Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D0671891	(X3) Date Survey Completed 03/05/2018
Name of Provider or Supplier Pediatric Assoc Of Western Ct Llc	**Street Address, City, State** 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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on proficiency testing (PT) record desk review, the laboratory failed to successfully achieve a score of 80 percent (%) in two of three testing events for 2017 for the subspecialty of bacteriology, specifically Event 1: 77% and Event 3: 77%. Refer to citation D2028.
D2028	BACTERIOLOGY CFR(s): 493.823(e) Failure to achieve an overall testing event score of satisfactory performance for two

	consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record desk review, the laboratory failed to successfully achieve a score of 80 percent (%) in two of three testing events for 2017 for the subspecialty of bacteriology. Findings include: 1. Record review of the Center for Medicare & Medicaid Services (CMS) CASPER 0155D Report on 3/5/18 revealed the laboratory obtained unsatisfactory scores for two of three PT events for analyte # 0005 Bacteriology as follows: Year/Event # PT Score 2017 - Event - 1 77% 2017 - Event - 2 100% 2017 - Event - 3 77% 2. Record review of the College of American Pathologists PT program results for survey MC2 Microbiology Combination survey on 3/5/18 revealed the laboratory obtained unsatisfactory scores in two of three PT events as evidenced below. Year/Event # PT Score 2017 - Event -1 78% 2017 - Event -2 100% 2017 - Event-3 78% 3. The laboratory performs 3,388 cultures annually in the subspecialty of bacteriology.