| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 04D2275644 | 01/24/2024 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Unity Health Jacksonville | 1400 Braden Street, Jacksonville, AR | |

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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| **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>Through review of the College of American Pathologists (CAP) Proficiency Test docuemtnation for 2023, lack of documentation, and interview with laboratory staff it was determined that the laboratory director failed to sign the attestation forms in seven of seven events surveyed for 2023. Finding follow: A) Review of the attestion forms from seven CAP 2023 proficiency test events revealed that the laboratory staff member (# 1 on the CMS form 209) signed the forms as laboratory director or designee. B) Upon request the laboratory could not produce documentation of laboratory staff member (# 1 on CMS form 209) having the designation to sign proficiency testing attestation forms for the laboratory director. C) In an interview on 1 /23/24 at 01:10 p.m., when asked if she had been delegated by the laboratory director to sign the attestations as the designee, the laboratory staff member (# 1 on the CMS form 209) replied, "no". |
| **D2016** | SUCCESSFUL PARTICIPATION<br>CFR(s): 493.803(a)(b)(c)<br><br>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action |

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| | when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of the 2023 College of American Pathologist (CAP) proficiency testing results, it was determined the laboratory failed to have initial successful participation in proficiency testing for the analyte Alcohol. Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance as cited at D2118. |
| **D2118** | TOXICOLOGY<br>CFR(s): 493.845(f)<br><br>Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the 2023 CAP proficiency testing results, it was determined the laboratory failed to have satisfactory participation in proficiency testing for the analyte Alcohol. Survey Findings follow: A) A review of the proficiency testing results revealed the laboratory received a score of 40% for the analyte Alcohol on the second proficiency testing event of 2023. B) A review of the proficiency testing results revealed the laboratory received a score of 0% for the analyte of Alcohol in the third proficiency testing event of 2023. |
| **D5311** | SPECIMEN SUBMISSION, HANDLING, AND REFERRAL<br>CFR(s): 493.1242(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Through review of laboratory reagent package inserts, patient records, and interview it was determined that the laboratory failed to follow policy pertaining to preanalytic handling of patient samples for Ammonia testing. Findings follow: A) Review of the laboratory package insert for Ammonia Ultra (6K89-30, 307237/R04, B6K8Q0, rev |

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| | July 2017) revealed that for Ammonia specimens "the standard recommendation id no motr yhsn 15 minutes from sample collection to start of centrifugation." B) Review of patient records for October 2024 showed one of two patent samples was accepted by the laboratory over 15 minutes from sample collection. Specimen # 1012:C00771S was collected on 10/12/23 at 22:00 and was accepted by the laboratory on 10/12/23 at 22:38. C) In an interview on 1/24/24 at 22:11 , Testing Person #1, as listed on the CMS 209 form, confirmed that the specimen identified above were accepted for testing despite having been collected over 30 minutes prior to it's arrival at the laboratory. |
| **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>Through reveiw of "Sysmex CA-660 QC (Quality Control) Print Outs", instrument validation data, patient reports, and "QAP" peer user group report for Dade Citrol QC03 material lot number 556569, documentation of corrective action, lack of documentation, and interview it was determined that the laboratory failed to meet system requirments for analytic systems as evidenced by: D5441: The laboratory failed to employ a system of quality control (QC) which monitored changes over time for Prothrombin Time (PT) and Partiel Thromboplastin Time (PTT) assays performed on the Sysmex CA-660 coagulation analyzer. D5469: The laboratory failed to use appropriate statistical methods to develop target and range values for acceptable QC results for PT and PTT analyses performed on the Sysmex CA-660 coagulation analyzer. D5481: The laboratory reported PT results when QC values were outside the laboratory's acceptable range. D5545: The laboratory failed to perform two levels of QC for PT analysis each eight hours of patient testing. D5779: The laboratory failed to document corrective action when QC failed to be within acceptable limits for PT testing. D5783: The laboratory failed to evaluate patient results back to the instance of last successful PT QC results when QC results were outside the laboratory's acceptable range. D5793: The analytic system quality assessment failed to review the effectiveness of corrective action. |
| **D5441** | CONTROL PROCEDURES<br>CFR(s): 493.1256(a)(b)(c)(g)<br><br>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) |

