Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D1016527	06/09/2023
Name of Provider or Supplier	**Street Address, City, State**	
Partners In Pediatrics	136 East Main Street, Prattville, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a review of the Medical Laboratory Evaluation (MLE) proficiency testing (PT) records and an interview with Testing Personnel #10, the surveyor determined the physicians reading the Bacteriology cultures failed to sign the attestation statements as testing personnel on ten out of eleven 2019 - 2023 survey events. The findings include: 1. A review of the 2019 - 2023 MLE records revealed the physicians reading the Bacteriology cultures failed to sign the attestation statements for 10 out of 11 survey events; only the 2022 M-1 attestation statement had the signature of the Laboratory Director who signed as the testing personnel after performing the reading for Urine Colony Counts. 2. During an interview on 6/8/2023 at 1:45 PM, Testing Personnel #10 reviewed and confirmed the above noted findings. .
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 a review of the Medical Laboratory Evaluation (MLE) proficiency testing (PT) records and an interview with Testing Personnel #10, the laboratory failed to: (1) document reviews of results for five of six 2020 - 2021 survey events; and (2)

	document investigation and implementation of corrective actions for scores less than 100% on two of six 2020 - 2021 survey events. The findings include: 1. A review of the MLE PT records (for Hematology and Bacteriology testing) revealed the laboratory failed to document review of the results (scores) for 2020-M1, -M2, -M3, 2021-M1 (Bacteriology only), and 2021-M2 survey events. 2. A further review of the MLE PT records revealed no documentation of investigation and implementation of corrective actions for the following surveys: A) 2020-M1: Red Blood Cells (RBC) with a score or 80%, resulting in a score of 96% in the specialty of Hematology, and Throat Culture with a score of 80%. B) 2021-M1: Throat Culture with a score of 80%, and Urine Culture with a score of 50% 3. During an interview on 6/8/2023 at 1:45 PM, Testing Personnel #10 reviewed and confirmed the above noted findings. .
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on a review of the Medical Laboratory Evaluation (MLE) proficiency testing (PT) records, and an interview with Testing Personnel #10, the surveyor determined the laboratory failed to perform effective Quality Assurance (QA) reviews of the PT records to ensure: (I) All attestation statements were signed by the testing personnel (physicians) reading the Bacteriology cultures; (II) Reviews of survey results (scores) were documented, and any surveys with results less than 100 % had documentation of corrective actions; (III) All surveys had sufficient QA review to ensure completeness; and (IV) Additional corrective actions were implemented for Bacteriology failures. This was noted to occur from the date of the previous survey on 7/25/2019 to the date of the current CLIA survey (6/9/2023). The findings include: 1. A review of the 2019 - 2023 MLE PT records revealed the laboratory failed to implement effective QA reviews to insure: A) Physicians reading the Bacteriology cultures signed the attestation statements as the testing personnel. (Refer to D2009.) B) Reviews of survey results (scores) were documented, with any surveys and results less than 100 % having documentation of corrective actions. (Refer to D5211.) C) Required survey documents were retained, as follows: i) Missing Hematology instrument printouts on the 2021 M-2 survey ii) Missing Bacteriology worksheets for the 2021-2022 PT surveys 2. The surveyor further noted the laboratory failed to document effective corrective actions when investigating failures in Bacteriology: 2021 M-3 and 2022 M-2 failed Urine Colony Counts (due to under-growth of the bacteria), however the only documented corrective action was "Continue to review the Urine Cultures with at least two physicians". There was no investigation of other factors that could affect the cultures (such as personnel training, set-up, incubation, or media quality). 3. During interviews on 6/8/2023 at 1:45 PM and on 6/9/2023 at 11:00 AM (during the exit summation), these concerns were reviewed and confirmed with Testing Personnel #10. .
