Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D1056451	(X3) Date Survey Completed 05/08/2019
Name of Provider or Supplier Mountainview Medical Associates	**Street Address, City, State** 205 E Hirst Road - Suite 203, Purcellville, 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 announced CLIA recertification survey was conducted at Mountain View Medical Associates on May 8, 2019 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiencies are as follows:
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records and an interview with the Laboratory Director (LD), the laboratory failed to attain a score of at least eighty (80) percent (%) of acceptable responses for one (1) out of six (6) hematology analytes on the 2017 Medical Laboratory Evaluation (MLE) M2 PT testing event. Findings include: 1. Review of the laboratory's MLE events for 2017 M2, 2017 M3, 2018 M1, 2018 M2, 2018 M3 and 2019 M1 PT records (a total of 6 events reviewed) revealed a score of less than 80 % for the following hematology analyte in the 2017 M2 event: 60% score-Red Blood Cell Count (RBC) HD-6 and HD-9 unacceptable. 2. In an exit interview with the LD at approximately 11:45 AM, the LD confirmed the findings.
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be

	maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on a review of the proficiency testing (PT) records, "Laboratory Quality Assurance" plan, and an interview with the Laboratory Director (LD), the laboratory failed to follow their established policy and document remedial action taken for the unacceptable analyte score of less than eighty (80) percent (%) for 2017 Medical Laboratory Evaluation (MLE) event M2 Red Blood Cell Count (RBC). Findings include: 1. Review of the laboratory's MLE events for 2017 M2, 2017 M3, 2018 M1, 2018 M2, 2018 M3 and 2019 M1 PT records (a total of 6 events reviewed) revealed a score of less than 80 % for the following hematology analyte in the 2017 MLE M2 event: 60% score-Red Blood Cell Count (RBC) HD-6 and HD-9 unacceptable. 2. Review of the "Laboratory Quality Assurance Plan" revealed a policy, "Proficiency Testing (P.T.)", which stated, "Technical Consultant will document resolution of any deficiencies on P.T " The surveyor requested documentation of the PT remedial action for the MLE 2017 M2 Event. The laboratory provided no documentation for review. 3. In an exit interview with the LD at approximately 11:45 AM, the LD confirmed the findings.
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 the review of the "Laboratory Quality Assurance" (QA) policy, quality assurance records, competency records, and an interview with the Laboratory Director (LD), the laboratory failed to follow the written QA policy for the review of their analytic test system from June 1, 2017 until the date of the survey, May 8, 2019. Findings include: 1. Review of the "Laboratory Quality Assurance" policy revealed the following statements: "QA Meetings: QA meetings will occur no less than quarterly as follows: January, April, July & October. QA Audits: QA audits should occur no less than Quarterly to coincide with QA meetings, no more than one week prior to each meeting. Auditing will be directed by QA Director and include: Review of CBC Quality Control Documentation; Review of waived testing QA documentation; Review of patient or provider complaints and their resolution; Quarterly audit report to present at QA meeting." 2. Review of the laboratory's QA records from June 1, 2017 to the date of the survey, May 8, 2019, revealed no documentation of the quarterly "QA Audits" for July 2017, October 2017, January 2018, April 2018, July 2018, October 2018, January 2019 and April 2019 (a total of eight quarters). The surveyor requested documentation of the quarterly "QA Audits" for July 2017, October 2017, January 2018, April 2018, July 2018, October 2018, January 2019 and April 2019. The laboratory provided no documentation to review. 3. In an exit interview with the LD at approximately 11:45 AM, the LD confirmed the findings.
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 a review of the laboratory's policies, personnel records, and interviews, the laboratory director failed: to ensure the competency assessment policy was followed for three (3) of 3 testing personnel in 2018 (Cross Reference D 6054 -REPEAT DEFICIENCY). ; and to ensure the laboratory followed their established policy to document the remedial action taken when Proficiency Testing scores for an analyte are unsatisfactory (Cross Reference D6019).
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on a review of the proficiency testing (PT) records, "Laboratory Quality Assurance" plan, and an interview with the Laboratory Director (LD), the Laboratory Director failed to ensure they followed their established policy to document remedial action taken for the unacceptable analyte score of less than eighty (80) percent (%) for 2017 Medical Laboratory Evaluation (MLE) event M2 Red Blood Cell Count (RBC). Findings include: 1. Review of the laboratory's MLE events for 2017 M2, 2017 M3, 2018 M1, 2018 M2, 2018 M3 and 2019 M1 PT records (a total of 6 events reviewed) revealed a score of less than 80 % for the following hematology analyte in the 2017 MLE M2 event: 60% score-Red Blood Cell Count (RBC) HD-6 and HD-9 unacceptable. 2. Review of the "Laboratory Quality Assurance Plan" revealed a policy, "Proficiency Testing (P.T.)", which stated, "Technical Consultant will document resolution of any deficiencies on P.T " The surveyor requested documentation of the PT remedial action for the MLE 2017 M2 Event. The laboratory provided no documentation for review. 3. In an exit interview with the LD at approximately 11:45 AM, the LD confirmed the findings.
D6054	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 annually, after the first year. This STANDARD is not met as evidenced by: **REPEAT DEFICIENCY** Based on a review of Centers for Medicare and

	Medicaid Services Laboratory Personnel Report form (CMS 209), the "Laboratory Quality Assurance" policy, laboratory personnel files, and an interview with the Laboratory Director (LD), the technical consultant (TC) failed to follow the established laboratory policy and perform annual competency evaluations for three (3) of three (3) Testing Personnel (TP) in 2018. Findings include: 1. Review of the "Laboratory Quality Assurance" policy revealed a statement, "Technical Consultant will ensure that competency assessments are performed on all clinical staff annually." 2. Review of the CMS Form 209: Laboratory Personnel Report revealed the LD also performed the duties of TC and there was 3 TP (TP A, B and D) who performed patient testing in 2018. 3. Review of the laboratory personnel files revealed that TP A, TP B and TP C lacked a 2018 annual competency evaluation. (See Personnel Code Sheet.) The surveyor requested documentation of the 2018 annual competencies for TP A, TP B and TP C. The laboratory provided not documentation for review. 4. In an exit interview with the LD at approximately 11:45 AM, the LD confirmed the findings.