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| | The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Through review of "Sysmex CA-660 QC (Quality Control) Printout" reports, interview, instrument validation data, and review of the "QAP" peer user group report for Dade Citrol QC03 material lot number 556569, it was determined that the laboratory's QC procedures did not monitor changes in method performance over time. Findings follow: A) Review of the "Sysmex CA-660 QC Printout" for Citrol QC03 material lot # 556569 for November 2023 revealed that Prothrombin Time (PT) had a mean value of 48.6 seconds and an acceptable range based upon plus/minus 2 standard deviations (SD) of 43.4 to 53.8 seconds. B) In an interview at 01:01 p.m. on 1 /24/24, the laboratory staff member, (#1 on CMS form 209) provided a data sheet labeled "30 replicates of each QC used to establish acceptable range" which listed a mean value of 44.73 seconds and an acceptable range of 42.7 to 46.7 seconds for QC03 Citrol lot # 556569 and stated the data was developed in January and February 2023 during validation of the instrument and that she did not enter that value to establish a target and acceptable range for QC03 lot # 556569 on the Sysmex CA-660 analyzer. C) Review of the "Sysmex CA-660 QC Printout" for Ctirol QC03 material lot # 556569 for November 2023 revealed that 73 of 97 total results were greater than the highest acceptable value as determined in the "30 replicates of each QC used to establish acceptable range" data set provided by the laboratory staff member (# 1 on CMS form 209) as cited above. D) Review of the "QAP" peer user group report for Dade Citrol QC03 material lot number 556569 for Decenber 2023 revealed that the peer group of laboratories performing PT analysis on the Sysmex CA-660 system reported an aggregate mean value of 45.74 seconds and a plus/minus 2SD range of 43.69 to 47.79 which approximated the initial target and range established by the laboratory in February 2023 as provided in the document "30 replicates of each QC used to establish acceptable range" . |
| **D5469** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Through observation, review of "Sysmex CA-0660 QC Printouts", and interviews with laboratory staff members it was determined that the laboratory did not use appropriate statistical methods to develop target and range values for acceptable quality control (QC) results. Findings follow: A) During a tour of the laboratory on 1 /23/24 at 08:47 a.m. a Sysmex CA-660 coagulation analyzer was observed with a |

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| | single hand-lettered note posted on the analyzer denoting the "Reportable Range" of the analyzer. B) Review of the 'Sysmex CA-660 Printout" for November 2023 revealed a list of QC results by date and time and a Levy Jennings (LJ)chart with lines denoting "Stop-UL" and "Stop-LL" with a legend of "Stop-UL 0.0 sec", "Target 0.0 sec", and "Stop-LL 0.0 sec". C) In an interview on 1/24/24 at 09:40 a.m., the laboratory staff member ( # 2 on CMS form 209) identified herself as the primary user of the Sysmex CA-660 coagulation instrument and, when asked how she determined if QC results were acceptable, stated "by experience" and sometimes she uses the LJ chart. |
| **D5481** | CONTROL PROCEDURES<br>CFR(s): 493.1256(f)(g)<br><br>(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Through review of the laboratory's policy and procedure for "Coagulation Quality Control PT and PTT" , "Sysmex CA-660 QC Printouts" report, patient results, and interview it was determined that the laboratory reported Prothrombin Time (PT) results when quality control (QC) results were outside of the laboratory's acceptable range. Findings follow: A) Review of the laboratory's policy and procedure "Coagulation Quality Control PT and PTT" revealed "QC should be within the laboratory's established limits" prior to reporting patient results". B) Review of the "Sysmex CA-660 QC Printouts" report for November 2023 revealed that QC03 lot # 556569 with a the instrument defined (plus/minus 2 standard deviations) acceptable range of 43.4 to 53.8 seconds was reported 54.7 on 11/7/23 at 23:48 hours, 55.8 on 11 /8/24 at 00:10 hours, as 55.8 on 11/9/23 at 07:30 hours, as 55.7 on 11/9/23 at 15:31 hours, before being acceptable on 11/9/23 at 16:15 hours. C) Review of patient results revealed that four PT tests were performed and reported on patients, identified as numbers 1 through 4 on a separate patient identification list, from 11/7/23 at 23:48 hours until 11/9/23 at 16:15 hours. D) In an interview on 1/24/24 the laboratory staff members (#'s 1 and 2 on the CMS form 209) confirmed that PT tests were performed and reported on patients identified above when quality control was unacceptable. |
| **D5545** | HEMATOLOGY<br>CFR(s): 493.1269(b)(d)<br><br>(b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section.<br><br>This STANDARD is not met as evidenced by:<br>Through a review of quality control documentation on "Sysmex CA-660 QC Printout reports for Prothrombin Time (PT) testing performed in November 2023, a review of patient test records in November 2023, and interviews with laboratory staff, it was determined the laboratory failed to perform two levels of quality control for PT testing each 8 hours of testing in 2 of 30 days reviewed. Survey findings include: A) A review "Sysmex CA-660 QC Printout reports for November 2023 revealed that |

