Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0305732	03/07/2018
Name of Provider or Supplier	**Street Address, City, State**	
Southern Cancer Center	6701 Airport Blvd, Mobile, AL	

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
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 reviews of the laboratory test menu, the IQCP (Individualized Quality Control Plan) for the Piccolo Xpress, the Piccolo quality control (QC) data, patient test volumes and an interview with Testing Personnel #1 (also the Laboratory Manager), the surveyor determined the laboratory failed to ensure both levels of QC (performed every 30 days and each new lot number) on the BMP (Basic Metabolic Profile) cartridges were within acceptable ranges. One level of Potassium (K+) QC was outside acceptable ranges for six out of 24 months of the 2016-2017 QC reviewed. The findings include: 1. A review of the laboratory menu revealed Chemistry testing was performed using patients' plasma samples on the Piccolo Xpress (a moderate-complexity test.) 2. A review of the QC for the Piccolo revealed the laboratory had previously implemented an IQCP on 12/18/2015 which specified personnel should perform QC every 30 days, and with each new lot number (#) of cartridges. 3. A review of the 2016-2017 Piccolo BMP cartridge QC data revealed the K+ QC was outside acceptable ranges for multiple lot numbers of cartridges for six months with no documentation of effective investigation or corrective action as follows: A) 11/04/2016: BMP Lot # 6311-K+ QC 2 was high. (The repeat was also high.) B) 12/12/2016: BMP Lot # 6354-K+ QC 1 was high. (The repeat was also

	high.) C) 01/16/2017: BMP Lot # 6434-K+ QC 2 was high. D) 02/02/2017: BMP Lot # 6434-K+ QC 2 was high. (The repeat was also high.) E) 02/02/2017: BMP Lot # 6495-K+ QC 2 was high. (The repeat was also high.) F) 03/13/2017: BMP Lot # 6495-K+ QC 2 was high G) 04/05/2017: BMP Lot # 6465-K+ QC 2 was high. (The repeat was also high.) H) 04/06/2017: BMP Lot # 7022-K+ QC 2 was high. (The repeat was also high.) [Note: Both levels of the monthly QC on the BMP cartridges were within acceptable ranges on 5/10/2018.] 4. During the exit interview on 3/07/2018 at 5:10 PM, the above noted findings were reviewed and confirmed with Testing Personnel #1 (TP #1), who stated most of the above QC was performed by a testing personnel who was no longer employed by the laboratory. When asked if patient BMP testing had been performed during this period, TP #1 stated she would have to forward this information to the CLIA office. This information was received via e-mail on 3/8 /2018; 147 patient BMP were performed between 11/4/2016 thru 5/9/2017. Thus the above noted findings were confirmed. .
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 a review of quality assurance documentation, the IQCP (Individualized Quality Control Plan) for the Piccolo Xpress, the Piccolo quality control (QC) data, and an interview with Testing Personnel #1 (also the Laboratory Manager), the surveyor determined the laboratory failed to monitor the effectiveness of their IQCP by implementing effective quality assessment reviews of the Piccolo quality control results. This was noted during a six-month period in 2016-2017 when the Piccolo QC was outside acceptable ranges. The findings include: 1. A review of the QC for the Piccolo revealed the laboratory had previously implemented an IQCP on 12/18/2015 which specified personnel should perform QC every 30 days, and with each new lot number of cartridges. 2. A review of the Piccolo QC data revealed one out of two levels of QC for Potassium on the BMP (Basic Metabolic Profile) cartridges were outside acceptable ranges for six months in 2016-2017. This occurred from 11/4/2016 thru 4/6/2017. (Refer to D4554.) 3. Implementation of an IQCP also requires on-going monitoring of the effectiveness of the IQCP through periodic quality assessment reviews. A review of quality assurance documentation revealed the laboratory routinely performed monthly quality assurance activities, however the reviews failed to note any problems with the Piccolo QC until January 2017. The previous testing personnel noted the Piccolo Potassium QC had been running high. The comment stated she had contacted the manufacturer for new controls and a new lot number of cartridges; she then concluded the problem was due to "just a bad batch of cartridges." However, the Piccolo records revealed the QC was high for multiple lot numbers of BMP cartridges with no corrective action for patients tested during this period. (Refer to D5445.) 4. During the exit interview on 3/07/2018 at 5:10 PM, the above noted findings were reviewed and confirmed with Testing Personnel #1, who stated the testing personnel mentioned above was no longer employed by the laboratory. Thus the above noted findings were confirmed. SURVEYOR: Laura T. Williams, BS, MT (ASCP) Licensure and Certification Surveyor