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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 26D0969305 | (X3) Date Survey Completed 07/30/2019 |
| Name of Provider or Supplier Jackson Medical Center | Street Address, City, State 2387 W Jackson Blvd, Jackson, MO | |
| 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 |
|---------------------------|--|
| D5200 | <p>GENERAL LABORATORY SYSTEMS CFR(s): 493.1230</p> <p>Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory policies, procedures, competency evaluations, and proficiency testing records the laboratory failed to follow policies and perform competencies for the position of technical consultant (refer to D5209) and failed to verify accuracy of non regulated analytes twice yearly (refer to D5217). This is a repeat deficiency previously cited on June 28, 2017.</p> |
| D5209 | <p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of the procedure manual, personnel documentation and interview with the testing personnel (TP) #1, the laboratory failed to follow the laboratory policy and perform a competency evaluation for 2018 and to date July 29, 2019 for the position of technical consultant. Findings: 1. Review of 2018, 2019 personnel</p> |

documentation revealed the laboratory failed to perform 1 of 1 competency assessment for the position of technical consultant. 2. Review of the policy for competency evaluation revealed "The competency of each employee will be documented. Evaluations will be performed twice during the first year of employment and annually thereafter." 3. Interview with the TP #1 on July 29, 2019 at 4:00PM confirmed the laboratory failed to follow and perform annual competencies for 2018 and to date July 29, 2019 for the position of technical consultant. TP #1 stated, "The technical consultant has not been here for one and one-half years." This is a repeat deficiency previously cited on June 28, 2017.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:
Based on review of the procedure manual, accuracy verification records, proficiency testing (PT) records for 2017, 2018 and to date July 29, 2019, and interview with the testing personnel #1, the laboratory failed to establish a means to verify the accuracy of the non-regulated analytes: C-reactive protein(CRP), urine microalbumin, potassium hydroxide (KOH) and urine microscopic exam testing twice a year. Findings: 1. Review of the quality assessment program policy showed "Two times per year accuracy verification will be accomplished through in-house look behind or send out to a reference laboratory for comparison testing." 2. Review of CRP PT for the third event of 2017 showed a result of 50 percent. 3. Review of CRP PT for the first event of 2018 showed a result of 0 percent. 4. Review of CRP PT for the second event of 2018 showed a result of 50 percent. 5. Review of CRP PT for the third event of 2018 showed a result of 50 percent. 6. Review of CRP PT for the first event of 2019 showed a result of 0 percent. 7. Review of PT records revealed the laboratory was not enrolled in PT testing to prove accuracy and did not perform accuracy verification procedures for urine microalbumin, KOH, and urine microscopic exam testing. 8. Interview with the testing personnel #1 on July 29, 2019 at 4:00 PM confirmed the laboratory failed to verify the accuracy of the non-regulated analytes: CRP, KOH, urine microalbumin and urine microscopic exam testing twice annually for 2017, 2018 and to date July 29, 2019. This is a repeat deficiency previously cited on June 28, 2017.

D5400

ANALYTIC SYSTEMS
CFR(s): 493.1250

Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:
Based on review of the procedure manual, quality control logs, calibration records, and interview, the laboratory failed to follow quality control parallel testing procedure

(refer to D5401), failed to follow the lab's procedure for calibration verification (refer to D5439), failed to verify quality control ranges (refer to D5441), and failed to follow quality control procedure (refer to D5447).

D5401

PROCEDURE MANUAL
CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

Based on review of Horiba ABX Pentra 400 chemistry procedure, chemistry quality control (QC) and interview with testing personnel #1, the laboratory failed to follow Horiba ABX Pentra QC procedure. Findings: 1. Review of Horiba ABX Pentra 400 chemistry procedure stated "prior to initiating use of any new lot number of controls, new controls must be performed in parallel to assure the viability of the new controls". No parallel testing of QC was documented for 2018 or to date July 29, 2019. 2. Interview with testing personnel #1 on July 29, 2019 at 4:30 PM confirmed the laboratory failed to follow the Horiba ABX Pentra 400 chemistry procedure.

