

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2134131	(X3) Date Survey Completed 09/04/2019
Name of Provider or Supplier Aqsa Laboratory, Inc	Street Address, City, State 10322 S Harlem Ave, Palos Hills, IL	
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
D5016	<p>ROUTINE CHEMISTRY CFR(s): 493.1210</p> <p>If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1267, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory records, direct observation, and interview with the technical consultant; the laboratory failed to meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299 for routine chemistry testing. Findings Include: 1. The laboratory failed to have procedures in place for 14 of 14 analytes tested on the Medica EasyRA chemistry analyzer. See D5401. 2. The laboratory failed to verify the reportable range for 14 of 14 analytes tested on the Medica Easy RA prior to patient testing. See D5421.</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 laboratory records and interview with the laboratory's technical consultant (TC); the laboratory failed to follow policies and procedures to assess the competency of the technical consultant and the clinical consultant. Findings Include: 1. Review of the laboratory procedure manual identified the laboratory's competency assessment policy, "Clinical Staff Competency Assessment Policy". 2. Review of the</p>

competency assessment policy revealed that supervisors are to have competency assessments based on their federal responsibilities, which is to be completed annually. 3. Review of competency assessment records found no annual competency assessments for the technical consultant (TC) and Clinical Consultant (CC), as identified on the CMS-209 (Laboratory Personnel Report), were completed in 2017 through 2019. 4. On survey date 09-04-2019, at 5:50 pm the TC confirmed the surveyor's findings that no annual competency assessments were completed for the federal responsibilities of the TC and CC.

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 laboratory records, direct observation, and interview with the technical consultant (TC); the laboratory failed to have a procedure manual for 14 of 14 analytes tested on the Medica EasyRA analyzer for the specialty of routine chemistry. Findings Include: 1. During a walkthrough of the laboratory on 9-4-2019 at 11:30 am the surveyor observed patients' specimens being tested on a Medica EasyRA chemistry analyzer. 2. Review of the laboratory test menu identified 14 analytes which are tested on the Medica EasyRA analyzer: Sodium, Potassium, Chloride, Carbon Dioxide, BUN (Blood Urea Nitrogen), Creatinine, Calcium, Glucose, Alkaline Phosphatase, AST (Aspartate Aminotransferase), ALT (Alanine Aminotransferase), Total Protein, Total Bilirubin, Albumin, Cholesterol, Triglyceride, and HDL (High-Density Lipoproteins) 3. Review of laboratory's policy and procedure manual revealed the laboratory failed to have procedures in place for 14 of 14 chemistry analytes ran on the Medica EasyRA analyzer. 4. On survey date 09-04-2019, at 5:50 pm, the surveyor's finding were confirmed by the TC.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
Based on direct observation, review of laboratory records, and interview with the technical consultant (TC); the laboratory failed to demonstrate the reportable range for 14 of 14 chemistry analytes performed on the Medica EasyRA analyzer prior to reporting patient test results for 35 patients from 8-13-2019 to date of survey 9-4-2019. Findings Include: 1. Direct observation of laboratory testing equipment during a walkthrough of the laboratory on 9-04-2019, at 11:30am, identified a Medica EasyRA

chemistry analyzer. 2. Review of the laboratory's test menu identified 14 analytes tested on the Medica EasyRA analyzer: Sodium, Potassium, Chloride, Carbon Dioxide, BUN (Blood Urea Nitrogen), Creatinine, Calcium, Glucose, Alkaline Phosphatase, AST (Aspartate Aminotransferase), ALT (Alanine Aminotransferase), Total Protein, Total Bilirubin, Albumin, Cholesterol, Triglyceride, and HDL (High-Density Lipoproteins) 3. Review of the verification of performance documentation for the Medica EasyRA analyzer revealed the laboratory failed to verify the reportable range for the 14 of 14 analytes. 4. Review of the verification of performance documentation revealed the laboratory put the Medica EasyRA in use for patient testing on 08-12-2019. 5. Review of patient testing logs identified 35 patients who had testing performed on the Medica EasyRA from 08-13-2019 to 9-4-2019 when the laboratory had failed to verify the reportable range for 14 of 14 routine chemistry analytes. 6. On survey date 09-04-2019, at 5:50 pm, the above findings were confirmed by the TC.