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| | quality control was performed on 11/8/23 at 00:10 hours and wasn't repeated until 11/9 /23 at 16:15 hours. B) A review of patient test records revealed the following examples of patients tested greater than 8 hours after quality control was performed: . patient #1 on the separate patient identification list the PT was performed and reported on 11/9/23 at 06:14 a.m. patient # 2 on the separate patient identification list the PT was performed and reported on 11/8/23 at 09:15 a.m., patient #3 on the separate patient identification list the PT was performed and reported on 11/8/23 at 10:14 a.m. C) During an interview at 01:31 on 1/24/24 the employee #1 (as listed on the form CMS-209) confirmed that the laboratory failed to perform PT quality control each eight hours of patient testing. |
| **D5779** | CORRECTIVE ACTIONS<br>CFR(s): 493.1282(a)<br><br>Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.<br><br>This STANDARD is not met as evidenced by:<br>Through review of the laboratory's policy for "Coagulation Quality Control PT and PTT", Sysmex CA-660 QC Printouts" report, the "CA-600 Corrective Action Log, lack of documentation, and interview with laboratory staff, it was determined that the laboratory failed to document corrective action when quality control (QC) failed to be within acceptable range on one of twelve occasions in November 2023. Findings follow: A) The laboratory's policy "Coagulation Quality Control PT and PTT" states "All rule violations, repeated QC, and the steps in the corrective action process for unacceptable controls must be documented in the appropriate corrective action logbook". B) Review of the "Sysmex CA-660 QC Printouts" report for November 2023 revealed that QC03 lot # 556569 with a instrument defined acceptable range of 43.4 to 53.8 seconds for PT testing was reported 54.7 on 11/7/23 at 23:48 hours, 55.8 on 11/8/24 at 00:10 hours, as 55.8 on 11/9/23 at 07:30 hours, as 55.7 on 11/9/23 at 15: 31 hours, before being acceptable on 11/9/23 at 16:15 hours. C) Review of the "CA-600 Corrective Action Log" for November 2023 revealed that there as no corrective action documented 11/7/23 and 11/8/23. D) Upon request, the laboratory could not provide documentation of corrective action taken on 11/7/23 and/11/8/23. E) In an interview on 11/24/24 at 01:01 p.m. the laboratory staff members (#'s 1 and 2 on CMS form 209) confirmed there was no documentation of corrective action for 11/7/23 and 11/8/23. |
| **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: |