D5435

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(b)(2)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

Based on observation of two of two centrifuges, the microscope used for urine microscopy, review of the policy and procedure manual, function check documentation, and interview with the testing personnel (TP) #1, the laboratory failed to perform a function check for 2017, 2018 and to date July 29, 2019. Findings: 1. Observation of the microscope used for urine microscopy revealed no function check for 2017, 2018 and to date July 29, 2019. 2. Review of the policy and procedure manual showed a policy "the microscope is to be serviced annually by an outside source." 3. Observation of the urinalysis/serum multi-speed centrifuge and chemistry fixed speed centrifuge revealed no documentation to show the laboratory performed function checks to verify the accuracy of the speed and timer mechanisms. 4. Interview with TP #1 on July 29, 2019 at 4:00 PM confirmed the laboratory failed to perform and document function checks to verify accurate performance of the laboratory centrifuges and the microscope used for urine microscopy.

D5439

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(b)

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.

This STANDARD is not met as evidenced by:

Based on review of the policy and procedure manual, 2017, 2018, and to date July 29, 2019 calibration verification records for the Tosoh A1A chemistry analyzer and interview with the testing personnel (TP) #1, the laboratory failed to perform calibration verification procedures at least once every six months that included at least a minimal value, a mid-point value and a maximum value near the upper limit to verify the laboratory's reportable range for prostatic specific antigen (PSA), testosterone (TEST), triiodothyronine uptake (T3U), thyroid stimulating hormone (TSH), and thyroxine (T4). Findings: 1. Review of the calibration verification policy showed "It is the policy for this company to perform every 6 months a calibration verification on all moderately complex instruments. This includes all non-waived analytes that do not have three or more calibrators." 2. No calibration verification records were available for review for the analytes: PSA, TEST, T4, T3U, TSH on the Tosoh A1A analyzer for 2017, 2018, and to date July 29, 2019. 3. Interview with TP #1 on July 29, 2019 at 4:00 PM confirmed the laboratory failed to perform calibration verification procedures for the analytes: PSA, TEST, T4, T3U, TSH performed on the Tosoh A1A analyzer at least once every six months. 38475 Based on review of policy and procedure manual, Emerald Celldyn hematology calibration verification, Horiba ABX Pentra 400 chemistry calibration verification, and interview with testing personnel (TP) #1 the laboratory failed to perform calibration verification procedures at least once every six months that included at least a minimal value, a mid-point value, and a maximum value near the upper limit to verify the laboratory's reportable range. Findings: 1. Review of the calibration verification policy revealed, "It is the policy for this company to perform every 6 months a calibration verification on all moderately complex instruments. This includes all non-waived analytes that do not have three or more calibrators." 2. Review of Emerald Celldyn hematology calibration revealed no calibration for 2018. 3. Review of Horiba ABX Pentra 400 chemistry calibration for CO2, Blood Urea Nitrogen, Creatinine, Albumin, Glucose, Alkaline phosphatase, Alanine Aminotransferase, Aspartate Aminotransferase, Total Bilirubin, Total Protein, Cholesterol, Triglycerides, High Density Lipoprotein, Direct Bilirubin, Uric Acid, C-reactive protein, and Low Density Lipoprotein revealed no calibration

for 2018 and to date July 29, 2019. 4. Interview with TP #1 on July 29, 2019 at 4:30 PM confirmed the laboratory failed to follow calibration verification procedure for the Emerald Celldyn and Horiba ABX Pentra 400. This is a repeat deficiency, previously cited on June 28, 2017.

