Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2153211	12/06/2018
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Assoc Charlottesville-Zion Crossroads	71 Jefferson Court, Zion Crossroads, 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 initial survey was conducted at Pediatric Associates Charlottesville-Zion Crossroads on December 6, 2018 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiency cited as follows:
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on a review of Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), analyzer installation validation records, manufacturer's users guide, laboratory personnel files, and an interview, the laboratory director (LD) failed to document initial hematology training and competency evaluations for two (2) of two (2) testing personnel (TP) after an instrument installation occurred in the laboratory on August 29, 2018. Findings include: 1. Review of the CMS 209 form revealed 2 TP perform patient hematology testing. 2. Review of the laboratory's instrument validation records revealed a hematology analyzer installation (Medonic M Series Serial Number 22128), was performed by a Medonic field service technical specialist on 8/29/18. 3. Review of the Medonic M Series User's Guide revealed manufacturer's instructions that the "M Series Training Checklist is to be completed prior to patient testing for all operators". 4. Review of the

	laboratory personnel files and installation records revealed that TP A and B lacked a Medonic M Series Training Competency checklist and evaluation. The inspector requested to review the training competency evaluations. No documentation was available for review. (See Personnel Code Sheet) 5. In an interview with the technical consultant at approximately 12:30 PM, it was confirmed that the LD failed to ensure initial training competency evaluations for TP A and B were documented, prior to their utilizing the Medonic instrument for patient testing, from September 5, 2018 through the date of the survey on December 6, 2018.