

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2052158	(X3) Date Survey Completed 12/03/2020
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	Based on a CLIA recertification survey performed on December 3, 2020, this facility was found to not be in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780.
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on proficiency test (PT) document review and staff interview, the testing personnel (TP) failed to attest to the routine integration of the PT samples into the patient workload as required. Findings include: See D2009 for details.</p>
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:</p>

	<p>Based on proficiency test (PT) document review and staff interview, the testing personnel (TP) failed to attest to the routine integration of the PT samples into the patient workload as required. Findings include: 1. Review of American Proficiency Institute (API) PT documents revealed Staff #2 (CMS 209) failed to sign the 2020 Core Chemistry attestation statement for Event Three. 2. An interview with Staff #2 (CMS 209) confirmed the aforementioned TP did not sign the 2020 Core Chemistry attestation statement for Event 3. REPEAT DEFICIENCY</p>
<p>D2015</p>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency test (PT) document review and staff interview, the laboratory failed to maintain a copy of PT program documents as required. Findings include: 1. Review of American Proficiency Institute (API) PT forms revealed there were no PT documents available at the time of survey for the following: 2019 Event 2 and 2020 Event 2 -- Hematology/Coagulation. 2 An interview with Staff #2 (CMS 209) in the breakroom on 12/3/2020 at approximately 2:00 p.m. confirmed the aforementioned missing PT documents at the time of survey.</p>
<p>D5293</p>	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c)</p> <p>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on quality assurance (QA) document review and staff interview, the laboratory failed to document all general laboratory systems QA activities as required. Findings include: 1. QA document review revealed the lack of QA monthly checklists available at the time of survey for 2020 (January through December, thus far). 2. An interview with Staff #2 (CMS 209) in the breakroom on 12/3/2020 at approximately 3:17 p.m. confirmed the lack of QA documents for the aforementioned time period.</p>
<p>D6076</p>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p>

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:

Based on proficiency test (PT) document review and staff interview, the laboratory director (LD) failed to ensure review of PT reports as required. Findings include: See D6091 for details.

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 proficiency test (PT) document review and staff interview, the laboratory director (LD) failed to ensure review of PT reports as required. Findings include: 1. Review of American Proficiency Institute (API) documents revealed the LD failed to sign the following PT reports: 2019 - Core Chemistry Event Three; 2020- Core Chemistry Event Two and Hematology/Coagulation Event Three. 2. An interview with Staff #2 (CMS 209) on 12/3/2020 in the breakroom at approximately 2:15 p.m. confirmed the lack of LD review of the aforementioned PT reports. REPEAT DEFICIENCY