Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0671891	06/13/2019
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Assoc Of Western Ct Llc	41 Germantown Rd, Ste 201, Danbury, CT	

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
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to investigate or take remedial action when unacceptable proficiency testing (PT) scores are received. Findings include: 1. Record review on 6/13/19 of the PT evaluation report from the College of American Pathologists revealed: a. Unacceptable test result was obtained for hemoglobin sample # HE-11 for PT event HE-C 2017. b. Investigation or remedial action was not documented for the above unacceptable results. 2. Staff interview with nurse manager on 6/13/19 at 12:00 PM confirmed the laboratory did not investigate the above unacceptable PT result. 3. The laboratory performs 3,000 complete blood count (CBC) tests annually.
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 record review and staff interview, the laboratory failed to check each lot number and shipment of media for its ability to support growth and, as appropriate, select or inhibit specific organisms in the specialty of microbiology. Findings include: 1. Record review on 6/13/19 of the laboratory's quality control (QC) log for Hardy Diagnostics Strep Select Agar (SSA) revealed the laboratory failed to document the ability of the media to select or inhibit specific organisms for each lot number and shipment. Specifically, 71 of 71 shipments between 6/28/17 through 6/3/19. 2. Review of the above QC log further revealed that the laboratory was using two Streptococcus species (S. pyogenes and S. agalactiae) as positive and negative QC organisms to meet the above stated CLIA QC requirement. Documentation of positive and negative QC indicted as "pass" for both QC organisms in the log. 3. Record review on 6/13/19 of the Hardy Diagnostics SSA package insert revealed the laboratory must use a Streptococcus species as positive QC which will support the growth in SSA and to use either Escherichia Coli or Staphylococcus species as negative QC which will inhibit the growth in SSA. 4. Staff interview with the nurse manager (NM) on 6/13/19 at 10:45 AM confirmed the above findings. The NM stated he/she was unaware the laboratory need to use two organisms; one to support the growth and another one to inhibit the growth for SSA. 5. The laboratory performs 3,046 cultures annually in the specialty of microbiology.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to take corrective action when the laboratory incubator temperature was out of range in the subspecialty of bacteriology. Findings include: 1. Record review on 6/13/19 of the 2017, 2018 and 2019 laboratory incubator temperature logs revealed: a. Acceptable incubator temperature range is 33 to 37 degrees Celsius. b. Corrective action when the incubator temperature was out of range was not documented for: (i) 170 of 364 working days in 2017. (ii) 178 of 364 working days in 2018. (iii) 155 of 165 working days so far in 2019. 2. Record review on 6/13/19 of the package insert for the Strep Select Agar from the manufacturer (Hardy Diagnostics) revealed, "Incubate the plates at 35 +/- 2 degrees Celsius." 3. Staff interview on 6/13/19 at 11:00 AM with the nurse manager (NM) confirmed the above findings. The NM further stated he/she was under the impression the appropriate incubator temperature was 37 degrees Celsius.

D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to provide documentation to ensure proficiency testing (PT) scores are reviewed by the LD and the appropriate staff to evaluate laboratory's performance and to identify problems. Findings include: 1. Record review on 6/13/19 of the laboratory's PT evaluation report from the College of American Pathologists revealed the following PT results were not reviewed and signed by the LD. (a) HE-C 2017 Hematology (b) MC-2B 2017 Microbiology combination (c) MC-2C 2017 Microbiology combination (d) HE-A 2018 Hematology (e) HE-B 2018 Hematology (f) HE-C 2018 Hematology (g) D1-B 2018 Throat culture (h) D1-C 2018 Throat culture (i) HE-A 2019 Hematology (j) D1-A 2019 Throat culture 2. Staff interview with the nurse manager on 6/13/19 at 12:30 PM confirmed the above findings.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory director failed to investigate and take corrective action when unacceptable proficiency testing scores are received. Refer to D2128.
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 record review and staff interview, the laboratory director (LD) failed to ensure new testing personnel (TP) received appropriate training to perform moderate complexity testing prior to reporting patient test results. Findings include: 1. Record review of the laboratory's personnel files on 6/13/19 revealed training documentation was not available for 2 of 2 new TP hired since last CLIA recertification survey in 2017 in the specialty of microbiology. 2. Staff interview with the nurse manager (NM) on 6/13/19 at 10:00 AM confirmed the above findings. The NM stated the above 2 new TP were trained by the LD but not documented. 3. The laboratory performs 3,046 cultures annually in the specialty of microbiology.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory director failed to establish policies and procedures to evaluate the competency of moderate complexity testing personnel to ensure accurate test results are reported. Findings include: 1. Review of the laboratory's policies and procedure manual on 6/13/19 revealed the laboratory did not have a policy in place to assess the competency of the technical consultant (TC) and clinical consultant (CC). 2. Record review on 6/13/19 of the laboratory's testing personnel records revealed competency assessment documentation for 1 of 1 TC and 10 of 10 CC are not available. 3. Staff interview with the nurse manager on 6/13/19 at 12:10 PM confirmed the laboratory did not have a policy in place to assess the competency of the above laboratory personnel and they were not assessed.