

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2154119	(X3) Date Survey Completed 03/05/2019
Name of Provider or Supplier A2z Diagnostics, Llc	Street Address, City, State 6 Industrial Way West, Eatontown, NJ	
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
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with the General Supervisor (GS), the laboratory failed to establish a a detailed procedure for Biannual Assessment (BA) for Histopathology testing from 9/1/18 to the date of survey. The GS confirmed on 3/5/19 at 9:55 am that a detailed BA procedure was not established.</p>
D5391	<p>PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Individualized Quality Control Plan (IQCP) and interview with the General Supervisor (GS), the laboratory failed to include a Quality Assessment Plan (QAP) in the IQPC the finding includes. 1) The IQPC has out outline QAP for preanalytic systems but does not have a detailed written plan. 2). The GS confirmed on 3/5/19 at 10:00 am the laboratory did not have a QAP in the IQPC.</p>
D5449	CONTROL PROCEDURES

CFR(s): 493.1256(d)(3)(ii)(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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Quality Control (QC) records and interview with the General Supervisor (GS), the laboratory failed to perform and document a negative and positive controls on each day of patient testing for Bio Fire Gastrointestinal and Respiratory panels from January 2019 to the date of survey. The findings include: 1. QC was being done once a month as per the Individualize Quality Control Plan but the plan was incomplete.. 2. Approximately 80 patients run and reported. 3. The GS confirmed on 3/5/19 at 1:40 pm that QC was not done on each day of testing.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Individualized Quality Control Plan (IQCP) and interview with the General Supervisor (GS), the laboratory failed to include a Quality Assessment Plan (QAP) in the IQPC the finding includes. 1) The IQPC has out outline QAP for analytical systems but does not have a detailed written plan. 2). The GS confirmed on 3/5/19 at 10:00 am the laboratory did not have a QAP in the IQPC.

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1299(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:

a) Based on surveyor review of the Procedure Manual and interview with the General Supervisor (GS), the laboratory failed to have a procedure to verify manually entered Bacteriology, Parasitology, and Virology test results into the Patient's Medical Record for accuracy from 1/8/19 to the date of the survey. The GS confirmed on 3/5/19 at 2: 15 pm that the laboratory did not have the procedure mentioned above. b) Based on surveyor review of the Individualized Quality Control Plan (IQCP) and interview with the General Supervisor (GS), the laboratory failed to include a Quality Assessment Plan (QAP) in the IQPC the finding includes. 1) The IQPC has out outline QAP for postanalytic systems but does not have a detailed written plan. 2). The GS confirmed on 3/5/19 at 10:00 am the laboratory did not have a QAP in the IQPC.