Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D1027919	10/24/2018
Name of Provider or Supplier	**Street Address, City, State**	
Hinds Medical Clinic Pc, The	215 Hawks Road, Martin, 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
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the quality assessment (QA)plan, the QA documentation, the erythrocyte sedimentation rate (ESR) records, the thyroid stimulating hormone (TSH), the prostatic specific antigen (PSA) records, the urine microalbumin records, and interview with the technical consultant, the laboratory failed to follow the QA plan monthly review of the ESR, TSH, PSA and microalbumin records, in 2017 and 2018. The findings include: 1) Observation on October 24, 2018 at 9:35 a.m. of the laboratory revealed the following instruments in use for patient testing: Excyte Automated ESR Analyzer, the Qualigen Fastpack Analyzer System, and the Alere Afinion AS100 Analyzer. 2) Review of the QA plan revealed the laboratory director is to perform the QA monthly for all non-waived testing. 3) Review of the 2018 ESR records revealed two levels of QC not recorded on 4-9-18 and 9-10-18, and on 4-12-18 no patient report recorded on the logsheet. 4) Review of the TSH and PSA records revealed the FastPack System Control Range Cards for January 2017 to July 2018 were not maintained for the acceptable QC limits of levels one and two. The QC lot expiration dates were not maintained from January 2017 to July 2018. 5) Review of the urine microalbumin records revealed no QC manufacture package insert with the acceptable limits were maintained from February 2017 to August 2018. No lot number and expiration dates for QC levels one and two were maintained from February 20187 to August 2018. 6) Interview on October 24, 2018 at 11:45 a.m. with the technical consultant confirmed the monthly QA did not include the ESR, TSH, PSA and urine microalbumin from 2017 to 2018.