D5441

CONTROL PROCEDURES
CFR(s): 493.1256(a)(b)(c)(g)

(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) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of Horiba ABX Pentra 400 chemistry quality control (QC) for 2018, to date July 29, 2019, and interview with testing personnel (TP) #1 the laboratory failed to monitor the accuracy and precision of QC materials. Findings: 1. Review of Horiba ABX Pentra 400 chemistry procedure states "After running the controls, review the results (the assay values are provided for each parameter specific for the lot number). The recovered values must fall within the limits of the expected values." 2. Review of QC for November 2018 revealed: - The creatinine QC level 1 confidence range (QC range) was 1.0-1.2. - Review of the Levey-Jennings graph revealed creatinine was not within acceptable range on November 6, 7, 10, 16, 17, 19, 27 and 28, 2018. The laboratory was unable to provide the QC package insert. 3. Review of QC for November 2018 revealed: - The glucose QC level 1 confidence range (QC range) was 26-277. - The mean was 255. - The standard deviation was 4. The laboratory failed to identify an accurate confidence range. The laboratory was unable to provide the QC package insert. 4. Review of QC for June 2019 revealed: - The glucose level 1 confidence range (QC range) was 26-277. - The mean was 243. - The standard deviation was 11. The laboratory failed to identify an accurate confidence range. The laboratory was unable to provide the QC package insert. 5. The laboratory could not provide documentation for Horiba ABX Pentra 400 chemistry QC in February 2018, May 2018, June 2018, August 2018, September 2018, October 2018, December 2018, and March 2019. Approximately patients were tested and those results were reported to ordering providers. 6. Interview with TP #1 on July 29, 2019 at 4:30 PM confirmed the laboratory failed to monitor the accuracy and precision of QC materials for 2018 and 2019.

D5447

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(i)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the policy and procedure manual, quality control (QC) logs, and interview with testing personnel (TP) #1, the laboratory failed to perform and document at least two levels of external controls each day of patient testing for urine microalbumin testing performed on the Afinion. Findings: 1. Review of the quality assessment policy revealed "perform and document two levels of control material each day patient samples are tested." 2. No QC documentation was available for review for 2017, 2018, and to date July 29, 2019. 3. 750 patients were tested and those results were reported to ordering providers. 4. Interview with TP #1 on July 29, 2019 stated "I cannot locate the QC for microalbumin from 2017 to now on the Afinion." 38475 Based on review of the Emerald Celldyn hematology procedure, quality control (QC) for 2018, 2019, Horiba ABX Pentra 400 chemistry procedure, and interview with testing personnel (TP) #1, the laboratory failed to document two QC materials of different concentrations each day of patient testing for 24 of 24 patient testing days in June 2019 for hematology, eight of twelve months in 2018 for chemistry, and one of seven months in 2019 for chemistry. Findings: 1. Review of Emerald Celldyn hematology QC procedure states "There are three levels of controls for the Emerald. At least two levels must be within range to report patient results". 2. Review of hematology QC showed no documentation of QC 6/2/19 through 6/30/19 and approximately 130 patient results were reported. 3. Review of Horiba ABX Pentra 400 quality control protocol states "There are two levels of control for each analyze being ran on the Pentra. At least one control must be within range to report patient results." 4. Review of chemistry QC revealed no documentation of Horiba ABX Pentra 400 QC for the analytes: CO₂, Blood Urea Nitrogen, Creatinine, Albumin, Glucose, Alkaline phosphatase, Alanine Aminotransferase, Aspartate Aminotransferase, Total Bilirubin, Total Protein, Cholesterol, Triglycerides, High Density Lipoproteins, Direct Bilirubin, Uric, c-reactive protein, Low Density Lipoproteins and for February, April, May, June August, September October and December 2018 and March 2019 and approximately 1416 patients samples were tested and those results were reported to ordering providers. 5. Interview with TP #1 on July 29, 2019 at 4:30 PM confirmed the laboratory failed to document two QC materials of different concentrations each day of patient testing.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

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.

This CONDITION is not met as evidenced by:

Based on review of quality control and quality assessment policies and procedures, personnel policies, and interviews, the director failed to provide overall management and direction; failed to ensure the appointed responsibilities for the technical consultant were properly performed (refer to D6004); failed to evaluate proficiency testing to identify problems (refer to D6018); failed to maintain the quality control program (refer to D6020); failed to maintain the quality assessment program (refer to D6021); and failed to ensure the quality control and quality assessment programs are established and maintained to identify failures (refer to D6022). This is a repeat deficiency previously cited on June 28, 2017.

