Department of Health & Human Services
Centers for Medicare & Medicaid Services

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Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2057342	(X3) Date Survey Completed 01/15/2019
Name of Provider or Supplier Accurate Medical Laboratories (Nc)	**Street Address, City, State** 1451 South Elm Eugene Street, Suite 1112, Greensboro, NC	
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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of laboratory procedure manual, quality control records and laboratory director interview 01/15/19, the laboratory's procedure manual was not complete and current for the testing performed. 1. Review of laboratory procedures for quality control revealed the quality control procedures for QuickVue+, Streptococcus A (Strep A) failed to define the frequency in which quality control is performed. For example: The laboratory procedure "Quality Control (QC) Procedure" states "This policy applies to any testing procedure associated with the...lab....

	Manufacturer recommendations must be followed....Laboratory Internal Quality Control Requirements:.....1. Laboratory Internal Quality Control material must be analyzed on a regular basis at least according to manufacturer recommendations....B. Internal Quality Control.....2. Qualitative Test Systems....2- Qualitative procedures are checked by positive and negative controls. 3- The frequency of controls is dependent on the manufacturer's recommendation as well as the lab confidence/experience with each method. As a minimum requirement, manufacturer recommendations have to be followed. New operators may run controls more frequently than the manufacturer's recommendations.....As per...policy, Quality Control specimens must be assayed for all test systems according to manufacturer recommendation and CLIA regulation." The laboratory procedure provided by manufacturer for QuickVue+ Strep A states "Positive and Negative controls can be run with each shipment of a new kit lot number and as otherwise required by your laboratory's standard quality control procedures." Review of quality control records for QuickVue+ Strep A revealed the laboratory performs quality control each time patient testing or proficiency testing occurs. 2. Review of laboratory procedure manual revealed no procedure for the reporting of patient test results. During interview at approximately 12:35 p.m., the laboratory director confirmed the laboratory did not have a written procedure for reporting patient test results. 3. During interview with laboratory director at approximately 1:30 p.m., he stated that stat specimens may be collected by their phlebotomists and the testing that was not performed by them would be referred to another testing facility. Review of laboratory procedure manual revealed no procedure for specimen referrals.
D6053	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 at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of personnel records, and interview with the laboratory director 1/15/19, the TC (technical consultant) failed to perform a semiannual competency evaluation for 1 of 2 testing personnel (TP #1) during the first year of testing patient specimens. The laboratory's "Laboratory Personnel" policy states "... Competency Each employee will have competency assessed and documented for each procedure the employee performs. This is done at initial training, six months after initial employment and annually thereafter. ... Records of training and competency assessments will be kept in the personnel files. ..." Review of personnel records revealed TP #1 was hired in October 2016. An initial "new hire" competency was performed in December 2016 after TP #1's training was completed. The next competency evaluation for TP #1 was documented in December 2017, approximately one year after training was completed. There was no documentation of a semiannual competency evaluation for TP #1 between December 2016 and December 2017. During interview at approximately 11:00 a.m., the laboratory director confirmed there was no documentation of a semiannual competency evaluation available for TP #1. He stated additional personnel records were stored at the laboratory's sister facility in another state, but he was unsure whether a semiannual competency was performed for TP #1.
D6056	CLINICAL CONSULTANT

	CFR(s): 493.1415 The laboratory must have a clinical consultant who meets the qualification requirements of 493.1417 of this part and provides clinical consultation in accordance with 493.1419 of this part. This CONDITION is not met as evidenced by: Based on review of personnel records 1/15/19 and the deficiency cited at D6057, the laboratory failed to have personnel that met the qualification requirements to serve as clinical consultant in a moderate complexity laboratory.
D6057	CLINICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1417 The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493.1405(b)(1), (2), or (3)(i); or (b) Be a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine and possess a license to practice medicine, osteopathy or podiatry in the State in which the laboratory is located. This STANDARD is not met as evidenced by: Based on review of personnel records, and interview with the laboratory director 1/15/19, the laboratory failed to have personnel that met the qualification requirements to serve as clinical consultant in a moderate complexity laboratory. Review of personnel records revealed the person listed by the laboratory as clinical consultant on the Form CMS-209 Laboratory Personnel Report has a Doctor of Osteopathy degree and a license to practice medicine in the state of Virginia. Personnel records did not include a license to practice medicine in North Carolina. During interview at approximately 10:15 a.m., the laboratory director stated that the person listed by the laboratory as clinical consultant on the Form CMS-209 Laboratory Personnel Report applied for a North Carolina medical license but has not received it yet.