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| | Through review of the laboratory's policy and procedure for "Coagulation Quality Control (QC) PT and PTT" "Sysmex CA-660 QC Printouts" report, patient results, lack of documentation, and interview it was determined that the laboratory failed to evaluate patient results back to the last successful Prothrombin Time (PT) QC results when quality control (QC) results were outside of the laboratory's acceptable range. Findings follow: A) Review of the "Sysmex CA-660 QC Printouts" report for November 2023 revealed that QC03 lot # 556569 with a laboratory defined acceptable range of 43.4 to 53.8 seconds was reported 54.7 on 11/7/23 at 23:48 hours, 55.8 on 11 /8/24 at 00:10 hours, as 55.8 on 11/9/23 at 07:30 hours, as 55.7 on 11/9/23 at 15:31 hours, before being acceptable on 11/9/23 at 16:15 hours. B) Review of the "Sysmex CA-660 QC Printouts" report for November 2023 revealed that the last successful QC results occured on 1/7/23 at 15:56 hours. C) Review of patient results revealed that four PT tests were performed and reported on patients, identified as numbers 1 through 4 on a separate patient identification list, from 11/7/23 at 23:48 hours until 11 /9/23 at 16:15 hours. D) Upon request, the laboratory was unable to provide documentation that the patient results identified above had been evaluated. E) In an interview on 1/24/24 the laboratory staff members (#'s 1 and 2 on the CMS form 209) confirmed that PT tests were performed and reported on patients identified above and had not been evaluated. |
| **D5793** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(b)(c)<br><br>(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.<br><br>This STANDARD is not met as evidenced by:<br>Through review of the laboratory's policy for "Quality Assurance", College of American Pathologist (CAP) proficiency test (PT) results for 2023, laboratory notes of corrective action, and interview it was determined that the corrective action employed to correct PT deficiencies was unsuccessful. Findings follow: A) Review of the laboratory's policy and procedure for Quality Assurance revealed "the lab assesses the effectiveness of corrective action taken to address any unacceptable, unsatisfactory or unseccessful PT results, the laboratory will take corrective action if there is a failure". B) Review of CAP 2023 General Chemistry and Therapeutic Drug Monitoring 2023 event "A" revealed a score of 0% for Ammonia determination. C) Review of the corrective action for the event identified above stated "Ammonia not run in 24 hours as per instructions". D) Review of CAP 2023 General Chemistry and Therapeutic Drug Monitoring 2023 event "C "revealed a score of 0% for Ammonia determination. E) Review of the corrective action for the event identified above stated "Ammonia not tested within 72 hours". F) Review of CAP 2023 Hematology 2023 event "B "revealed a score of 0% for Mean Corpuscular Hemoglobin Concentration (MCHC) with corrective action "we reported to CAP in grams per deciliter instead of grams per liter". G) Review of CAP 2023 Hematology 2023 event "C" revealed a score of 0% for Mean Corpuscular Hemoglobin Concentration (MCHC) caused by reporting the results in incorrect units.. H) In an interview the laboratory staff member (#1 on the CMS form 209) confirmed that corrective actions for the deficient PT performances were not effective. |
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| **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>The Laboratory Director failed to provide overall management and direction as evidenced by: D6016: The lab director failed to ensure the laboratory successfully participated in proficiency testing for the Chemistry test of Alcohol as cited at D2118 D6025: The laboratory director failed to ensure test results are reported only when testing systems are functioning properly. D6032: The laboratory director failed to ensure the laboratory was staffed with personnel who are competent and authorized by the laboratory director to perform testing. |
| **D6016** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(4)(i)<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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the 2023 proficiency testing events, it was determined the laboratory director failed to ensure the laboratory successfully participated in proficiency testing for the Chemistry test of Alcohol as cited at D2118. |
| **D6025** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(7)<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)(7) Ensure that patient test results are reported only when the system is functioning properly.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of quality control documentation for November 2023, and through interviews with laboratory staff, it was determined the Laboratory Director failed to ensure patient results were only reported when the system was functioning properly which had the potential to affect all patient coagulation testing. Survey findings include: The laboratory failed to take and document corrective actions when controls failed to meet the instrument calculated acceptable range as cited at D5779. The |