D6004

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(a)(b)

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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on review of the policy and procedure manual and interview with the testing personnel (TP) #1 and the laboratory director, the laboratory director failed to ensure the responsibilities of the technical consultant (TC) were properly performed.

Findings: 1. Review of the policy and procedure manual revealed a policy for technical consultant responsibilities "the technical consultant must be accessible to the laboratory...the technical consultant is responsible for the following: Establishing a quality control program and ensuring that is carried out. Resolving technical problems and ensuring that remedial actions are carried out. Ensuring that patient test results are not reported until the test systems are functioning properly. Evaluating competency of testing personnel." 2. Interview with the TP #1 on July 29, 2019 at 1:30 PM stated "the technical consultant has not been here for one and one-half years." and "The quality control has not been reviewed by the technical consultant for that time." 3. Review of competency evaluations showed the TC failed to perform one of three competencies for moderate complexity testing (refer to D6046). 4. Review of quality control documentation showed the TC failed to review, monitor, and address QC problems (refer to D5441 and D5447). 5. Interview with the laboratory director on July 29, 2019 at 4:30 PM confirmed the TC has not been at the laboratory for one and one-half years and has not performed his duties. The laboratory director failed to ensure the TC performed his appointed duties.

D6018

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(iii)

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;

This STANDARD is not met as evidenced by:

Based on review of proficiency testing (PT) results from 2017, 2018, and to date July 29, 2019 and interview with the testing personnel (TP) #1, the laboratory director failed to ensure that each PT result was reviewed in order to determine the laboratory's performance. Findings: 1. Review of the second event of 2018 for hematology specialty revealed the laboratory received a 60 percent for the analyte

monocytes. No documentation of review and corrective action was available. The laboratory director failed to document, review, and evaluate any corrective action. 2. Review of the first event for 2018 for endocrinology testing revealed the laboratory received a score of 67 percent for the analyte testosterone. The laboratory director failed to document, review, and evaluate any corrective actions. 3. Review of the second event for 2018 for immunology revealed the laboratory received a 50 percent score for the analyte C-reactive protein. The laboratory director failed to document, review, and evaluate any corrective actions. 4. Review of the first and second events for 2019 for the analyte Low Density Lipoprotein revealed the laboratory received scores of 40 and 60. The laboratory director failed to document, review, and evaluate any corrective actions. 5. Interview with the TP #1 on July 29, 2019 at 4:00 PM confirmed the laboratory director failed to ensure that the unsuccessful performance was reviewed, documented, and corrective action was performed or evaluated.

D6020

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

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 program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on review of Emerald Celldyn hematology procedure, hematology quality control (QC), Horiba ABX Pentra 400 chemistry procedure, and Tosoh A1A chemistry procedure, chemistry quality control (QC), and interview with testing personnel (TP) #1, the laboratory director failed to ensure a quality control program is established and maintained for hematology and chemistry to assure the quality of laboratory services provided. Findings: 1. Review of Emerald Celldyn hematology QC procedure states "There are three levels of controls for the Emerald. At least two levels must be within range to report patient results". 2. Review of Emerald Celldyn hematology QC revealed June 2, 2019 through June 30, 2019 no documentation of QC performed and approximately 130 patient's samples were tested and those results were reported to ordering providers. 3. Review of Emerald Celldyn hematology QC revealed no documentation of review for 2018 and January 1, 2019 to May 31, 2019. 4. Review of Horiba ABX Pentra 400 quality control protocol states "There are two levels of control for each analyte being ran on the Pentra. At least one control must be within range to report patient results." 5. Review of Horiba ABX Pentra 400 chemistry QC revealed no documentation for CO₂, Blood Urea Nitrogen, Creatinine, Albumin, Glucose, Alkaline phosphatase, Alanine Aminotransferase, Aspartate Aminotransferase, Total Bilirubin, Total Protein, Cholesterol, Triglycerides, High Density Lipoproteins, Direct Bilirubin, Uric Acid, c-reactive protein, Low Density Lipoproteins and QC for the months of February 2018, April 2018, May 2018, June 2018, August 2018, September 2018, October 2018, and December of 2018, and approximately 1215 patient's samples were tested and those results were reported to ordering providers. 6. Review of Horiba ABX Pentra 400 chemistry QC revealed no documentation of review for CO₂, Blood Urea Nitrogen, Creatinine, Albumin, Glucose, Alkaline phosphatase, Alanine Aminotransferase, Aspartate Aminotransferase, Total Bilirubin, Total Protein, Cholesterol, Triglycerides, High Density Lipoproteins, Direct Bilirubin, Uric Acid, c-reactive protein, Low Density

