

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0904183	(X3) Date Survey Completed 05/15/2019
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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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory proficiency testing (PT) records and interview with the lead testing personnel, the laboratory failed to ensure the laboratory director signed the attestation statements for proficiency testing events 2017 event two miscellaneous chemistry, 2017 event three hematology, 2018 event one miscellaneous chemistry, and 2018 event two hematology (4 of 10 PT events). The findings include: 1) Review of the laboratory 2017, 2018, and 2019 proficiency testing records revealed attestation statements were not signed by the laboratory director for the following proficiency testing events: 2017 event two for miscellaneous chemistry, 2017 event three for hematology 2018 event one for miscellaneous chemistry, 2018 event two for hematology 2) Interview with the lead testing personnel on May 15, 2019 at 10:30 am confirmed the laboratory failed to ensure the laboratory director signed attestation statements for 4 of 10 proficiency testing events in 2017 and 2018.</p>
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of the laboratory quality control (QC) records and interview with the lead testing personnel, the laboratory failed to retain the complete blood count (CBC) and urine microalbumin and creatinine QC manufacturer assay sheets in 2018 and 2019. The findings include: 1) Review of the laboratory quality control records for CBC revealed the following lot numbers in use from September 9, 2018 through April 1, 2019: 8183, 8267, 8351. No manufacturer QC assay sheets were present. 2) Review of the laboratory quality control records for urine microalbumin and urine creatinine revealed lot numbers 10196679 and 10196680 in use during 2018 and 2019. No manufacturer assay sheets were present. 3) Interview with the lead testing personnel on May 15, 2019 at 3:30 pm confirmed the laboratory failed to retain the manufacturer assay sheets for CBC control lots 8183, 8267, and 8351; and urine microalbumin and urine creatinine QC lot numbers 10196679 and 10196680 in 2018 and 2019.

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES
CFR(s): 493.1235

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.

This STANDARD is not met as evidenced by:
Based on review of the laboratory procedure manual, and interview with the laboratory director, the laboratory failed to have a procedure that met the personnel requirements in subpart M to include all six criteria for assessing personnel competency. The procedure did not include semiannual competency during the first year of patient testing by testing personnel. The findings include: 1) Review of the laboratory procedure titled Quality Assurance Plan, under the section titled PERSONNEL ASSESSMENT, revealed the following six criteria were not included in the procedure: direct observation of routine patient test performance; monitoring the recording and reporting of test results; review of intermediate test results or worksheets, quality control records, proficiency testing results and preventative maintenance records; direct observation of performance of instrument maintenance and function checks; assessment of test performance through previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and assessment of problem solving skills. The procedure did not include requirements for semiannual competency assessment during the first year of patient testing. 2) Interview on May 15, 2019 at 5:00 p.m. with the laboratory director confirmed the testing personnel competency procedure did not include all six criteria for testing personnel competency assessment required by the Centers for Medicare and Medicaid Services (CMS) and did not include a procedure for assessing competency at least semiannually during the first year of patient testing.

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 observation of the laboratory, review of the laboratory proficiency testing

records and interview with the laboratory director, the laboratory failed to verify the accuracy of urine microalbumin and urine creatinine twice a year in 2018. The findings include: 1) Observation of the laboratory on May 15, 2019 at 8:30 am revealed the Alere Afinion AS100 moderately complex instrument in use for patient testing for urine microalbumin and urine creatinine testing. 2) Review of the laboratory proficiency testing records revealed enrollment in proficiency testing for two events per year. For 2018 event one the laboratory scored a 67% for urine microalbumin and 67% for urine creatinine. No documentation was present for verification of accuracy of the urine microalbumin and urine creatinine assay. 3) Interview with the laboratory director on May 15, 2019 at 5:00 pm confirmed the laboratory failed to verify the accuracy of the urine microalbumin and urine creatinine assay twice a year in 2018.

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 the laboratory procedure manual, quality control records, and interview with the laboratory director, the laboratory failed to follow quality control procedure for complete blood count (CBC) in 2018 and 2019. The findings include: 1) Review of the laboratory procedure manual revealed that quantitative quality control values will be plotted on Levey Jennings graphs. 2) Review of the complete blood count quality control revealed that quality control data for lot numbers 8183, 8267, and 8351 (in use 9.6.18 through 4.1.19) was not plotted on Levy Jennings graphs. 3) Interview with the laboratory director on May 15, 2019 at 5:00 pm confirmed the laboratory failed to follow laboratory quality control policy for CBC in 2018 and 2019.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:
Based on observation of the laboratory, review of the manufacturer package insert, and interview with the lead testing personnel, the laboratory failed to label complete blood count (CBC) controls with open date and corrected expiration date in 2019. The findings include: 1) Observation of the laboratory on May 15, 2019 at 8:30 am revealed CBC controls in use for patient testing that were not labeled with open dates or corrected expiration dates. 2) Review of the CBC control manufacturer package insert revealed the following statement: "8 Consecutive-Day Open-Tube Stability" 3) Interview with the lead testing personnel on May 15, 2019 at 11:30 am confirmed the

laboratory failed to label CBC controls with open dates and corrected expiration date in 2019.

