Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0695446	02/10/2022
Name of Provider or Supplier	**Street Address, City, State**	
Partners In Pediatrics	8160 Seaton Place, Montgomery, AL	

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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of the 2020 - 2021 MLE (Medical Laboratory Evaluation) proficiency testing (PT) records, and an interview with the Laboratory Director, the surveyor determined the Laboratory Director failed to sign attestation statements for three of seven surveys reviewed. The findings include: 1. A review of the 2020 - 2021 MLE PT records revealed the Laboratory Director failed to sign the attestation statements for the 2020-M3, 2021-M2, and 2021-M3 surveys. 2. In the Day 1 exit summation on 2/9/2022 at 4:00 PM the surveyor reviewed and confirmed the above noted findings. .
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.

	This STANDARD is not met as evidenced by: Based on a review of Hematology and Chemistry records, and an interview with Testing Personnel #2, the laboratory failed to retain the manufacturer's package inserts for two of six Hematology analyzer calibrators, and the Bilirubin quality controls (QC) inserts except the current lot number in use. The findings include: 1. A review of Hematology records revealed no calibrator assay sheets for the calibrations performed on 1/30/2020 and 6/16/2020. 2. A review of Chemistry records revealed the laboratory retained the manufacturer's package insert for the current lot number of Bilirubin QC only. 3. During an interview on 2/9/2022 at 3:05 PM Testing Personnel #2 confirmed the above findings. .
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of Hematology records, a review of the User's Manual for the new Beckman Coulter DxH500 Hematology analyzer, and an interview with Testing Personnel #2 and the Laboratory Director, the surveyor determined the Laboratory Director failed to review, sign and date approval of the procedures before the Testing Personnel began using the instrument for patient testing. This affected procedures in use for one of one new instruments performing moderate-complexity tests. The findings include: 1. A review of Hematology records revealed validation records for the BC DxH500, installed in January 2021. Patient CBC (Complete Blood Count) testing began on 2/12/2021. 2. A review of the "Beckman Coulter Instructions for Use" Manual revealed no documentation of the Laboratory Director's review and approval (as indicated by a signature and date) of the procedures in use by the testing personnel. 3. In the Day 1 exit summation on 2/9/2022 at approximately 4:00 PM, the surveyor reviewed CLIA requirements, and confirmed the above noted findings with the Laboratory Director and Testing Personnel #2. .
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on a review of the installation and validation records for the Beckman Coulter (BC) DxH500 Hematology analyzer, and an interview with the Laboratory Director, the surveyor determined the Laboratory Director failed to document review and approval of the procedures as verification of the manufacturer's performance

	specifications before patient testing began. This affected one of one new instruments performing moderate-complexity tests. The findings include: 1. A review of the validation records for the BC DxH500 revealed no documentation (signature and date) of the Laboratory Director's review and approval of the procedures verifying the manufacturer's performance specifications. Patient CBC (Complete Blood Count) testing began on 2/12/2021. 2. A further review of the installation records revealed CBC printouts from approximately 28 patients run on the BC DxH500 and the BC AcT diff (the previous analyzer) for a comparison study, however there was no documentation the data had been evaluated and values calculated to prove the accuracy of the new instrument. The surveyor also noted no documentation of the reference ranges verification. 3. In the Day 1 exit summation on 2/9/2022 at 3:50 PM, the surveyor reviewed the records with the Laboratory Director, and confirmed the above noted findings. .
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 reviews of personnel files, Hematology records and an interview with Testing Personnel #2, the surveyor determined the Laboratory Director failed to ensure training on the new Beckman Coulter DxH500 (installed January 2021) was performed and documented for twelve of twelve Testing Personnel hired on or before January 2021. The findings include: 1. A review of Hematology records revealed the new Beckman Coulter (BC) DxH500 Hematology analyzer was installed in January 2021. 2. A review of personnel files and the installation records for the BC DxH500 revealed no documentation of training on the instrument for the twelve Testing Personnel who were on staff and performing patient testing in January 2021. 3. During an interview on 2/9/2022 at 2:45 PM, Testing Personnel #2 confirmed she had a training manual for the new DxH500, however there was no training documentation for the testing personnel working when the new analyzer was installed. .
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of

	Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on reviews of personnel files, and an interview with Testing Personnel #2 and the Laboratory Director, the surveyor determined the laboratory failed to ensure four of twelve new Testing Personnel presented educational documentation, as required per CLIA regulations. The findings include: 1. A review of personnel files revealed four employees with no documentation of educational credentials (a high school diploma or equivalent, or a degree in a chemical, physical or biological science) as required for the position of moderate-complexity testing personnel, as follows: A) TP #4 had provided a Medical Assisting Diploma transcript only. B) TP #5 had provided a Certificate in Practical Nursing only C) TP #6 had provided a Certificate in Practical Nursing only D) TP #15 had no educational documentation 2. In the Day 1 exit summation on 2/9/2022 at 4:00 PM the surveyor reviewed educational requirements for moderate-complexity testing personnel, and confirmed the above noted findings with the Laboratory Director and Testing Personnel #2 The laboratory was unable to provide the required records during the survey. SURVEYOR ID#32558 Licensure and Certification Surveyor