Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0986736	11/26/2019
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Partners Of Memphis	6063 Mt Moriah Ext Suite 13, Memphis, TN	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assurance policy/procedure, employee personnel records for 2018 and 2019, and interview with the lead testing personnel, the laboratory failed to have a procedure to include all six criteria for assessing personnel competency. The findings include: 1) Review of the laboratory's quality assurance policy/procedure revealed the laboratory's policy did not specify the methods to be used when assessing testing personnel competency. The following six criteria were not included in the procedure and competency documentation: direct observation of routine patient test performance; monitoring the recording and reporting of test results; review of intermediate test results or worksheets, quality control records, proficiency testing results and preventative maintenance records; direct observation of performance of instrument maintenance and function checks; assessment of test performance through previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and assessment of problem solving skills. 2) Review of the 2018 and 2019 employee personnel records revealed no documentation of competency assessment that included all six required criteria. 3) Interview on November 26, 2019 at 12:30 p.m. with the lead testing personnel confirmed the testing personnel competency procedure and documentation did not include the six criteria for testing personnel competency assessment required by the Centers for Medicare and Medicaid Services (CMS).
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 observation of the laboratory, review of the Verification of Performance Specifications (VoPS) studies for the Beckman Coulter AcT Diff 2 Complete Blood Count (CBC) instrument and interview with the lead testing personnel, the laboratory director failed to review and approve the VoPS studies for the Beckman Coulter AcT Diff CBC instrument in 2019. The findings include: 1) Observation of the laboratory on November 26, 2019 at 8:30 am revealed the Beckman Coulter AcT Diff 2 CBC instrument (serial number 59394676) on the counter in use for patient testing. 2) Review of the VoPS studies for the Beckman Coulter AcT Diff 2 CBC instrument, performed March 21, 2019, revealed no review or approval by the laboratory director. 2) Interview with the lead testing personnel on November 26, 2019 at 10:30 am confirmed the laboratory director failed to review and approve the VoPS for the Beckman Coulter AcT diff 2 instrument in 2019.