Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D1016527	07/25/2019
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
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 a review of the test menu, a review of the MLE (Medical Laboratory Evaluation) proficiency testing records, and an interview with Testing Personnel (TP) #7 (also the Laboratory Manager). the surveyor determined the laboratory failed to implement and document corrective actions for an unacceptable Throat Culture proficiency testing result for Event MLE M2, 2018. This affected one of six proficiency testing events reviewed by the surveyor. The findings include: 1. During an initial tour of the laboratory on 7/25/19, TP #7 stated throat and urine cultures were interpreted at the laboratory. 2. A review of the proficiency testing records for Event MLE M2, 2018 revealed the laboratory scored eighty percent (80 %) for Throat Cultures. MLE found the laboratory's results for Specimen TC #9 unacceptable. 3. The laboratory did not implement and document corrective actions for this unacceptable score/specimen. The results were highlighted but not addressed. 4. During an interview on 7/25/19 at 1:00 PM, the above noted findings were discussed with TP #7.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the

	manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of policies and procedures, a review of media quality control records, and interviews with Testing Personnel (TP) #7, TP #10 and the Laboratory Director (also the Technical Consultant), the surveyor determined the laboratory failed to check each batch of media (lot number and/or shipment), used for throat and urine cultures, for its ability to support growth. This affected media batches, lot numbers and/or shipments received for the survey period of August 2017 - July 25, 2019. The findings include: 1. During the initial tour of the laboratory on 7/25/19, TP #7 stated the laboratory performs testing of throat and urine cultures. The laboratory uses Uricult media (culture paddles) for semi-quantitative analysis for presumptive identification, and TSA (Trypticase soy agar) with 5 % blood for the detection of bacteria in throat cultures. 2. A review of the policies and procedures revealed for urine cultures the media was checked for sterility and agar integrity (visual inspection) upon arrival from the supplier; and the results were recorded in the media log. The laboratory's policy also included a statement that the manufacturer of the media performed the quality control checks. The policies and procedures for the throat cultures included instructions to check the integrity of the media, and upon receipt of the media, check one plate for agar deterioration and sterility. The Bacitracin discs, used with the TSA media, was quality controlled with each new lot number. 3. A review of the media quality control records for the Uricults, for 7/19/17 - 5/21/19, revealed the laboratory staff documented the dates received, lot numbers with expiration dates, and whether the media passed or failed visual inspection. For the TSA media, the laboratory documented the dates received, lot numbers with expiration dates, visual and sterility checks, and pasted the labels for QC organisms positive and negative with the Bacitracin discs. (The laboratory did not document actual reactions to the discs). The laboratory did not perform media quality control to assure the media could support bacterial growth. 4. During an interview on 7/25/19 at 12:23 PM, testing personnel from a sister laboratory stated she brought the manufacturer's insert for the Uricult and asked the surveyor to read it. The surveyor read the insert and explained to this personnel and TP #7 the responsibility, as per the CLIA regulations, for the end-user to perform the media quality control, in accordance with the standard CLIA regulation or develop and IQCP (Individualized Quality Control Plan), which became effected January 1, 2016, preceded by an educational and training period of approximately two years. 5. At approximately 1:00 PM on 7/25 /19, the surveyor discussed the media quality control requirements with the Laboratory Director (Technical Consultant), testing personnel of the sister location, and TP #7 and #10.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on an observation during the initial tour of the laboratory on 7/25/19, a review of quality control records, a review of patient test logs, and an interview with Testing Personnel (TP) #7, the surveyor determined the laboratory failed to ensure at least two

