Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D1106621	07/20/2018
Name of Provider or Supplier	**Street Address, City, State**	
Accurate Medical Lab	109 Deer Run Rd, Danville, VA	

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	An unannounced Clinical Laboratory Improvement Amendments (CLIA) complaint investigation (Complaint #VA00042600) was conducted at Accurate Medical Lab on July 20, 2018 by Medical Facilities Inspectors from the Virginia Department of Health, Office of Licensure and Certification. The laboratory holds a Certificate of Accreditation and operates under CLIA # 34D1106621. Based on review of the documents and interviews, the inspectors found one (1) of the four (4) complainant's allegations to be substantiated. Deficiencies cited are as follows:
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records and an interview, the laboratory failed to retain instrument printouts of proficiency testing (PT) samples for three (3) of three (3) PT events reviewed from December 2017 until July 2018. Findings include: 1. Review of the laboratory's American Proficiency Institute (API) PT records revealed the laboratory participated in the following: 2017 Chemistry and Hematology Third Event, 2018 Chemistry and Hematology Second Event, 2018 Remedial Proficiency sample. The inspector requested the instrument printouts for the proficiency testing samples for the events listed above. No documentation was available for review. 2. An interview with laboratory director, at approximately 1:30 PM, confirmed that the laboratory did not retain the instrument printouts for the API 2017 Chemistry and Hematology Third Event, 2018 Chemistry and Hematology Second Event and 2018 Remedial Proficiency samples 62R-CH-01, 62R-CH-02, 62R-CH-03, 62R-CH-04 and 62R-CH-05.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250

	Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a review of the laboratory's Quality Control (QC) records from April 1, 2018 through July 20, 2018, patient data logs, policies, quality assurance (QA) records, patient test reports and interviews, the laboratory failed to monitor and evaluate analytic quality by: 1. failure to have two levels of QC within acceptable ranges while reporting eleven (11) patient Complete Blood Counts (CBC) and sixteen (16) patient chemistry panels (Cross Reference D5447). 2. failure to follow their written corrective action plan for a temporary cease testing agreement (dated May 1, 2018) for chemistry testing on the Vitros 5600 while reporting seven (7) patient chemistry panels on June 8, 2018 (Cross Reference D5779).
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: A. Based on a review of hematology analyzer quality control (QC) records, policies, a laboratory tour, patient requisitions, patient logs and an interview, the laboratory failed to document two (2) levels of QC within acceptable ranges on seven (7) days while reporting eleven (11) patient Complete Blood Count (CBC) results during the seventeen (17) weeks reviewed. Findings include: 1. Review of the available Sysmex XS 1000i hematology analyzer QC records from April 1, 2018 through July 20, 2018 revealed the laboratory uses Sysmex e-check hematology QC material Level 1, 2 and 3 and that Lot Numbers 8072 and 8128 were utilized in the review period. 2. Review of the laboratory's QC policy states: "QC must be done and passed each day of patient testing. Two levels of QC is the minimum required for each test." 3. During a tour of the hematology testing area from approximately 10:00 to 11:00 AM, the laboratory director (LD) pulled up seventeen (17) weeks of QC data from the Sysmex 1000i instrument as requested by the inspectors. The inspectors reviewed, with the LD, all data on the analyzer from 4/1/18 to 7/20/18. The inspectors noted the following seven (7) days of patient testing without documentation of QC data: 4/14/18, 4/15/18, 4/22 /18. 4/28/18, 4/29/18, 5/12/18, and 5/27/18. No other QC documentation for hematology testing on the Sysmex instrument was available for review. 4. Review of the laboratory's patient test requisitions and logs from 4/1/18 to 7/20/18, revealed the following eleven (11) patient test identification numbers (ID #) were requisitioned, assayed on the Sysmex and reported as "STAT" on the dates outlined above: 04/14 /18- patient #'s 180001335,180001336, 04/15/18- patient #'s 180001337, 180001338, 04/22/18- patient # 180001574, 04/28/18- patient #'s 180001803, 180001805, 04/29