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 the Beckman Coulter DxH500 Hematology analyzer records and interviews with Testing Personnel #10 and the Laboratory Director, the laboratory failed to ensure procedures were approved (as indicated by signature and date) by the Laboratory Director before the instrument was used for patient testing on 1/19/2021. The manual was not signed by the Laboratory director until 3/3/2022, more than a year later. This affected one of one new moderate-complexity instruments. The findings include: 1. A review of the "Instructions for Use Manual" for the Beckman Coulter DxH500 Hematology analyzer revealed the procedures were signed by the Laboratory Director on 3/3/2022. 2. During an interview with Testing Personnel #10 on 6/8/2023 at 2:20 PM, the surveyor asked when patient testing began on the Beckman Coulter DxH500; Testing Personnel #10 replied, "1/19/2021". 3. During the exit summation on the first day of the survey, 6/8/2023 at 4:30 PM, the Laboratory Director confirmed the above findings. .
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of the Beckman Coulter DxH500 Hematology analyzer records and an interview with Testing Personnel #10, the laboratory failed to ensure maintenance procedures were performed and documented with the frequency prescribed by the manufacturer. The laboratory had no documentation of daily and monthly maintenance from January 2021 (when the instrument was installed) to October 2022. The findings include: 1. A review of the Beckman Coulter DxH500 Hematology analyzer records revealed the instrument was installed in January 2021, however only maintenance records from November 2022 to June 2023 were available. 2. A review of the "Instructions for Use Manual" and the Maintenance Checklist for the Beckman Coulter DxH500 Hematology analyzer revealed daily maintenance requirements included a shutdown, daily checks (background counts), running quality controls, and cleaning the sample probe and rinse cup. Cleaning procedures were also required each month (or every 1000 cycles). 3. During an interview on 6/8/2023 at 2:42 PM, the surveyor asked if the laboratory had Beckman Coulter DxH500 maintenance logs from January 2021 to October 2022. Testing Personnel #10 stated the laboratory was told they needed to document the maintenance in November 2022; the laboratory had performed the maintenance before this time, but had not documented it. .
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)

	(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on a review of calibration records for the Beckman Coulter DxH 500 Hematology analyzer, a review of the manufacturer's instructions, and an interview with Testing Personnel #10 and the Laboratory Director, the laboratory failed to ensure: (1) calibrations were performed and documented every six months; (2) repeatability and reproducibility was performed and documented each time a calibration was performed; and (3) quality controls (QC) were performed after calibration and before patient testing. These problems were noted to have occurred from the date of installation (1/15/201) through the date of the current survey (6/8 /2023). The findings include: 1. A review of calibration records for the Beckman Coulter DxH 500 Hematology analyzer revealed the following: (1) Regarding calibration frequency, the surveyor noted the following: A. The new Beckman Coulter DxH 500 Hematology analyzer was installed on 1/15/2021, however the laboratory failed to retain documentation of the calibration performed during the installation. B. The Beckman Coulter DxH 500 calibration binder included documentation of the Repeatability (precision) and Carryover studies performed on 6/2/2021, however the laboratory failed to print the calibration factors. The laboratory had no documentation of a calibration during the first year of use until 12/30/2021, almost a year after patient testing began. (2) Regarding Repeatability and Carryover, the laboratory failed to perform and document these studies during the 5/1/2022 and 12/2/2022 calibrations, two of two calibrations performed in 2022. (3) Regarding quality controls, the surveyor noted the laboratory failed the perform and document QC after a calibration and before patient testing, as follows: A. 12/30/2021 at 3:37 PM; 1 patient CBC (Complete Blood Count) performed B. 5/1/2022 at 10:11 AM; 15 patient CBC's performed C. 12/2/2022 at 10:07 AM; 3 patient CBC's performed 2. A review of the Beckman Coulter DxH 500 "Instructions for Use Manual", under Chapter 11 Quality Assurance revealed, "...Calibration...When to Verify Calibration You should verify the calibration of your instrument: As dictated by your laboratory procedures and ... national regulations ...". A further review of the procedure revealed instructions on how to perform the Repeatability and Carryover studies with the calibration. 3. During an interview with Testing Personnel #10 and the Laboratory Director on 6/8/2023 at 2: 15 PM, Testing Personnel #10 confirmed there was no documentation of the 1/15 /2021 calibration or the calibration factors for the 6/2/2021 calibration. In addition, Testing Personnel #10 stated she followed the manufacturer's procedure for performing a calibration, however she did not realize she needed to print the Repeatability and Carryover studies with each calibration. 4. As the interview continued the surveyor illustrated to Testing Personnel #10 and the Laboratory Director how a calibration changed the calibration factors in the instrument. The surveyor explained any time, a calibration was performed the laboratory was required to verify the QC was still within the manufacturer's acceptable ranges, as per CLIA regulations. .
