Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0695446	07/23/2019
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
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 MLE (Medical Laboratory Evaluation) proficiency testing records and an interview with Testing Personnel (TP) #2 and #10 and the Laboratory Director (new director since April of 2019), the surveyor determined the laboratory failed to review and evaluate the results of proficiency testing for Event MLE M2 and Event MLE M3 of 2018. This affected two of six testing events reviewed by the surveyor. The findings include: 1. A review of the MLE proficiency testing records for Event MLE M2 of 2018 (Hematology, Routine Chemistry, and Microbiology) revealed the laboratory failed to review and evaluate the results returned by the program provider. The review/evaluation form failed to include the Laboratory Director's or delegate's signature, which would indicate a review of the results. The surveyor's review revealed the laboratory scored eighty percent (80 %) for Throat Culture Interpretations. Specimen TC #9 (one/five specimens) was reported as positive, but the expected and acceptable response was negative. 2. A review of the MLE proficiency testing records for Event MLE M3 of 2018 (Hematology, Routine Chemistry, and Microbiology) revealed the laboratory failed to review and evaluate the results returned by the program provider. The review/evaluation form failed to include the Laboratory Director's or delegate's signature, which would indicate a review of the results. 3. During the exit interview on 7/23/2019 at 1:30 PM, the surveyor discussed the above noted findings with TP #2 and #10 and the Laboratory Director. The surveyor further discussed the requirement for the laboratory to review and evaluate all proficiency testing results to ensure accuracy was verified and corrective actions implemented, when necessary.

D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a review of the test menu and proficiency testing records, a lack of documentation of accuracy verifications, or policy for verifying the accuracy of urine sediment examinations (provider- performed microscopy), and an interview with Testing Personnel (TP) #2 and #10, and the Laboratory Director (new director since April of 2019), the surveyor determined the laboratory failed to verify the accuracy of urine sediment examinations for the survey review period of September 2017 - date of the survey (July 23, 2019). The findings include: 1. During the initial tour of the laboratory on 7/23/2019 at approximately 9:30 AM, TP #10 stated urine sediment examinations were performed at the laboratory by the physician. 2. The MLE (Medical Laboratory Evaluation) proficiency testing records for 2017 Event #3 - 2019 Event #2 did not include proficiency testing for the urine sediment examinations (microscopy), also a moderate complex test. 3. During the exit interview on 7/23/2019 at 1:30 PM, the surveyor asked if any accuracy verifications were performed on the urine examinations. The Laboratory Director confirmed no proficiency testing was performed on the urine sediments and no alternative policy had been established for this non-regulated CLIA analyte, which qualifies for accuracy verifications at least twice per year.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on a review of the MLE (Medical Laboratory Evaluation) proficiency testing records and an interview with Testing Personnel (TP) #2 and #10 and the Laboratory Director (new director since April of 2019), the surveyor determined the laboratory failed to implement and document corrective actions for proficiency testing scores of less than one hundred percent, sometimes unsatisfactory scores (less than eighty percent). This affected 2017 MLE M3, 2018 MLE M2 and 2019 MLE M2, three of six testing events reviewed by the surveyor. The findings include: 1. A review of the MLE proficiency testing records for Event MLE M3 of 2017 (Hematology, Routine Chemistry, and Microbiology) revealed the laboratory scored zero percent (0 %) for Urine Cultures. The review/evaluation form was signed by the former laboratory director, however no corrective actions were implemented and documented for this failing score (the results of 2/2 specimens were unacceptable). 2. The proficiency testing records for Event MLE M2, 2018 revealed the laboratory scored 80 % for Throat Culture Interpretations (colony counts). Specimen TC #9 (one/five specimens) was reported as positive, but the expected and acceptable response was negative. The laboratory failed to implement and document corrective actions. 3. A review of the MLE proficiency testing records for Event MLE M2, 2019 revealed the laboratory scored 80 % for Throat Cultures. The laboratory reported positive for Group A Streptococcus for specimen TC #6; however the expected result was negative. The laboratory did not document and implement corrective actions. 4. During the exit

	interview on 7/23/2019 at 1:30 PM, the surveyor discussed the above noted findings with TP #2 and #10 and the Laboratory Director. The surveyor further discussed the requirement for the laboratory to review and evaluate all proficiency testing results to ensure accuracy was verified and corrective actions implemented, when necessary. The Laboratory Director reviewed the results for Event 2017 MLE M3 and confirmed the failing score with no corrective actions taken. .
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 personnel records and interviews with Testing Personnel (TP) #2, #10 and the Laboratory Director (new director since April of 2019), the surveyor determined the Laboratory Director failed to ensure TP #3 presented with the appropriate educational credentials to qualify for a moderate-complexity testing personnel, prior to training, testing patient specimens and reporting the results. This affected one of seven testing personnel, hired since the previous survey in August of 2017. The findings include: 1. The laboratory listed twenty-three testing personnel on the CMS form #209 (Laboratory Personnel Report, CLIA), which included seven employees hired since the survey conducted on August 15, 2017. 2. The personnel records failed to include the minimum qualifications of a high-school diploma (General Education Diploma or transcript) or science degree to ensure TP #3 was qualified to perform moderate-complexity testing. The file of TP #3 included the staff member's nursing license. 3. At 11:00 AM on 7/23/19, the surveyor requested of TP #2 and #10, the laboratory managers, to see the educational credentials of TP #3, other than a certificate or nursing license. The surveyor discussed the documentation type needed for an employee to qualify as a testing personnel of moderate-complexity testing. 4. During the exit interview on 7/23/19 at 1:30 PM, the surveyor discussed the above noted findings with TP #2, #10 and the Laboratory Director. The laboratory was given until 12:00 Noon on Friday, July 26 to provide acceptable educational credentials for TP #3. No further documentation of education was provided by the laboratory by 2:00 PM on August 1.