D5783

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(2)

(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.

This STANDARD is not met as evidenced by:

Based on review of the laboratory quality control (QC) records, patient test reports for urine microalbumin and urine creatinine, quality assessment records for urine microalbumin and urine creatinine and interview with the laboratory director, the laboratory failed to take corrective action for patients tested when quality control was unacceptable or when there were gaps in performance of quality control in 2017 and 2019. The findings include: 1) Review of the laboratory urine microalbumin and urine creatinine quality control records revealed unacceptable QC with patient testing for the following dates: 06.30.2017, 09.20.2017, 04.04.2019. The 30 day QC was not performed 11.2017 or 12.2017 with patient testing performed. 2) Review of patient numbers 9, 10, 11, 12, and 13 revealed patient reporting for urine microalbumin and urine creatinine when quality control was unacceptable or not performed. 3) Review of the laboratory quality assessment records for the specified dates revealed no patient results were evaluated to determine possible adverse effects. 4) Interview with the laboratory director on May 15, 2019 at 5pm confirmed the laboratory failed to perform evaluate patient results for adverse effects when there was unacceptable quality control and gaps in quality control in 2017 and 2019.

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 laboratory quality assurance plan, monthly quality assessment forms, records for urine microalbumin and urine creatinine quality control and patient testing, proficiency testing records, and interview with the laboratory director, the laboratory director failed to ensure the quality assessment plan was followed in 2017, 2018 and 2019. The findings include: 1) Review of the laboratory quality assurance plan revealed the following: "Evaluate the effectiveness of our written policies and procedures; identify problems in our laboratory corrective actions, assure that accurate and reliable test results are obtained and reported; revised our laboratory policies and

procedures whenever necessary" "Patient Test Management: We will evaluate our criteria for: a. Patient preparation, specimen collection, labeling, preservation, and transportation; b. the laboratory test requisition requirements; c. the criteria used for specimen rejection; The test report for completeness, usefulness and accuracy of the report information necessary for the interpretation or utilization of report, and e. the timely reporting of test results based on testing priorities such as state and routine." "We will evaluate the results of our proficiency testing (PT) with the laboratory director within one week of their return from the PT program. We will evaluate any unacceptable, unsatisfactory, or unsuccessful proficiency testing result in an effort of identify the cause of failure." 2) Review of the form used for documenting quality control and patient test results for urine microalbumin and urine creatinine revealed multiple errors including: Incomplete dates or no date recorded when quality control was performed (07.2018, 08.2018, 11.2018, 01.2019). Incomplete dates for patient testing: June 2017 through May 2019. Quality control ranges not recorded (08.2018, 09.2018, 10.2018, 12.2018, 09.2018, 10.2018, 12.2018, 01.2019, 02.2019, 3.2019, 04.2019, 05.2019) No package inserts were present for determining correct QC ranges. Incorrect or no record of quality control lot number used (03.22.18, 4.12.18, 09.27.18) No record of the test cartridge lot number and expiration date used for patient testing from August 2018 to May 2019 Unacceptable quality control with no repeat testing or corrective actions (6.30.17, 9.20.17, 04.04.19) Dates when the 30 day quality control was not performed (11.2017, 12.2017) 3) Review of the laboratory monthly quality assessment documents from June 2017 through April 2019 revealed the following: "Our PATIENT TEST MANAGEMENT SYSTEM was followed as written"; "Our QUALITY CONTROL POLICIES were performed as specified"; "Our LABORATORY SAFETY POLICIES were followed"; "Our PROFICIENCY TESTING POLICIES have been followed"; "Our PERSONNEL POLICIES were followed"; and "Our QUALITY ASSURANCE PROGRAM is monitored for compliance." Check marks were present for each item reviewed each month with no documented corrective actions for the errors. Each monthly checklist was signed by the laboratory director. 4) Review of laboratory records revealed no documents were present for patient test management review for 2017, 2018 and 2019. 5) Review of patient test reports for urine microalbumin and urine creatinine revealed no units of measure were present on the final patient test reports (patient numbers 5,6,7,8,9,10,11,12 and 13) with no corrective action. 6) Review of laboratory proficiency testing records for 2018 event one for urine microalbumin and urine creatinine revealed unacceptable scores for MA-03 for microalbumin and MA-01 for creatinine with no effective investigation into the cause of the failures and no evaluation of patients to determine if possible adverse effects were possible as a result of the failure. 7) Interview with the laboratory director on May 15, 2019 at 5pm confirmed the laboratory director failed to ensure the quality the quality assessment program was maintained in 2017, 2018 and 2019.

