

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D2008505	<b>(X3) Date Survey Completed</b> 09/18/2019
<b>Name of Provider or Supplier</b> Care Fertility	<b>Street Address, City, State</b> 1250 8th Avenue Suite 365, Fort Worth, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	<p>Noted deficiencies and plans of correction were discussed with laboratory representatives at the entrance and exit conferences. The facility representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. Based upon the onsite survey conducted 09/18/2019, this facility was found NOT to be in compliance with the CLIA regulations found at 42 CFR 493.1250 Analytic Systems 493.1441 Laboratory Director, (high complexity) 493.1487 Testing Personnel (high complexity) The laboratory's failure to be in compliance with these regulations was found to pose IMMEDIATE JEOPARDY to the patients served by the laboratory. NOTE: The laboratory was asked to cease SpermMar IgG and SpermMar IgA testing for sperm antibodies. The laboratory voluntarily ceased sperm antibody testing on patients. See letter dated 09/19/2019 and signed by the laboratory director. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider /supplier, the State Survey Agency (SA) should be notified immediately.</p>
<b>D5217</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of laboratory records, laboratory proficiency test (PT) records (2017, 2018, and 2019) and confirmed in staff interview, the laboratory failed to verify the accuracy of non-regulated hematology analytes at least twice annually for 5 of 5 testing events. Findings included: 1. Review of laboratory records revealed 2</p>

locations for the Center for Assisted Reproduction (Forth Worth, Texas and Bedford, Texas). The Bedford, Texas location operated under a different CLIA number. Further review of laboratory records revealed the following tests were performed at the laboratory: a. Manual sperm counts and percent motility b. Sperm IgG and IgA Antibody c. Eosin Staining for sperm viability 2. Review of the laboratory document titled "Andrology Proficiency Testing" for 2017, 2018, and 2019 revealed the laboratory performed twice annual accuracy assessments for manual sperm counts with percent motility, sperm IgG and IgA sperm antibody testing, and eosin staining for sperm viability at the Bedford, Texas facility for 5 of 5 testing events. The laboratory failed to verify the accuracy of the non-regulated analytes at the laboratory's physical location and environment, utilizing this laboratory's reagents and test kits. 3. In an interview on 09/18/2019 at 1045 hours in the facility breakroom, the Technical Supervisor (TS) was asked to describe how twice annual accuracy assessment was performed. He stated that testing persons from the laboratory and the Bedford, Texas laboratory came together at the Bedford location and performed testing on 2 patients and then compared results. The TS was asked to provide documentation of twice annual accuracy assessment performed at this location. No documentation was provided. The laboratory failed to verify the accuracy of this laboratory's non-regulated hematology analytes at least twice annually for 5 of 5 testing events.

**D5400**

**ANALYTIC SYSTEMS**  
CFR(s): 493.1250

Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:  
Based on review of laboratory policy, review of the laboratory's verification records, review of the laboratory's quality control records, review of the laboratory's patient test records, direct observation, and staff interview, it was revealed the laboratory failed to meet analytic systems requirements. Findings included: 1. The laboratory failed to ensure that 1 of 1 bottles of Sigma Eosin Y stain were labeled with an identifying lot number and storage requirements. Refer to D5415 2. The laboratory failed to have documentation of verification studies for the Hamilton Thorn IVOS semen analyzer system. Refer to D5421 3. The laboratory failed to document complete establishment studies for the FertiPro SpermMar IgG and IgA latex test for the detection of sperm antibodies. Refer to D5423 4. The laboratory failed to have documentation of a mechanism to detect immediate error due to test system failure, adverse environmental conditions, and operator performance for the Hamilton Thorn IVOS semen analyzer system and the FertiPro SpermMar IgG and IgA latex test. Refer to D5441 5. The laboratory failed to test at least two levels of external quality control each day of patient testing or develop an Individualized Quality Control Plan (IQCP) to modify the frequency of QC testing for the Hamilton Thorn IVOS semen analyzer system. Refer to D5445 I 6. The laboratory failed to test at least two levels of external quality control each day of patient testing or develop an Individualized Quality Control Plan (IQCP) to modify the frequency of QC testing for the FertiPro SpermMar IgG and IgA latex test for the detection of sperm antibodies. Refer to

D5445 II 7. The laboratory failed to have an alternate mechanism to detect immediate errors when commercial control materials were not available for the SpermMar IgA latex test for sperm antibodies. Refer to D5485.