Lipoprotein and QC for the month of March 2019 and approximately 201 patient's results were reported. 7. Review of the Tosoh A1A chemistry QC revealed no documentation of review for prostatic specific antigen, testosterone, thyroid specific antigen, thyroxine, and triiodothyronine uptake for 2018 and to date July 29, 2019. 8. Interview with TP #1 on July 29, 2019 at 4:30 PM confirmed the laboratory director failed to ensure a quality control program is established and maintained for hematology and chemistry to assure the quality of laboratory services provided. Based on review of Horiba ABX Pentra 400 chemistry procedure, chemistry quality control (QC) and interview with TP #1, the laboratory director failed to ensure the laboratory performed ABX Pentra QC parallel testing per the laboratory's policy and procedure manual. Findings: 1. Review of Horiba ABX Pentra 400 chemistry procedure stated "prior to initiating use of any new lot number of controls, new controls must be performed in parallel to assure the viability of the new controls". No parallel testing of QC was documented for 2018 or 2019. 2. Interview with TP #1 on July 29, 2019 at 4:30 PM confirmed the laboratory director failed to ensure the laboratory followed the QC parallel testing procedure for the Horiba ABX Pentra 400 chemistry analyzer. This is repeat deficiency, previously cited on June 28, 2017.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

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 quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on review of the quality assessment (QA) program, calibration verification policy, Horiba ABX Pentra 400 chemistry procedure, Horiba ABX Pentra 400 chemistry quality control (QC), Horiba ABX Pentra 400 chemistry calibration verification, Emerald Celldyn QC, Emerald Celldyn calibration verification, Horiba ABX Pentra 400 QC parallel testing, and interview with testing personnel (TP) #1 the laboratory director failed to ensure the QA program is maintained to assure the quality of laboratory services provided. Findings: 1. Review of the QA program states "perform and document two levels of control material each day patient samples are tested." and "Have a quality control acceptance policy." 2. Review of chemistry QC revealed no documentation of ABX Pentra 400 QC for the analytes: CO₂, Blood Urea Nitrogen, Creatinine, Albumin, Glucose, Alkaline phosphatase, Alanine Aminotransferase, Aspartate Aminotransferase, Total Bilirubin, Total Protein, Cholesterol, Triglycerides, High Density Lipoprotein, Direct Bilirubin, Uric, C-reactive protein, Low Density Lipoprotein, for February, April, May, June August, September, October, December 2018 and March 2019 and patient results were reported. 3. Review of Horiba ABX Pentra 400 chemistry QC: - November 2018 revealed creatinine QC level 1 confidence range (QC range) was 1.0-1.2. Per the Levey-Jennings graph the creatinine was not within acceptable range on November 6, 7, 10, 16, 17, 19, 27 and 28, 2018. The laboratory was unable to provide the QC package insert. - November 2018 revealed glucose QC level 1 confidence range (QC range) was 26-277. The mean was 255. Standard deviation was 4. The laboratory director failed to identify an inaccurate confidence range. The laboratory was unable to provide QC package insert. - June 2019 revealed glucose level 1 confidence range