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 laboratory records and interview with the laboratory's technical consultant (TC); the laboratory director (LD) failed to provide the overall management and direction in accordance with 493.1407. Findings Include: 1. The LD failed to ensure proficiency testing failures were identified and a corrective action was taken for a blood cell identification/differential failure in event 2 of 2019. See D6018. 2. The LD failed to ensure the quality assessment plan was maintained as outlined in the quality assessment plan for 2018 through 2019. See D6021. 3. The LD failed to ensure the duties and responsibilities of each person engaged in testing were specified, in writing. See D6032.

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 laboratory records and interview with the laboratory's technical consultant; the laboratory director failed to ensure the laboratory identified a proficiency testing (PT) failure for blood cell identification/differential in the second event of 2019. Findings Include: 1. Medical Laboratory Evaluation (MLE) proficiency records were reviewed for 2017 through 2019. 2. Review of proficiency testing performance records for the second event of 2019 for blood cell identification

/differential revealed the laboratory received an unsuccessful performance score of 60% for blood cell identification/differential. 3. Review of proficiency testing records failed to indicate a corrective action for the blood cell identification/differential failure for event 2 of 2019. 4. On survey date 09-04-2019, at 5:50 pm the surveyor's findings were confirmed by the TC.

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 laboratory records and interview with the laboratory's technical consultant (TC), the laboratory director (LD) failed to ensure the quality assessment plan was maintained in 2018 through 2019. Findings Include: 1. Review of the laboratory's policy and procedure manual identified the laboratory's Quality assessment plan, which was approved for use on 1-1-2018. 2. The laboratory quality assessment plan indicated the following items will be checked and documented: "Monthly Checklist of Analytical Phase - maintenance, calibration, quality control - MONTHLY Patient test management - Quarterly Critical Values, Turnaround Time, Error Correction - QUARTERLY Communication, Complaints, Incidents - ANNUALLY Proficiency Testing Checklist - THREE TIMES PER YEAR/FOR EACH PT EVENT Quality Assessment Plan - ANNUALLY" 3. Review of laboratory records revealed the laboratory failed to document any quality assessments, as outlined in the quality assessment plan. 4. On survey date 09-04-2019, at 5:50 pm, the surveyor's findings were confirmed by the TC.

D6032

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(14)

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.

This STANDARD is not met as evidenced by:

Based on review of laboratory records interview with the laboratory's technical consultant (TC); the laboratory director failed to identify the responsibilities and duties of each person engaged in all phases of testing. Findings Include: 1. Review of the laboratory's policy and procedure manual revealed the laboratory director failed to

specify, in writing, the responsibilities and duties of each person engaged in 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 2. On survey date 9-04-2019, at 5:50 pm, the surveyor's findings were confirmed by the TC.

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 laboratory records and interview with the laboratory's technical consultant; the technical consultant (TC) failed to provide the technical oversight in accordance with 493.1413. Findings Include: 1. The TC failed to evaluate 2 of 2 testing personnel prior to performing patient testing when new instrumentation (Medica EasyRA analyzer) was put into use for chemistry testing. See D6055.

D6055

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results.

This STANDARD is not met as evidenced by:
Based on review of laboratory records and interview with the laboratory's technical consultant (TC); the TC failed to evaluate and document the performance for 2 of 2 testing personnel performing testing on the Medica EasyRA chemistry analyzer prior to reporting patient test results. Findings Include: 1. Review of the laboratory policy, "Clinical Staff Competency Assessment Policy", states "Competency must also be assessed, prior to reporting results, whenever there are test methodology or instrumentation changes." 2. Review of verification of performance documentation found the Medica EasyRA chemistry analyzer was put into use for patient testing on 08-12-2019. 3. Review of competency assessment records revealed no competency assessments were documented for 2 of 2 testing personnel listed on the CMS-209 (Laboratory Personnel Report) prior to patient testing on the Medica EasyRA chemistry analyzer. 4. On survey date 09-04-2019, at 3:30 pm, the TC confirmed the laboratory failed to complete competency assessments for the 2 testing personnel identified on the CMS-209, for the new chemistry analyzer (Medica EasyRA) prior to reporting patient results.