Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0670151	07/13/2018
Name of Provider or Supplier	**Street Address, City, State**	
Mid-South Internal Medicine Specialist Pc	7550 Wolf River Blvd Suite 102, Germantown, 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 observation of the laboratory, review of the Quality Assessment (QA) Program Outline, the laboratory personnel records and interview with the technical consultant, the laboratory failed to follow the QA program outline for competency of testing personnel for the Abbott Drew 3 complete blood count (CBC) instrument and Qualigen instrument in 2017. The findings include: 1) Observation of the laboratory on July 13, 2018 at 9:20 a.m. revealed the Abbott Drew 3 CBC instrument and two Qualigen IP FastPak System instruments in use for patient testing. 2) Review of the QA Program Outline revealed, "Competency of Testing Personnel Training /Competency will be performed and documented by the technical consultant initially, at 6 months, and annually thereafter". 3) Review of the laboratory personnel records revealed testing personnel number one hire date is March 2017. The March 21, 2017 initial and October 24, 2017 six month competency records did not have the CBC instrument and the Qualigen instrument marked as trained or competent for testing personnel number one. Testing personnel number two hire date is October 20, 2017 did not have the initial training completion date. 4) Interview on July 13, 2018 at 3:45 p.m. with the technical consultant confirmed the initial and six month competency for the CBC instrument and the Qualigen instrument were not marked for testing personnel number one. Testing personal number two did not have the date of initial training completion documented.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)

	Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the Individual Quality Control Plan (IQCP), the 2018 Qualigen instrument quality control (QC) records, the 2017, the 2018 proficiency testing (PT) records, the patient testing reports, and interview with the technical consultant, the laboratory failed to include IQCP risk assessment, QC plan, and quality assessment (QA)when weekly QC is not performed and when there are PT failures. The findings include: 1) Observation of the laboratory on July 13, 2018 at 9:10 a.m. revealed two Qualigen IP FastPack System instruments (labeled instrument A and instrument B) in use for patient testing. 2) Review of the IQCP revealed the plan did not include reassessment of the verification process when there is unsatisfactory or unsuccessful PT scores, and the plan did not include risk assessment, QC plan and QA for what to do when the weekly QC is not performed. 3) Review of the 2018 Qualigen QC records revealed no weekly QC performance on June 4 and June 27, 2018 for the thyroid stimulating hormone (TSH), prostatic specific antigen (PSA) and Vitamin D analytes. 4) Review of the 2017 and 2018 PT records revealed the following: TSH 2018 event 1=80%; PSA 2017 event 2=67%, 2018 event 1= 67%; Vitamin D 2017 event 2= 67%, 2018 event 1 67%. 5) Review of the patient testing reports revealed TSH, PSA, and Vitamin D were reported during the period of PT unsatisfactory scores and the during the weeks when weekly QC was not performed. 6) Interview with the technical consultant on July 13, 2018 at 3:15 p. m. confirmed the IQCP did not include what the laboratory is to do when weekly QC is not performed. The IQCP PT did not include reassessment of the verification process when unsatisfactory or unsuccessful PT scores were received.