(QC range) 26-277. The mean was 243. The standard deviation was 11. The laboratory director failed to identify an inaccurate confidence range. The laboratory was unable to provide QC package insert. -The laboratory director reviewed and failed to take action on unacceptable QC. 4. Review of the Horiba ABX Pentra 400 chemistry calibration for CO2, Blood Urea Nitrogen, Creatinine, Albumin, Glucose, Alkaline phosphatase, Alanine Aminotransferase, Aspartate Aminotransferase, Total Bilirubin, Total Protein, Cholesterol, Triglycerides, High Density Lipoproteins, Direct Bilirubin, Uric Acid, c-reactive protein and Low Density Lipoproteins revealed no calibration for 2018 to date July 29, 2019. 5. Review of Emerald Celldyn hematology QC revealed no documentation of laboratory director review for 2018/2019 and no documentation of QC from 6/2/19 through 6/30/19. 6. Review of the calibration verification policy revealed: "It is the policy for this company to perform every 6 months a calibration verification on all moderately complex instruments. This includes all non-waived analytes that do not have three or more calibrators." 7. Review of Emerald Celldyn hematology calibration revealed no calibration verification for 2018. 8. Review of Horiba ABX Pentra 400 chemistry procedure stated "prior to initiating use of any new lot number of controls, new controls must be performed in parallel to assure the viability of the new controls". No parallel testing of QC was documented for 2018 or 2019. 9. Interview with TP #1 on July 29, 2019 at 4: 30 PM confirmed the laboratory director failed to ensure the QA program is maintained to assure the quality of laboratory services provided. This is a repeat deficiency, previously cited on June 28, 2017.

D6022

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

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.

This STANDARD is not met as evidenced by:

Based on review of the Horiba ABX Pentra 400 chemistry procedure, Horiba ABX Pentra 400 chemistry quality control (QC) for 2018, 2019, and interview with testing personnel (TP) #1, the laboratory director failed to monitor the accuracy and precision of QC materials in 2018 and 2019 and failed to identify failures in quality as they occur. Findings: 1. Review of the Horiba ABX Pentra 400 chemistry procedure states "After running the controls, review the results (the assay values are provided for each parameter specific for the lot number). The recovered values must fall within the limits of the expected values." 2. Review of QC for November 2018 revealed creatinine QC level 1 confidence range (QC range) was 1.0-1.2. Per the Levey-Jennings graph, creatinine was not within acceptable range on November 6, 7, 10, 16, 17, 19, 27 and 28, 2018. The laboratory was unable to provide the creatinine QC package insert. The laboratory director reviewed the QC and failed to take action on unacceptable QC. 3. Review of QC for November 2018 revealed glucose QC level 1 confidence range (QC range) was 26-277. The mean was 255. The standard deviation was 4. The laboratory failed to identify that the assigned confidence range was inaccurate. The laboratory was unable to provide the glucose QC package insert. The laboratory director reviewed the QC and failed to take action on unacceptable QC. 4. Review of QC for June 2019 revealed glucose level 1 confidence range (QC range) 26-

277. The mean was 243. The standard deviation was 11. The laboratory failed to identify that the assigned confidence range was inaccurate. The laboratory was unable to provide the glucose QC package insert. The laboratory director reviewed the QC and failed to take action on unacceptable QC. 5. The laboratory could not provide documentation for Horiba ABX Pentra 400 chemistry QC in February, May, June, August, September, October and December 2018, and March 2019. 6. Interview with TP #1 on July 29, 2019 at 4:30 PM confirmed the laboratory director failed to monitor the accuracy and precision of QC materials in 2018 and 2019 and failed to identify failures in quality as they occur.

D6033

TECHNICAL CONSULTANT-MODERATE COMPEXITY
CFR(s): 493.1409

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.

This CONDITION is not met as evidenced by:
Based on review of quality control and quality assessment policies and procedures, personnel policies, and interviews, the technical consultant failed to provide technical and scientific oversight (refer to D6036); failed to be accessible to the laboratory (refer to D6038); failed to ensure acceptable levels of analytic performance are maintained throughout the entire testing process and to identify problems (refer to D6042) and failed to evaluate the competency of all testing personnel (refer to D6046).

D6036

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413

The technical consultant is responsible for the technical and scientific oversight of the laboratory.