	levels of quality control were acceptable on 4/27/18, prior to testing patient CBC (Complete Blood Count) specimens and reporting the results. This affected one day of sixteen months of quality control reviewed by the surveyor. The findings include: 1. During the initial tour of the laboratory with TP #7, the surveyor observed the Beckman Coulter Act Diff for CBC testing (Hematology). TP #2 stated the instrument was new since January 2019. 2. A review of the CBC quality control testing revealed on 4/27/18, the normal and high controls of the three levels tested were outside of the acceptable ranges. These controls were tested at 8:00 - 8:10 AM. There were no other CBC quality control documented for this day (the controls were not repeated). 3. The patient test logs indicated four patient CBC specimens were run between 8:39 AM - 3: 03 PM on 4/27/18. 4. In an interview on 7/25/19 at 12:31 PM, the surveyor asked TP #7 to review the quality control and patient records for 4/27/18. TP #7 reviewed the records and confirmed the two unacceptable levels of control on 4/27, without any repeat testing; and the four patient specimens tested. TP #7 further confirmed no patient remediation had occurred.
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 an observation, a review of the installation and validation records for the Beckman Coulter Act Diff Hematology analyzer and an interview with Testing Personnel (TP) #10 (identified as in-training for laboratory manager), the surveyor determined the Laboratory Director failed to approve and sign the validation of performance of the analyzer, prior to allowing the testing personnel to use the analyzer to test patient specimens. The analyzer was installed on January 7, 2019. The findings include: 1. During the initial tour of the laboratory with TP #7, the surveyor observed the Beckman Coulter Act Diff for CBC testing (Hematology). TP #7 stated the instrument was new since January 2019. 2. A review of the installation and validation records revealed the records were dated 2016. At 11:35 AM on 7/25/19, TP #10 stated the analyzer was refurbished and delivered to the laboratory in January of 2019. The installation and validations records from 2016 accompanied the analyzer. Additionally, TP #10 stated the manufacturer's representative allowed her to observe testing of one linearity standard and instructed her to complete the linearity study for validation of the instrument. TP #10 completed the linearity study on 1/7/19; however the Laboratory Director did not review the data and approve (via signature) the analyzer to be used in the laboratory. Patient testing continued.
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 an interview with Testing Personnel (TP) #7 (also the laboratory manager), the surveyor determined the Laboratory Director (LD) failed to ensure each TP of moderate complexity testing presented with the appropriate educational credentials and was trained, prior to performing testing on patient specimens and reporting the results. This affected four of seventeen testing personnel. The findings include: 1. A review of the personnel records revealed missing appropriate and acceptable educational credentials or initial training documentation for the following testing personnel: a) TP # 2's date of hire was 1/22 /18. The initial training was documented in February of 2018. The personnel's file included a nursing license, but no diploma or degree or other verification of education. b) TP #6 (date of hire was not provided) did not have documentation of initial training; but the employee's competency was assessed in June of 2019. c) TP #8's date of hire was not provided. The personnel's file included a nursing license, but no diploma or degree or other verification of education. TP #8 also failed to have documentation of initial training; however the employee's competency was assessed in June of 2019. d) TP #12 was hired on 9/17/18. The laboratory did not provide documentation of the initial training for TP #12; although the employee's competency was assessed in June of 2019. 2. During an interview on 7/25/19 at 10:11 AM, the surveyor discussed the above noted missing diplomas or degrees (per CLIA requirements) with TP #7, the laboratory manager. The surveyor also discussed the missing documentation of initial training. At this time, TP #7 was asked to review each personnel file with the surveyor to clarify what had been documented (or not documented) for each testing personnel. TP #7 confirmed the above noted findings. .
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of personnel records, a review of the Quality Assurance Program policy and procedure, and an interview with Testing Personnel (TP) #7 and a testing personnel from a sister laboratory, the surveyor determined the Technical Consultant (also the Laboratory Director) failed to assess the competency of TP #6 , TP #10 and TP #13 and provide documentation, semiannually during the first year of employment as a testing personnel of moderate complexity testing. This affected three of seventeen testing personnel. The findings include: 1. A review of the personnel records revealed the following personnel without documentation of a semiannual competency assessment: a) TP #6 's date of hire was not provided. There was no documentation of initial training (see D6029). The personnel file included an annual competency assessment, dated June, 2019; however there was no documentation of a semiannual competency assessment. b) TP #10 was hired on 9/10/18 and trained to perform

	moderate complexity testing in the same month of hire. The personnel file included an annual competency assessment, dated June of 2019; but failed to include documentation of a semiannual competency assessment. c) TP #13's date of hire was provided, and initial training documented and dated October, 2018. The personnel file included a competency assessment, dated June of 2019, which TP #7 identified as an annual competency assessment. There was no documentation of a semiannual assessment. 2. During an interview on 7/25/19 at 10:11 AM, the surveyor discussed the above noted missing or misidentified competency assessments with TP #7, the laboratory manager. At this time, TP #7 was asked to review each personnel file with the surveyor to clarify what had been documented (or not documented) for each testing personnel. TP #7 confirmed the above noted findings. 3. On 7/25/19 at 12:23 PM, the testing personnel (laboratory manager) from the sister laboratory brought additional personnel documentation for TP #12 and #13. At this time, the testing personnel confirmed the June 2019 assessment was an annual and there was no documentation of a semiannual competency assessment for TP #13. 4. A review of the policy and procedure manual (Quality Assurance Program), Section titled Personnel Assessments revealed personnel competencies should be assessed semiannually during the first year of employment and annually, thereafter.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of personnel records, a review of the Quality Assurance Program policy and procedure, and an interview with Testing Personnel (TP) #7, the surveyor determined the Technical Consultant (also the Laboratory Director) failed to assess the competency of TP #5 in 2018 (annually after the first year of employment). The laboratory identified TP #5 on the CMS form #209 (Laboratory Personnel Report for CLIA) as testing personnel of moderate complexity testing. This affected one of seventeen testing personnel. The findings include: 1. A review of the personnel records revealed TP #5 was hired on 4/24/17, and initial training was completed June 19, 2017. The laboratory documented a semiannual competency assessment in September, 2017 and an annual assessment in June of 2019. There was no documentation of an annual competency assessment in 2018 for TP #5. 2. During an interview on 7/25/19 at 10:11 AM, the surveyor discussed the above noted missing competency assessment with TP #7, the laboratory manager. At this time, TP #7 was asked to review each personnel file with the surveyor to clarify what had been documented (or not documented) for the testing personnel. TP #7 confirmed the above noted findings. 3. A review of the policy and procedure manual (Quality Assurance Program), Section titled Personnel Assessments revealed personnel competencies should be assessed semiannually during the first year of employment and annually, thereafter.