**D5415**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:  
Based on direct observation, laboratory records, and staff interview, it was revealed the laboratory failed to ensure that 1 of 1 bottles of Sigma Eosin Y stain were labeled with an identifying lot number and storage requirements. Findings included: 1. During a tour of the laboratory on 09/18/2019 at 0930 hours, one bottle of reconstituted Eosin Y stain was observed in a laboratory cabinet. The bottle was labeled with a prepared date of 04/18/2019 and expiration date of 05/18/2019. The bottle was NOT labeled with an identifying lot number or storage requirements. 2. Review of the laboratory record titled "Reagent Lot Change Log" stated, "New reagent lots and/or shipments of .....Eosin stain must be tested in parallel with old lots before or concurrently with being placed in service to ensure the new lot of reagent has maintained consistent results for patient specimens. Stain reactivity should be noted and be identical to the previous lot. Tolerance limit is 20% of the previous lot." Further review of the "Reagent Lot Change Log" revealed the following entry: "Date: 04/18/2019; Reagent: Eosin; Lot: 4-18-2019; Stain reactivity: Pass; Difference in Lots: 0.7%; Pass/Fail: P" This form was completed at the Bedford, Texas location. The log did NOT document a current lot number or previous lot number of Eosin stain. 3. In an interview on 09/18 /2019 at 0930 hours in the laboratory, testing person #1 and the Technical Supervisor were asked how the Eosin Y stain was prepared. Testing person #1 stated that the stain was prepared by adding 100 mL of phosphate buffered saline to .5 grams of Eosin Y powder. She further stated that the stain was prepared at the Bedford location and then sent to this location. Technical Supervisor was asked to provide documentation of storage requirements for the Eosin Y stain. No documentation was provided. The laboratory failed to ensure the Eosin Y stain was labeled with an identifying lot number and storage requirements.

**D5421**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**  
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on direct observation, review of the laboratory records and confirmed in staff interview, it was revealed the laboratory failed to have documentation of verification studies for the Hamilton Thorn IVOS semen analyzer system. Findings included: 1. During a tour of the laboratory on 09/18/2019 at 0930, a Hamilton Thorn IVOS semen analyzer (Serial Number 9658) was observed. 2. The laboratory was asked to provide documentation of verification studies for the IVOS analyzer that included accuracy (including accuracy of diluted specimens), precision, reportable range, and reference intervals. No documentation was provided. 3. The laboratory performs 300 semen analysis annually. 4. In an interview on 09/18/2019 at 1136 hours in the breakroom, the Technical Supervisor was asked if verification studies had been performed on the IVOS semen analyzer. He stated that the instrument was initially used at the Bedford, Texas location and he thought verification studies had been performed there. The TS was asked if verification studies had been performed when the analyzer was moved to this facility location. He stated that verification studies had NOT been performed when the analyzer was moved to this location. This confirmed the above findings.

**D5423**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**  
 CFR(s): 493.1253(b)(2)

Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:  
 Based on review of Food and Drug Administration (FDA) database for approved tests, laboratory records, patient test records, and confirmed in interview, the laboratory failed to document complete establishment studies for the FertiPro SpermMar IgG and IgA latex test for the detection of sperm antibodies. 1. Review of the FDA database for FDA approved tests revealed the FertiPro SpermMar IgG and IgA latex test for the detection of sperm antibodies was NOT an FDA approved test. 2. The laboratory was asked to provide documentation of establishment studies that included accuracy, precision, analytical sensitivity, analytical specificity (including interfering substances), reportable range of test results and reference intervals. No documentation was provided. 3. Review of test records from 01/08/2018 through 09/18/2019 revealed 110 patients for IgG and IgA sperm antibodies using the FertiPro SpermMar IgG and IgA latex test. The following is a random sample of patients tested: a. Patient 114712; Date of test 11/14/2018 b. Patient 114694; Date of test 11/30/2018 c. Patient 110997; Date of test 12/07/2018 d. Patient 114945; Date of test 12/11/2018 e. Patient 114780; Date of test 12/14/2018 f. Patient 115764; Date of test 03/01/2019 g. Patient 114787; Date of test 04/23/2019 h. Patient 116482; Date of test 05/10/2019 i. Patient 116316; Date of test 05/29/2019 j. Patient 117699; Date of test 08/02/2019 4. The above findings were confirmed by the Technical Supervisor in an interview on 09/18/2019 at 1450 hours in the breakroom.

