

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2052158	(X3) Date Survey Completed 07/19/2018
Name of Provider or Supplier Massey Fertility Services, Llc	Street Address, City, State 3193 Howell Mill Road, Ste 214, Atlanta, GA	
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
D0000	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on July 19, 2018. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency test (PT) records and interview with the laboratory testing person (TP) , the lab director (LD) and the testing person failed to attest that PT samples were tested in the same manner as patient specimens. Findings include: 1. Review of the 2017 PT documents revealed the LD failed to sign 3 of 3 attestation statements for the specialty of Chemistry and 1 of 3 attestation statements (1st event) for the specialty of Hematology. 2. Review of the 2017 PT documents revealed the TP failed to sign the Hematology testing event # 1. 3. Interview with the TP (CMS 209 form) on 7/19/18 at approximately 1 PM in the front office confirmed the aforementioned missing signatures.</p>
D6084	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2)</p> <p>The laboratory director must ensure that the physical plant and environmental conditions provide a safe environment in which employees are protected from physical, chemical, and biological hazards.</p>

This STANDARD is not met as evidenced by:
Based on observation and staff interview, the laboratory director (LD) failed to provide a flame resistant cabinet or container for reagent storage. Findings include: 1. Observation during the lab tour at approximately 10:15 AM revealed the storage of Methyl Alcohol (lot#8024 Exp. 1/24/20) under the sink cabinet, not contained in a flame resistant cabinet or container. 2. Interview with the TP (CMS 209 form) on 7/19 /18 at approximately 10:15 AM in the lab confirmed the lack of a flame resistant cabinet or container.

D6091

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(4)(iii)

The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.

This STANDARD is not met as evidenced by:
Based on review of the Proficiency Testing (PT) performance evaluation documents and interview with the testing person (TP), the lab director (LD) failed to review/sign the returned results. Findings include: 1. Review of the PT performance evaluation forms revealed the LD did not review/ sign the returned results for 2017 Chemistry testing events # 2 & 3 or 2017 Hematology testing event #3. The Clinical Consultant's (CC) (CMS 209 form) signature was stamped on the forms. 2. Interview with the TP (CMS 209 form) on 7/19/18 at approximately 1 PM in the front office confirmed the LD did not review/sign the performance evaluation sheets and the CC's review was stamped on.