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 Beckman Coulter DxH500 Hematology analyzer records and interviews with Testing Personnel #10 and the Laboratory Director, the Laboratory Director failed to document review and approval of the validation procedures as verification of the manufacturer's performance specification before patient testing began on 1/19/2021, more than a year before the Director's signed approval on 3/4 /2022. This affected one of one new moderate-complexity instruments. The findings include: 1. A review of the installation and validation records for the Beckman Coulter DxH500 Hematology analyzer revealed validation procedures for the new instrument were performed in January 2021, and originally signed by a previous testing personnel on 1/20/2021. 2. A further review of the Beckman Coulter DxH500 validation records revealed the Laboratory Directory signed the Accuracy/Reportable Range summation sheet on 3/4/2022. 3. During an interview on 6/8/2023 at 2:20 PM, Testing Personnel #10 confirmed the above findings. The surveyor then asked when patient testing began on the Beckman Coulter DxH500; Testing Personnel #10 replied, "1/19/2021". 4. During the exit summation on the first day of the survey, 6/8 /2023 at 4:30 PM, the Laboratory Director also confirmed the above findings. .
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: Based on a review of personnel files and an interview with Testing Personnel #10, the Technical Consultant (also the Laboratory Director) failed to ensure: (1) Training records included more detailed documentation that included all aspects of the Testing personnel's responsibilities for 11 of 11 new testing personnel; and (2) Training records for the new Beckman Coulter DxH500 Hematology analyzer were available for 12 out of 16 testing personnel. The findings include: 1. A review of employee files for eleven new testing personnel listed on the Form CMS-209 (Laboratory Personnel Report) revealed training was documented on the "Laboratory Personnel Checklist". Testing Personnel signed the sheet as having performed ten patient CBC's (Complete Blood Counts), three Urine Cultures, and waived testing. 2. A review of employee files for the sixteen testing personnel listed who performed Hematology testing revealed only four testing personnel had documentation of the manufacturer's training on the new Beckman Coulter (B-C) DxH500 Hematology analyzer (installed January 2021). 3. During an interview on 6/8/2023 at 10:30 AM (with the Laboratory Director/ Technical Consultant present), Testing Personnel #10 confirmed the "Laboratory Personnel Checklist" was the only documentation for testing personnel training. The surveyor explained the checklist failed to document whether a testing

	personnel was trained to run Hematology quality controls, perform required maintenance and calibration, whether training included the critical results procedure, troubleshooting, pre-analytical processes, such as mixing and recognizing an unacceptable specimen, and post-analytical processes, such as results entry. In addition, testing personnel needed detailed instruction on how to set up urine culture since it was a critical part of this test procedure. 4. During a later interview on 6/8 /2023 at 1:45 PM regarding the B-C DxH500 training documentation, Testing personnel #10 explained she only had the DxH500 training records for the full-time employees at this location. All the other testing personnel were part-time with no set schedule. The surveyor stated the laboratory was required to retained training documentation for all personnel listed on the CMS-209. SURVEYOR ID #32558 Licensure and Certification Surveyor