quality control (QC) record and procedure manual review and phone interview and email communication with the technical consultant, the laboratory failed to document corrective action procedures when chemistry QC did not meet the laboratory's criteria for acceptability. Cross-refer to D5401, part III |
| **D5791** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(a)(c)<br><br>(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>Note: This is a repeat deficiency. The laboratory was cited during the re-certification survey on 10/23/2018 for not accurately documenting analytic systems problems in their quality assessment reviews. The plan of correction stated that this would be corrected. Based on quality control (QC) and quality assurance (QA) record and procedure manual review and interview with the technical consultant (TC), the laboratory did not 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. Findings: 1. In emails sent to the TC on 4/28/2021, 7/26/2021, 9/10/2021, 9/21/2021, 9/24/2021, and 9/29/2021 the surveyor requested documents needed to complete a remote survey of the laboratory. The laboratory did not submit a procedure for performing QA reviews, however the TC did send completed "Quality Assessment Review" forms from October and November of 2019 and 2020. 2. On the "Quality Assessment Review" forms the QA review lists the QA tasks that the TC performs as part of the QA review each month. The TC checks "YES," "NO," or "N/A" to indicate that the task was performed. 3. Under the heading "Analyzer/Test Process," "Medica EZ RA" are the tasks, "Was all maintenance (daily, weekly, monthly and periodic) performed as required by the manufacturer?" and "Was all maintenance documented by performing tech?" All tasks were marked, "YES." Record review showed that the laboratory did not ensure that |

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| | daily maintenance was performed on the Medica EasyRA chemistry analyzer as recommended by the manufacturer. Cross-refer to D5429 4. The tasks, "Was Action Log reviewed for any issues with analyzer/testing?" and "Were issues addressed, resolved, documented?" were marked "YES." During a phone interview the TC stated that the laboratory did not have or use an "Action Log." Cross-refer to D5783 5. Under the heading "Quality Control," "Daily Performance," is the task, "Any required Corrective Action properly documented." All tasks were marked, "YES." Record review showed that the laboratory failed to document corrective action procedures when chemistry QC did not meet the laboratory's criteria for acceptability. Cross-refer to D5783 6. During an interview on 10/8/2021 at 10:00 AM, the TC confirmed that analytic systems problems were not accurately documented in the QA reviews. |
| **D6000** | MODERATE COMPLEXITY LABORATORY DIRECTOR<br>CFR(s): 493.1403<br><br>The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.<br><br>This CONDITION is not met as evidenced by:<br>Based on record review and interview with the technical consultant, the laboratory director failed to ensure that all proficiency testing reports were reviewed to evaluate the laboratory's performance and to identify any problems that require corrective action (D6018); failed to ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory (D6019); failed to ensure that quality control and quality assurance procedures monitored the overall operation of the laboratory to identify failures in quality as they occur (D6022); and failed to ensure that the laboratory had documentation that all testing personnel had the appropriate education, experience, and training to perform laboratory testing (D6029). |
| **D6018** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(4)(iii)<br><br>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;<br><br>This STANDARD is not met as evidenced by:<br>Based on proficiency testing (PT) record review and interview with the technical consultant (TC), the laboratory director (LD) failed to ensure that all PT reports were reviewed to evaluate the laboratory's performance and to identify any problems that require corrective action. Findings: 1. The laboratory ordered 2 sets of "Remedial PT" as part of their corrective action for failed chemistry PT in October, 2019. 2. PT record review showed that the laboratory had a copy of the performance evaluation (scores) for "Chemistry - Core - Event 65R" and "Chemistry - Core - Event 66R" for the analytes calcium, carbon dioxide, and sodium dated 10/29/2019. The PT report |

