

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0187659	(X3) Date Survey Completed 05/08/2018
Name of Provider or Supplier Fertility Center Llc	Street Address, City, State 130 Leader Heights Road, York, 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 quality assurance (QA) policy, laboratory QA document, and interview with the laboratory technical supervisor (TS) #2, the laboratory failed to document monthly QA reviews in 2018. Findings include: 1. The laboratory QA policy (the laboratory director signed off on 04/01/2018) states during the month, the laboratory will monitor care indicators and record any findings, including corrective actions, on the "Internal QA Review". 2. The laboratory could not provide any (4 of 4) Internal QA Reviews (01/2018 - 04/2018). 3. The laboratory had no other 2018 QA review records. 4. The TS #2 confirmed above findings on 05/08/2018 at 10:00 AM.</p>