**D5441**

**CONTROL PROCEDURES**

CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's quality control records from 2018 through 09/18/2019, and staff interview, it was revealed the laboratory failed to have documentation of a mechanism to detect immediate error due to test system failure, adverse environmental conditions, and operator performance for the Hamilton Thorn IVOS semen analyzer system and the FertiPro SpermMar IgG and IgA latex test. Findings included: 1. Review of laboratory QC records (2018 through 09/18/2019) revealed the laboratory performed external QC testing on the IVOS semen analyzer once a week and on each new lot of the FertiPro SpermMar IgG latex test. The laboratory did NOT perform quality control testing on the FertiPro SpermMar IgA latex test. The laboratory failed to have a mechanism to detect immediate error due to test system failure, adverse environmental conditions, and operator performance for the IVOS semen analyzer and the FertiPro SpermMar IgG and IgA latex test. 2. The above findings were confirmed by the Technical Supervisor in an interview on 09/18/2019 at 1136 hours in the breakroom.

**D5445**

**CONTROL PROCEDURES**

CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

I. Based on review of laboratory policy, quality control (QC) records from 2018 through 09/18/2019, and confirmed in staff interview, the laboratory failed to test at least two levels of external quality control each day of patient testing or develop an Individualized Quality Control Plan (IQCP) to modify the frequency of QC testing for the Hamilton Thorn IVOS semen analyzer system. Findings included: 1. Review of the laboratory policy titled "Semen Analysis Protocol" stated "Accubead high and low control analysis are done weekly and digital image analysis is done daily and checked against previous set values to ensure that the IVOS system is properly analyzing the specimen. Accubead controls must fall within a pre-established range." 2. Review of

QC records from 2018 through 09/18/2019 revealed Accubead QC was performed each week on the IVOS semen analyzer. 3. The laboratory was asked to provide documentation of an IQCP to modify the frequency of QC testing. No documentation was provided. 4. The laboratory performs 300 semen analysis annually. 5. In an interview on 09/18/2019 at 1136 hours in the breakroom, the Technical Supervisor was asked if an IQCP was performed to modify the frequency of QC testing to once a week. He stated that the laboratory did NOT develop an IQCP. II. Based on review of laboratory policy, direct observation, quality control (QC) records from 2018 through 09/18/2019, patient test records, and confirmed in staff interview, the laboratory failed to test at least two levels of external quality control each day of patient testing or develop an Individualized Quality Control Plan (IQCP) to modify the frequency of QC testing for the FertiPro SpermMar IgG and IgA latex test for the detection of sperm antibodies. Findings included: 1. Review of the laboratory policy titled "Direct Immunobead Sperm Antibody Assay" stated, "1. Controls with a known negative sperm donor and a positive SpermMar IgG control are performed once on each new IgG SpermMar kit. Controls are not commercially available for IgA." 2. During a FertiPro SpermMar IgG and IgA latex test demonstration by Testing Person #1 on 09/18/2019 at 1250 hours, one kit of SpermMar IgG (Lot number FP18G12, Expiration date 04/2020) and one kit of SpermMar IgA (Lot number FP18A13, Expiration date 12/2019) was observed. 3. Review of FertiPro SpermMar IgG and IgA latex test QC form titled "SpermMar IgG Kit/Control Lot Validation Log" revealed each new kit of FertiPro SpermMar IgG was tested with a positive control. The QC record did NOT document the results of negative quality control material. The following is the last documented SpermMar IgG kit documented on the "Sperm Mar IgG kit/Control Lot Validation Log": Date: 03/11/2017; SpermMar IgG kit lot/Expiration date: FP16602, 08/31/2017; SpermMar IgG Control lot/expiration date: FP15GP03, 02/28/2017; % Binding (pass if >90%): 93%. The current in-use lot number for SpermMar IgG latex test (FP18G12, Expiration date 04/2020) was not documented on the submitted log. 4. During an interview on 09/18/2019 at 1250 hours in the laboratory, Testing Person #1 was asked when the QC was performed on the FertiPro SpermMar IgG and IgA latex test. She stated that QC was performed on each new IgG kit at the Bedford, Texas location and the kit was sent to this location. She further stated that there was no available QC material for the IgA kit and no QC was performed on this kit. Testing Person #1 was asked which laboratory provided the "SpermMar IgG Kit/Control Lot Validation Log". She stated that the record originated from the Bedford, Texas location. 5. The laboratory was asked to provide documentation of an IQCP to modify the frequency of QC testing. No documentation was provided. 6. Review of test records from 01/08/2018 through 09/18/2019 revealed 110 patients for IgG and IgA sperm antibodies using the FertiPro SpermMar IgG and IgA latex test. The following is a random sample of patient tested: a. Patient 114712; Date of test 11/14/2018 b. Patient 114694; Date of test 11/30/2018 c. Patient 110997; Date of test 12/07/2018 d. Patient 114945; Date of test 12/11/2018 e. Patient 114780; Date of test 12/14/2018 f. Patient 115764; Date of test 03/01/2019 g. Patient 114787; Date of test 04/23/2019 h. Patient 116482; Date of test 05/10/2019 i. Patient 116316; Date of test 05/29/2019 j. Patient 117699; Date of test 08/02/2019 7. The above findings were confirmed in an interview with the Technical Supervisor on 09/18/2019 at 1450 hours in the breakroom.