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:
The technical consultant failed to ensure quality control programs were maintained (Refer to D6042), corrective actions were taken for unacceptable quality control

(Refer to D6043) and patient tests were not reported until quality control was acceptable (Refer to D6044).

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 laboratory procedure manual, 2017, 2018, and 2019 quality control records for the urine microalbumin and urine creatinine and interview with the laboratory director, the technical consultant failed to ensure the quality control (QC) plan for urine microalbumin and urine creatinine was maintained in 2017, 2018, and 2019. The findings include: 1) Review of the laboratory procedure manual revealed an individualized quality control plan for urine microalbumin and urine creatinine. Quality control protocol stated that controls should be done with "each new shipment, each new lot number and every 30 days." No patient samples could be tested until controls are within acceptable limits. If controls are outside the acceptable limits, the controls should be retested and patient results must be declared invalid when controls do not perform as expected, customer service would be contacted, and the lab director notified. All actions taken to resolve problem will be documented. 2) Review of the laboratory quality control records for the urine microalbumin and urine creatinine revealed the following: Unacceptable quality control on 06.30.2017, 09.20.2017, 04.04.2019. No 30 day quality control was performed for 11.2017 and 12.2017. Dates of QC performance were not recorded for the months of 07.2018, 08.2018, 11.2018, and 01.2019. Incorrect or no record of quality control lot number used on 03.22.18, 04.12.18, and 09.27.18. Quality control acceptable ranges were not recorded on 05.2018, 09.2018.10.2018, 12.2018, 09.2018, 10.2018, 12.2018, 01.2019, 02.2019, 03.2019, 04.2019). No package inserts were present to determine the acceptable ranges for these dates. The test cartridge lot number that was being used for patient testing and quality control was not recorded from August 2018 to May 2019. 3) Review of patient test reports revealed urine microalbumin and urine creatinine patient testing reported for patient numbers: 5 on 5.14.19, 6 on 04.07.19, 7 on 5.1.18, 8 on 11.6.17, 9 on 7.3.2017, 10 on 9.21.2017, 11 on 11.14.17, 12 on 12.12.2017, and 13 on 4.4.2019. 4) Interview with the technical consultant on May 15, 2019 at 5pm confirmed the technical consultant failed to ensure the quality control program was maintained in 2017, 2018, and 2019.

D6043

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(5)

(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;

This STANDARD is not met as evidenced by:

Based on review of the laboratory quality control records for urine microalbumin and

urine creatinine for 2017 and 2019 and interview with the technical consultant, the technical consultant failed to ensure that corrective actions were taken when quality control was unacceptable in 2017 and 2019. The findings include: 1) Review of the laboratory quality control records for the urine microalbumin and urine creatinine revealed unacceptable quality control on 06.30.2017, 09.20.2017 and 04.04.2019 with patient testing performed (Patient number 9 reported on 7.3.2017, number 10 reported on 9.21.2017, number 11 reported on 11.14.17). 2) Interview with the technical consultant on May 15, 2019 at 5 pm confirmed the technical consultant failed to ensure remedial actions were taken when quality control was unacceptable for urine microalbumin and urine creatinine in 2017 and 2019.

D6044

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(6)

(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;

This STANDARD is not met as evidenced by:

Based on review of the laboratory quality control records and patient test reports for 2017 and 2019, and interview with the laboratory director, the technical consultant failed to ensure patient test results were not reported for urine microalbumin and urine creatinine when quality control was unacceptable. The finding include: 1) Review of the laboratory quality control records for the urine microalbumin and urine creatinine revealed unacceptable quality control on 06.30.2017, 09.20.2017, 04.04.2019. 2) Review of patient test reports revealed patient testing was performed when quality control was unacceptable as follows: Patient number 9 reported on 7.3.2017, number 10 reported on 9.21.2017, and number 13 reported on 4.4.2019. 3) Interview with the laboratory director on May 15, 2019 at 5 pm confirmed the technical consultant failed to ensure patient testing for urine microalbumin and urine creatinine was not reported when quality control was unacceptable in 2017 and 2019.