	/18- patient # 180001807, 05/12/18- patient #'s 180002223, 180002224, 05/27/18- patient # 180002663. 5. In an interview with the LD at approximately 3:30 PM, it was confirmed that the laboratory reported eleven (11) patient hematology CBC results without verifying that two (2) levels of acceptable QC were documented on the Sysmex analyzer for seven (7) of one hundred nineteen (119) days reviewed. B. Based on a review of the laboratory's Vitros 5600 chemistry analyzer quality control (QC) records, policies, a laboratory tour, patient requisitions, patient logs and an interview, the laboratory failed to document two (2) levels of QC on eight (8) days while reporting sixteen (16) patient chemistry panels during the seventeen (17) weeks reviewed. Findings include: 1. Review of the available Vitros 5600 chemistry analyzer QC records from April 1, 2018 through July 20, 2018 revealed the laboratory uses BioRad Lyphocheck Unassayed QC material Level 1, 2 and 3. The record review revealed that the laboratory documented BioRad Lot numbers 47310, 47360, and 47590 in use during the review period. 2. Review of the laboratory's QC policy states: "QC must be done and passed each day of patient testing. Two levels of QC is the minimum required for each test." 3. During a tour of the chemistry testing area from approximately 11:00 AM to 12:00 PM, the laboratory director (LD) pulled up seventeen (17) weeks of QC data from the the Vitros instrument as requested by the inspectors. The inspectors reviewed, with the LD, all data on the analyzer from 4/1/18 to 7/20/18. The inspectors noted the following eight (8) days of patient testing without documentation of QC data: 4/14/18, 4/15/1, 4/21/18, 4/22/18, 4/27/18, 4/28/18, 4/29 /19, and 4/30/18. No other QC documentation for chemistry testing on the Vitros 5600 instrument was available for review. 4. Review of the laboratory's patient test requisitions, reports, and logs from 4/1/18 to 7/20/18, revealed the following sixteen (16) patient test identification numbers (ID #) were requisitioned, assayed on the Vitros 5600 chemistry analyzer and reported on the dates outlined above: 04/14/18- patient #'s 180001334, 180001335, 180001336, 04/15/18- patient #'s 180001337, 180001338, 04/21/18- patient # 180001568, 180001569, 180001570, 180001571, 04 /22/18- patient #'s 180001574, 180001576, 04/27/18- patient #'s 180001804, 04/28 /18- patient #'s 180001803, 180001804, 04/29/19- patient # 180001806, 04/30/18- patient # 180001859. 5. In an interview with the LD at approximately 3:30 PM, it was confirmed that the laboratory reported sixteen (16) patient chemistry panels without verifying that two (2) levels of acceptable QC were documented for the Vitros chemistry analyzer on the dates outlined above.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on review of policies, quality assurance (QA) records, chemistry analyzer patient data logs, patient test reports, and an interview, the laboratory failed to follow their written corrective action plan for a temporary cease testing agreement (dated May 1, 2018) for chemistry testing on the Vitros 5600 while reporting seven (7) patient chemistry panels on June 8, 2018. Findings include: 1. Review of the laboratory's QA policy revealed a corrective action documentation policy and monthly QA review for all corrective action documents to be performed by the lab director (LD). 2. Review of the laboratory's 2018 QA records revealed a written corrective action plan dated May 1, 2018 for a temporary cease testing agreement for chemistry

	testing on the Vitros 5600 in response to a COLA routine recertification survey finding of unacceptable proficiency testing scores and documentation of corrective action. 3. Review of the Vitros 5600 data log from 5/1/18 to 7/20/18 revealed the following seven (7) patient identification numbers (ID #) were assayed on 6/8/18: 180002945, 180003023, 180003025, 180003026, 1800003010, 180003023, 180003054. 4. Review of the patient requisitions and printed test reports revealed the ID #'s listed above were reported on 6/8/18 as performed by Accurate Medical Lab. 5. In an interview with the LD on at approximately 3:30 PM, it was confirmed that the laboratory failed to follow their QA corrective action plan for a voluntary temporary cease testing agreement (dated May 1, 2018) for chemistry testing on the Vitros 5600 while reporting seven (7) patient chemistry panels on June 8, 2018.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient test reports, and interviews, the laboratory failed to ensure the test report accurately indicated the laboratory name and address where testing was performed for five (5) of five (5) patient reports reviewed from May 2018 to July 20, 2018. Findings include: 1. In an interview with the Laboratory Director (LD) at approximately 2:00 PM, the LD stated the laboratory ceased patient testing on May 1, 2018 and began sending all specimens to a reference laboratory. 2. Review of patient test reports revealed that five (5) of five (5) patient reports (patient numbers 180001813, 180001848, 180001849, 180001850, 180001851) resulted on May 1, 2018 identified the testing laboratory as the name and address of the requesting laboratory. The reports did not contain the name and address of the reference laboratory where the testing was performed. 3. An interview with the LD at approximately 2:30 PM confirmed the laboratory did not ensure the test report indicated the reference laboratory address as the location where patient testing was performed. The LD stated he/she: "knew that the reference laboratory address should have been entered for all testing performed at the reference laboratory from May 1, 2018 until July 20, 2018".
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 the laboratory's policies, quality control (QC) records, patient

	records and interviews, the laboratory director failed ensure that quality control policies were followed and QC was performed on the Chemistry and Hematology analyzers prior to reporting of patient test results (Cross reference D6020).
D6020	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 the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, patient test logs and requisitions, QC records, and interview, the laboratory director failed to ensure that quality control policies were followed prior to reporting twenty eight (28) patient results during the seventeen (17) weeks reviewed (Cross reference D5447).