This STANDARD is not met as evidenced by:
Based on review of 2017, 2018, and to date July 29, 2019 calibration verification procedures for the Tosoh A1A chemistry analyzer, quality control (QC) on the Tosoh A1A and Afinion analyzers and interview with the testing personnel (TP) #1, the technical consultant failed to provide technical and scientific oversight of the laboratory. Findings: 1. No documentation was available to show calibration verification procedures were performed for the Tosoh A1A for prostatic specific antigen (PSA), testosterone (TEST), triiodothyronine uptake (T3U), thyroid stimulating hormone (TSH), and thyroxine (T4) for the years 2017, 2018, and to date July 29, 2019. 2. Review of QC documentation for the Tosoh A1A showed no technical consultant review for PSA, TEST, TSH, T4, T3U for 2018 and to date July 29, 2019. 3. No QC documentation was available for review for 2017, 2018 and to date July 29, 2019 for the Afinion analyzer for urine microalbumin testing. 4. Interview with the testing personnel #1 on July 29, 2019 at 1:30 PM stated "the technical consultant has not been here for one and one-half years." The testing personnel #1 stated "the quality control has not been reviewed by the technical consultant for that time." The testing personnel #1 confirmed the technical consultant failed to provide technical and scientific oversight. 38475 Based on review of Horiba ABX Pentra 400 chemistry procedure, Horiba ABX Pentra 400 chemistry quality

control (QC), Horiba ABX Pentra 400 chemistry calibration verification, Emerald Celldyn QC, Emerald Celldyn calibration verification, Horiba ABX Pentra 400 QC parallel testing, and interview with testing personnel #1 the technical consultant failed to provide technical and scientific oversight of the laboratory. Findings: 1. Review of chemistry QC revealed no documentation of Horiba ABX Pentra 400 QC for the analytes: CO2, Blood Urea Nitrogen, Creatinine, Albumin, Glucose, Alkaline phosphatase, Alanine Aminotransferase, Aspartate Aminotransferase, Total Bilirubin, Total Protein, Cholesterol, Triglycerides, High Density Lipoproteins, Direct Bilirubin, Uric Acid, c-reactive protein, and Low Density Lipoproteins for February, April, May, June, August, September, October, and December 2018, and March 2019. 2. Review of Horiba ABX Pentra 400 chemistry QC revealed: -November 2018 creatinine QC level 1 confidence range (QC range) was 1.0-1.2. According to the Levey-Jennings graph the creatinine was not within acceptable range on November 6, 7, 10, 16, 17, 19, 27, and 28 2018. -November 2018 glucose QC level 1 confidence range (QC range) was 26-277. The mean was 255. The standard deviation was 4. The technical consultant failed to identify that the confidence range was inaccurate. -June 2019 glucose level 1 confidence range (QC range) was 26-277. The mean was 243. The standard deviation was 11. The technical consultant failed to identify that the confidence range was inaccurate. -The laboratory could not provide documentation of technical consultant review for any chemistry QC for 2018 and to date July 29, 2019. 3. Review of Horiba ABX Pentra 400 chemistry calibration for CO2, Blood Urea Nitrogen, Creatinine, Albumin, Glucose, Alkaline phosphatase, Alanine Aminotransferase, Aspartate Aminotransferase, Total Bilirubin, Total Protein, Cholesterol, Triglycerides, High Density Lipoprotein, Direct Bilirubin, Uric Acid, C-reactive protein and Low Density Lipoprotein revealed no calibration for 2018 and to date July 29, 2019. 4. Review of Emerald Celldyn hematology QC revealed no documentation of technical consultant review for 2018 and to date July 29, 2019. 5. Review of Emerald Celldyn hematology QC revealed no documentation of QC June 2, 2019 through June 30, 2019. 6. Review of Emerald Celldyn hematology calibration revealed no calibration for 2018. 7. Review of Horiba ABX Pentra 400 chemistry procedure stated "prior to initiating use of any new lot number of controls, new controls must be performed in parallel to assure the viability of the new controls". No parallel testing of QC was documented for 2018 or 2019. 8. Interview with TP #1 on July 29, 2019 at 4:30 PM confirmed the technical consultant failed to provide technical and scientific oversight of the laboratory.

