Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0918578	11/30/2023
Name of Provider or Supplier	**Street Address, City, State**	
Mountain View Pediatrics, Pa	111 Hilltop Street, Rutherford College, 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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of 2021, 2022, and 2023 API (American Proficiency Institute) proficiency testing records and interview with TP (testing personnel) #1 on 11/30/23, the laboratory failed to evaluate ungraded and unacceptable proficiency testing results for 3 of 8 hematology test events reviewed. Findings: Review of 2021, 2022, and 2023 API proficiency testing records revealed the laboratory failed to evaluate ungraded and unacceptable proficiency testing results on the following test events to ensure corrective action was taken and documented as needed: 1. 2021 3rd hematology - no documentation of evaluation for 1 ungraded wet prep sample (VKP-03) and 1 ungraded educational blood cell identification sample (ECI-15). 2. 2022 2nd Hematology - no documentation of evaluation for 1 unacceptable blood cell identification result (BCI-09). 3. 2023 1st Hematology - no documentation of evaluation for 2 ungraded educational blood cell identification samples (ECI-02, ECI-05). During interview at approximately 2:00 p.m., TP #1 stated she was unaware the ungraded and unacceptable results had not been evaluated.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number

	and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of 2021, 2022, and 2023 quality control records, and interview with TP #2 on 11/30/23, the laboratory failed to perform and document quality control each day of patient testing or establish an IQCP (Individualized Quality Control Plan) for the throat and urine cultures performed. Review of the laboratory's "Group A Beta Strep: Backup Culture" procedure revealed "... H. Quality Control: Media 1. Upon receipt, examine media for contamination of defects... Document visual inspection and keep Quality Control Certificate label. ... 2. Upon receipt of each shipment, incubate one plate for 18-24 hours and examine for growth. ... 3. Quality control: Taxo Discs Streak plate with a known GABS culture and a known non-GABS culture... Add discs, incubate for 18-24 hours, and record results on quality control log. ..." Review of 2021, 2022, and 2023 quality control records revealed the laboratory had retained documentation of the manufacturer's quality control testing and had documented sterility testing for each lot number of media received, but had not performed growth checks using control organisms for throat and urine cultures each day of patient testing. There was no documentation available to indicate that the laboratory had established an IQCP. During interview at approximately 4:00 p.m., TP #2 confirmed that the laboratory did not have an IQCP in place for their throat and urine cultures.
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of 2021, 2022, and 2023 media quality control records and interview with TP #2 on 11/30/23, testing personnel failed to document visual inspection of each new lot number of media used for urine and throat cultures. The laboratory's "Group A Beta Strep: Backup Culture" procedure stated "... H. Quality Control: Media 1. Upon receipt, examine media for contamination of defects (uneven filling, bubbles, cracks, etc.). Document visual inspection and keep Quality Control Certificate label. ..." Review of 2021, 2022, and 2023 media quality control records revealed the laboratory had documented a sterility check for each new lot number of media and saved the label from each new lot number to document the manufacturer's performance of quality control, but had not documented a visual inspection of each new lot number. During interview at approximately 2:30 p.m., TP #2 confirmed the testing personnel had not documented visual inspection of each new lot number of media. She stated they always perform a visual inspection when media is received, but they did not realize documentation of the visual inspection was required.