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| | was not signed and dated by the LD to show that they had reviewed the remedial PT. 3. During an interview on 10/8/2021 at 10:00 AM, the TC confirmed that chemistry PT results were not reviewed by the appropriate staff to evaluate the laboratory's performance. |
| **D6019** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(4)(iv)<br><br>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.<br><br>This STANDARD is not met as evidenced by:<br>Note: This is a repeat deficiency. The laboratory was cited during the re-certification survey on 10/23/2018 for the laboratory director not ensuring that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. The plan of correction stated that this would be corrected. Based on proficiency testing (PT) record review and interview with the technical consultant, the laboratory director failed to ensure that corrective action was taken and documented for failed chemistry PT for 5 PT events in 2019 through 2021. Cross-refer to D5221 |
| **D6022** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<br><br>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.<br><br>This STANDARD is not met as evidenced by:<br>Based on quality assurance (QA) and quality control (QC) record review, and interview with the technical consultant (TC), the laboratory director (LD) failed to ensure that QC and QA procedures monitored the overall operation of the laboratory to identify failures in quality as they occur. Findings: 1. The laboratory did not ensure that all the testing personnel who tested patient samples performed the proficiency testing. Cross-refer to D2007 2. The laboratory failed to retain all analytic systems records for at least 2 years. Cross-refer to D3031 3. The laboratory did not ensure that a copy of all PT documents was maintained by the laboratory for a minimum of two years from the date of the PT testing event. Cross-refer to D3037 4. The laboratory failed to document all corrective actions taken to prevent recurrence of the proficiency testing (PT) failures. Cross-refer to D5221 5. The laboratory did not follow the written procedures in the laboratory's procedure manual. Cross-refer to D5401, parts I through IV 6. The laboratory did not ensure that daily maintenance was performed on the Medica EasyRA chemistry analyzer as recommended by the manufacturer. Cross-refer to D5429 7. The laboratory failed to ensure that calibrations for the Medica |

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| | EasyRA chemistry analyzer were verified at least once every 6 months. Cross-refer to D5439 8. The laboratory failed to document corrective action procedures when chemistry QC did not meet the laboratory's criteria for acceptability. Cross-refer to D5783 9. The laboratory did not 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. Cross-refer to D5791 10. During a phone exit interview on 10/8/2021 at 10:00 AM, the TC confirmed that the LD failed to ensure that QC and QA procedures monitored the overall operation of the laboratory to identify failures in quality as they occur. |
| **D6029** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(11)<br><br>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) 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 record review and interview with the technical consultant (TC), the laboratory director (LD) failed to ensure that the laboratory had documentation that all testing personnel had the appropriate education, experience, and training to perform laboratory testing. Findings: 1. The laboratory currently has 4 testing personnel listed on the "Laboratory Personnel Report (CMS-209)" form. 2. A review of training and competency assessment records from 2018 to 2021 showed that 2 of 4 testing personnel had an "annual" competency assessment performed on 4/5/2021. There were no other competency assessments available for these 2 testing personnel at the time of the survey. 3. During a phone interview on 10/8/2021 at 10:00 AM, the TC confirmed that the LD did not ensure that all testing personnel had the appropriate education to perform laboratory testing. |
| **D6033** | TECHNICAL CONSULTANT-MODERATE COMPEXITY<br>CFR(s): 493.1409<br><br>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.<br><br>This CONDITION is not met as evidenced by:<br>Based on record review and interview with the technical consultant (TC), the TC failed to ensure that corrective action procedures were performed and documented when the chemistry quality control did not meet the laboratory's criteria for acceptability (D6043); failed to ensure that patient test results are reported only when the system is functioning properly (D6044); and failed to evaluate the competency of all testing personnel and ensure that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently (D6046). |
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| **D6043** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(5)<br><br>(b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;<br><br>This STANDARD is not met as evidenced by:<br>Note: This is a repeat deficiency. The laboratory was cited during the re-certification survey on 10/23/2018 for the technical consultant not ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications. The plan of correction stated that this would be corrected. Based on quality control (QC) and quality assurance record and procedure manual review and interview with the technical consultant (TC), the TC failed to ensure that corrective action procedures were performed and documented when the chemistry QC did not meet the laboratory's criteria for acceptability. Cross-refer to D5783 |
| **D6044** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(6)<br><br>(b) The technical consultant is responsible for-- (b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly;<br><br>This STANDARD is not met as evidenced by:<br>Note: This is a repeat deficiency. The laboratory was cited during the re-certification survey on 10/23/2018 for not ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly. The plan of correction stated that this would be corrected. Based on quality control record and procedure manual review and interview with the technical consultant (TC), the TC failed to ensure that patient test results are reported only when the system is functioning properly. Cross-refer to D5401, part IV |
| **D6046** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(8)<br><br>(b) The technical consultant is responsible for-- (b)(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview with the technical consultant (TC), the TC failed to evaluate the competency of all testing personnel and ensure that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. Cross-refer to D6029 |