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| | laboratory reported patient results when controls failed to meet the laboratory's acceptable limits as cited at D5481. The laboratory failed to perform two levels of QC for coagulation testing within eight hours of patient testing as cited at D5545. |
| **D6032** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(14)<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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.<br><br>This STANDARD is not met as evidenced by:<br>. Through a review of personnel files for the twelve testing personnel listed on the form CMS-209, lack of documentation, and interviews with laboratory staff, it was determined the laboratory director failed to authorize five of twelve testing personnel to perform testing without direct supervision. Survey findings include: A) During a review of personnel files for twelve testing personnel listed on form CMS-209 (Personnel #1 - #12) the surveyor determined employees numbers 8 through 12 (as listed on the form CMS-209) failed to have written authorization, from the laboratory director, to perform moderate complexity Arterial Blood Gas (ABG) testing without direct supervision. B) In an interview, at 10:05 a.m. on 1/23/24, laboratory employee #1 (as listed on the form CMS-209) confirmed the lack of written authorizations to test for employees numbers 8 through 12. |
| **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>Through review of CMS 209 form, review of Quality Control (QC) records, corrective action documentation, personnel competency assessments, lack of documentation, and interview it was determined that the laboratory had failed to employ a Technical Consultant and responsibilities of the Technical Consultant were not being met. Findings follow: A) On 1/23/24 at 08:45 a.m. the CMS 209 form prepared by the laboratory did not designate a Technical Consultant. B) The responibilities of the Technical consultant were not being met as evidenced by: D6046: Competencies were not performed on five of twelve testing personnel, D6042: QC procedures did not monitor test performance over time, as cited in D5441 QC target and acceptable limits were not determined by an appropriate statistical method, as cited at D5469 D6043: Quality assurance procedures did not incude a review of the effectiveness of corrective actions taken to resolve problems as cited at D5793 D6044: Patient results |

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| | were reported when QC was outside acceptable limits as cited at D5481 C) In an interview on 1/23/24 at 01:10 p.m., the laboratory staff member (# 1 on the CMS form 209) confirmed that she did not have responsibilities of the technical consultant delegated to her by the laboratory director. |
| **D6042** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(4)<br><br>(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;<br><br>This STANDARD is not met as evidenced by:<br>Through review of "Coagulation Quality Control PT and PTT" policy and procedure, quality control (QC) result reports, Sysmex CA-660 validation data, QAP peer group reports for Citrol lot # 556569 and interview, it was determined that a quality control program appropriate for the testing performed was not established as cited at: D5441: QC procedures did not monitor test over time. D5469: QC target and acceptable limits were not determined by the appropriate statistical methods. D5545: The laboratory failed to perform two level of QC every eight hourrs of patient testing for coagulation testing. |
| **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>Through review of quality control reports, quality control corrective action logs, patient results and interview it was determined that the laboratory failed ensure that patient results are not reported until remedial actions have been taken and the test system is functioning properly. as cited at: D5481: Patient Prothrombin Time results were reported when QC was outside the intrument determined acceptable limit. |
| **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 review of the personnel records, lack of documentation, as well as interview with laboratory staff, it was determined the Technical Consultant failed to evaluate the competency of testing personnel for using the required competency assessment components as evidence by: A) A review of personnel records revealed that testing |

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| | personnel (numbers 8 through 12 on the CMS form 209) , who perform moderately complex Arterial Blood Gas (ABG) testing, had a form documenting training /orientation but no competency assessment using the following required components: a. Assessment of problem solving skills b. Direct observation of routine patient test performance, including patient preparation. c. Monitoring the recording and reporting of test results. d. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records e. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. B) Upon request, thew laboratory could not produce competency assessments for the persoonel identified above. C) In an interview at 10:05 on 1/23/24, employee #1 (as listed on the form CMS-209) confirmed the that competency assessments including the documentation of: assessment of problem solving skills; direct observation; monitoring recording and reporting of test results; review of worksheets; quality control records; maintenance; and proficiency samples; or assessment through blind testing samples were not presnt for the employees identified above. . |