D6038

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(a)

The technical consultant must be accessible to the laboratory to provide on-site, telephone, or electronic consultation.

This STANDARD is not met as evidenced by:
Based on interview with the testing personnel (TP) #1 and laboratory director, the technical consultant failed to be accessible to the laboratory. Findings: 1. TP #1 on July 29, 2019 at 2:00 PM stated "the technical consultant has not been here for one and one-half years. I have had no contact with him for that time frame." 2. Interview with the laboratory director on July 29, 2019 at 4:00 PM confirmed the technical consultant has not been there since 2017.

D6042

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(4)

(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;

This STANDARD is not met as evidenced by:

Based on review of the Emerald Celldyn hematology procedure, Emerald Celldyn hematology quality control (QC), Horiba ABX Pentra 400 chemistry procedure, Horiba ABX Pentra chemistry QC, and interview with testing personnel (TP) #1, the technical consultant failed to ensure acceptable levels of analytic performance for the hematology and chemistry quality control programs is established and maintained. Findings: 1. Review of Emerald Celldyn hematology QC procedure states "There are three levels of controls for the Emerald. At least two levels must be within range to report patient results". 2. Review of Emerald Celldyn hematology QC from June 2, 2019 through June 30, 2019 revealed no documentation of QC performed, and patient's samples were tested and those results were reported to ordering providers. 3. Review of Horiba ABX Pentra 400 quality control procedure states "There are two levels of control for each analyze being ran on the Pentra. At least one control must be within range to report patient results." 4. Review of Horiba ABX Pentra 400 chemistry QC revealed no documentation for CO2, Blood Urea Nitrogen, Creatinine, Albumin, Glucose, Alkaline phosphatase, Alanine Aminotransferase, Aspartate Aminotransferase, Total Bilirubin, Total Protein, Cholesterol, Triglycerides, High Density Lipoprotein, Direct Bilirubin, Uric Acid, C-reactive protein, and Low Density Lipoprotein QC for the months of February, April, May, June, August, September, October and December of 2018 and approximately 1215 patient samples were tested and those results were reported to ordering providers. 5. Review of Horiba ABX Pentra 400 chemistry QC revealed no documentation for CO2, Blood Urea Nitrogen, Creatinine, Albumin, Glucose, Alkaline Phosphatase, Alanine Aminotransferase, Aspartate Aminotransferase, Total Bilirubin, Total Protein, Cholesterol, Triglycerides, High Density Lipoprotein, Direct Bilirubin, Uric Acid, C-reactive protein, Low Density Lipoprotein QC for the month of March 2019 and approximately 201 patient samples were tested and those results were reported to ordering providers.. 6. Interview with TP #1 on July 29, 2019 at 4:30 PM confirmed the technical consultant failed to ensure acceptable levels of analytic performance in hematology and chemistry quality control program is established and maintained.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(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.

This STANDARD is not met as evidenced by:

Based on review of the technical consultant responsibilities, personnel documentation, procedure manual and interview with the testing personnel (TP) #1, the technical consultant failed to perform one of three competency evaluations for 2017, 2018 and to date 2019. Findings: 1. Review of the technical consultant responsibilities policy showed "The technical consultant must be accessible to the laboratory to provide

consultation. The technical consultant is responsible for the following: evaluation competency of testing personnel." 2. Review of 2017, 2018 and to date July 29, 2019 employee competencies revealed the technical consultant failed to perform competency for TP #3 of moderate complexity testing, urine microscopy. 3. Review of the procedure manual showed a policy stating "competency evaluations will be performed twice during the first year of employment and annually thereafter." 4. Interview with TP #1 on July 29, 2019 at 2:00PM confirmed the technical consultant failed to perform the annual competency for TP #3 for 2017, 2018 and to date 2019. This is a repeat deficiency previously cited on June 28, 2017.