

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2134131	(X3) Date Survey Completed 03/21/2018
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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the laboratory director (LD); the laboratory failed to have a procedure in place for microscopic urinalysis testing. Findings Include: 1. Review of laboratory's policy and procedure manual found the laboratory failed to have a procedure in place for microscopic urinalysis testing. 2. On survey date 3-21-2018, at 12:15 PM, the LD confirmed no written procedure for microscopic urinalysis had been established by the laboratory.</p>
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the lab director (LD); the</p>

laboratory failed to demonstrate it can obtain performance specifications for microscopic urinalysis testing prior to reporting patient testing results. Findings Include: 1. Review of the laboratory's policy and procedure manual confirmed the laboratory performs "urinalysis with Microscope". 2. The surveyor requested verification of performance documentation for microscopic urinalysis on 03-21-2018 at 10:25 am from the LD and the LD confirmed no verification of performance for microscopic urinalysis had been performed. 3. Review of patient test records identified 3 of 4 patient test reports for microscopic urinalysis testing. Patient Identification Test Date P2 03-05-2018 P3 02-14-2018 P4 02-14-2018 4. On survey date 03-21-2018, at 12:15 pm, the above findings were confirmed by the LD.

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 laboratory records and interview with the lab director (LD); the laboratory failed to ensure two levels of quality control (QC) materials were ran each day of testing before reporting patient test results for microscopic urinalysis. Findings include: 1. Interview with the lab director (LD) at 9:22 am, on 3-21-2018, confirmed no quality controls for microscopic urinalysis are performed. 2. Review of patient test reports for microscopic urinalysis found no documented quality control records for 3 of 3 patient testing dates reviewed. Patient Identification Test Date P2 03-05-2018 P3 02-14-2018 P4 02-14-2018 3. On survey date 03-21-2018, at 12:15 pm, the LD confirmed that two levels of quality control material were not performed each day of patient testing for microscopic urinalysis.

D5787

TEST RECORDS
CFR(s): 493.1283(a)

The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:
Based on review of laboratory records and interview with the lab director (LD), the laboratory failed to identify the testing personnel who performed each laboratory test. Findings Include: 1. Review of 4 of 4 patient test reports found the laboratory had no way to identify the testing personnel for each test performed. Patient Identification Test Date P1 03-05-2018 P2 03-05-2018 P3 02-14-2018 P4 01-15-2018 2. Interview with the LD on 3-21-2018, at 12:15 pm, confirmed the laboratory had no way to identify the person performing each test.

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 director (LD), the LD failed to ensure that a quality assessment plan was established. Findings Include: 1. Review of the laboratory's policy and procedure manual found no quality assessment plan for the laboratory. 2. On survey date 03-21-2018, at 12:15 pm, the LD confirmed no quality assessment plan had been established for the laboratory.