

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D1075504	(X3) Date Survey Completed 01/15/2019
Name of Provider or Supplier Avala	Street Address, City, State 67252 Industry Lane, Covington, LA	
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
D0000	A Certification Survey was performed at January 15, 2019 at Avala, CLIA ID # 19D1075504. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
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 record review and interview with personnel, the laboratory failed to establish and follow written policies and procedures to assess competency for testing personnel. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not include the following six (6) procedures as a minimal requirement for assessing the competency of all personnel performing laboratory testing: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting of test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f) Assessment of problem solving skills. 2. In interview on January 15, 2019, Personnel 1 confirmed the laboratory's competency policy did not include at a minimum the identified six (6) procedures.</p>
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the laboratory failed to define an acceptable cryostat temperature for Histopathology testing. Findings: 1. Review of the laboratory's "Thermo Cryotome" policy under "Preparation For Use" section revealed "The temperature must be correct for the specimen being cut (-17 thru -25 degrees Celsius)." 2. Review of the laboratory's "Cryostat Quality Control Log" revealed the following acceptable cryostat temperature: "Cryobar Temp Range: > -20 degrees Celsius" "Working Temp Range: > -20 degrees Celsius" 3. In interview on January 15, 2019, Personnel 1 confirmed the temperature range included in the laboratory's policy differed from that included on the cryostat log.

D5433

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(b)(1)

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 establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the laboratory failed to perform cryostat maintenance per laboratory policy. Findings: 1. Review of the laboratory's "Decontamination, Cleaning and Maintenance of the Thermo Cryostat" policy revealed "The refrigerated chamber should only be washed and cleaned after the chamber is thoroughly decontaminated by fumigation. Fumigation takes place after 10 frozen sections or the first Monday of each month (which ever comes first)." 2. Review of the laboratory's "Cryostat Quality Control Log" for 2017 and 2018 revealed the laboratory did not perform maintenance procedures on the following months: July 2017: Clean with ETOH and fumigate November 2017: Fumigate December 2017: Fumigate July 2018: Clean with ETOH and fumigate August 2018: Fumigate October 2018: Clean with ETOH and fumigate 3. In interview on January 15, 2019, Personnel 1 confirmed the identified months did not have documented performance of cryostat maintenance.

D5481

CONTROL PROCEDURES

CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test

results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the laboratory failed to ensure testing personnel assessed and documented the stain quality for Histopathology testing. Findings: 1. In interview on January 15, 2019, Personnel 1 stated the laboratory performs frozen section utilizing Hematoxylin and Eosin (H & E)stain. 2. Review of random selection of patients and quality control records revealed the laboratory did not have documented QC assessment performed by the testing personnel identified on the laboratory's CMS 209 form (Laboratory Personnel Report) for the following dates: December 22, 2017 November 8, 2018 3. In interview on January 15, 2019 at approximately 11:00 am, Personnel 1 stated the pathologist reading the slides assess the stain quality. Personnel 1 stated for the identified dates, she thinks the initials documented were that of a histotechnician.

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 record review and interview with personnel, the laboratory failed to follow established quality assessment procedures for Histopathology testing. Findings: 1. Review of the laboratory's "Cryostat Quality Control Logs" for 2017 and 2018 revealed the Laboratory Director, who also serves as the laboratory's Technical Supervisor, did not have documentation of monthly review for the following five (5) months: November 2017 December 2017 October 2018 November 2018 December 2018 2. In interview on January 15, 2019, Personnel 1 confirmed the identified months did not have documented review of the quality control logs.

D6087

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(3)(iii)

The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required for accurate and reliable results. Refer to D5413.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

	<p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that quality control programs were established to assure the quality of laboratory testing. Refer to D5481.</p>
<p>D6094</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Refer to D5791.</p>
<p>D6095</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6)</p> <p>The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that the laboratory performed the required maintenance to ensure acceptable levels of analytical performance. Refer to D5433.</p>
<p>D6103</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13)</p> <p>The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures were established for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Refer to D5209.</p>