Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0099246	02/21/2019
Name of Provider or Supplier	**Street Address, City, State**	
Milton F Armm Md	3180 Main St, Suite 305, Bridgeport, CT	

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
D2003	ENROLLMENT CFR(s): 493.801(a)(2)(ii) For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1) This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to enroll in an HHS approved proficiency testing (PT) program or maintain accuracy of its testing procedures in the specialty of Hematology in 2018. Findings include: 1. Record review of the laboratory's PT records on 2/21/19 revealed: a. No records of PT documents for 2018. b. No records for accuracy testing for semen analysis (SA) for 2018. 2. Staff interview with the laboratory director on 2/21/19 at 10:15 AM confirmed: a. The laboratory did not enroll in an HHS approved PT program in 2018. b. Accuracy testing for SA was not performed for 2018. 3. The laboratory performs 24 SA annually.
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

	This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to investigate or take remedial action when unsatisfactory and unacceptable Proficiency Testing (PT) scores are received. Findings include: 1. Record review of the laboratory's American Proficiency Institute (API) PT records on 2/21/19 for 2017 revealed: A. Unsatisfactory score of 0% was obtained for the following tests in the 1st event. a. Sperm count (post vasectomy) b. Sperm morphology (image) c. Sperm motility d. Sperm progressive motility B. Unsatisfactory score of 50% was obtained for the following tests in the 3rd event. a. Sperm classification b. Sperm motility c. Sperm progressive motility C. Unsatisfactory score of 0% was obtained for sperm count test in the 3rd event. D. Unacceptable PT scores were obtained for the following samples in the 1st event. a. Sample # PVS-02 for sperm count (post vasectomy) b. Sample # SCL-03 for sperm classification c. Sample # SM-02 for sperm morphology d. Sample# MOT-01 & MOT-02 for sperm motility (%) and sperm progressive motility (%) E. Unacceptable PT scores were obtained for the following samples in the 3rd event. a. Sample # SPC-03 and SPC-04 for sperm count b. Sample # SCL-16 through 20 for sperm morphology c. Sample# MOT-03 for sperm motility (%) and sperm progressive motility (%) 2. Staff interview with the laboratory director on 2/21/19 at 10:00 AM confirmed the laboratory did not investigate or take corrective actions when unsatisfactory and unacceptable PT results were obtained. 3. The laboratory performs 24 semen analysis annually.
D5543	HEMATOLOGY CFR(s): 493.1269(a)(d) (a) For manual cell counts performed using a hemocytometer-- (a)(1) One control material must be tested each 8 hours of operation; and (a)(2) Patient specimens and control materials must be tested in duplicate. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to perform and document quality control (QC) results on each day of testing patient samples to ensure accurate and reliable test results are obtained in the specialty of Hematology. Findings include: 1. Record review of the laboratory's QC log from 2017 through 2019 on 2/21/19 for semen analysis (SA) revealed: a. Two levels of Accubead QC's were performed on 2/11/17 but QC results were not recorded in the log to indicate acceptable results were obtained. No further QC's were documented in 2017. b. Two levels of Accubead QC's were not tested or documented in 2018. c. Two levels of Accubead QC's performed on 1/3/19, 1/5/19, 1/16/19, 1/17/19 and 1/19/19 but QC results were not recorded in the log to indicate acceptable results were obtained. 2. Record review of the Accubead manufacturer's package insert on 2/21/19 revealed "record all results along with pertinent information such as the chamber used and the name of the person performing the QC procedure." 3. Staff interview with the laboratory director (LD) on 2/21/19 at 9:30 AM confirmed the above findings. The LD stated that QC's were performed but were not recorded to indicate acceptable results were obtained. 4. The laboratory performs 24 SA tests annually.
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 record review and staff interview the laboratory director failed to review or document Proficiency Testing (PT) evaluation reports. Findings include: 1. Record review of American Proficiency Institute (API) PT comparative evaluation report on 2 /21/19 revealed the laboratory director (LD) did not review or document the following PT evaluation reports: a. 2017 Event-1 b. 2017 Event-3 The laboratory did not enroll in a PT program in 2018. 2. Investigation or remedial action was not documented for the unacceptable results obtained in the above PT events. 3. Staff interview with the LD on 2/21/19 at 10:00 AM confirmed the above findings. 4. The laboratory performs 24 semen analysis tests annually.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to establish policy and procedures to assess the skills and competency of testing personnel (TP) to perform semen analysis (SA) testing. Findings include: 1. Record review of the laboratory's semen analysis/andrology competency challenge records from 'Fertility Solutions' on 2/21/19 revealed: a. TP participated in a competency challenge for semen analysis in 2017 but records of individual results not available to asses TP competency. b. TP participated in a competency challenge for semen analysis in 2018 and obtained unacceptable individual results for sperm concentration and sperm motility competency. c. TP did not participate in sperm viability, post vasectomy and sperm morphology competencies in 2017 and 2018. 2. Staff interview with the laboratory director on 2/21/19 at 10:30 AM confirmed the above findings. 3. The laboratory performs 24 SA annually.