

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0928351	(X3) Date Survey Completed 10/18/2018
Name of Provider or Supplier Core Laboratory	Street Address, City, State 204 Sigma Drive, Ridc Park, Pittsburgh, PA	
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
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>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 general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory standard operation procedure (SOP), laboratory quality assessment (QA) policy, and interview with the technical supervisor (TS) #2, the laboratory failed to have QA procedures for monitoring different testing phases in 2018. Findings include: 1. The laboratory 2018 SOP lacks QA procedures to assess pre-analytical, analytical and post-analytical testing phases. 2. The laboratory had no other QA measures for these (3 of 3) testing stages in 2018. 3. The TS #2 confirmed above findings on 10/18/2018 at 11:30 AM.</p> <p>=====</p>