**D5485**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(h)

If control materials are not available, the laboratory must have an alternative mechanism to detect immediate errors and monitor test system performance over time.

The performance of alternative control procedures must be documented.

This STANDARD is not met as evidenced by:

Based on review of laboratory policy, patient test records, and confirmed in interview, the laboratory failed to have an alternate mechanism to detect immediate errors when commercial control materials were not available for 110 of 110 patients from 01/08/2018 through 09/18/2019. Findings included: 1. Review of the laboratory policy titled "Direct Immunobead Sperm Antibody Assay" stated, "1. Controls with a known negative sperm donor and a positive SpermMar IgG control are performed once on each new IgG SpermMar kit. Controls are not commercially available for IgA." 2. Review of test records from 01/08/2018 through 09/18/2019 revealed 110 patients for IgA sperm antibodies using the FertiPro SpermMar IgA latex test. The following is a random sample of patient tested: a. Patient 114712; Date of test 11/14/2018 b. Patient 114694; Date of test 11/30/2018 c. Patient 110997; Date of test 12/07/2018 d. Patient 114945; Date of test 12/11/2018 e. Patient 114780; Date of test 12/14/2018 f. Patient 115764; Date of test 03/01/2019 g. Patient 114787; Date of test 04/23/2019 h. Patient 116482; Date of test 05/10/2019 i. Patient 116316; Date of test 05/29/2019 j. Patient 117699; Date of test 08/02/2019 3. During an interview on 09/18/2019 at 1250 hours in the laboratory, Testing Person #1 was asked when the QC was performed on the FertiPro SpermMar IgA latex test. She stated that there was no available QC material for the IgA kit and no QC was performed on this kit. Testing Person #1 was asked if the SpermMar IgA patient testing was performed in duplicate. She stated that the laboratory did NOT perform duplicate testing. This confirmed the above findings.

**D5793**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**

CFR(s): 493.1289(b)(c)

(b) The analytic 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 analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on review of laboratory's procedure manual, laboratory records, reagents manufacturer's instructions, and Quality Control data, the laboratory failed to have an effective QA (quality assessment) system in place to identify and correct problems for the analytical phase of testing as evidenced by: 1. The laboratory failed to have documentation of verification studies for the Hamilton Thorn IVOS semen analyzer system. Refer to D5421 2. The laboratory failed to document complete establishment studies for the FertiPro SpermMar IgG and IgA latex test for the detection of sperm antibodies. Refer to D5423 3. The laboratory failed to have documentation of a mechanism to detect immediate error due to test system failure, adverse environmental conditions, and operator performance for the Hamilton Thorn IVOS semen analyzer system and the FertiPro SpermMar IgG and IgA latex test. Refer to D5441 4. The laboratory failed to test at least two levels of external quality control each day of patient testing or develop an Individualized Quality Control Plan (IQCP) to modify the frequency of QC testing for the Hamilton Thorn IVOS semen analyzer system. Refer to D5445 I 5. The laboratory failed to test at least two levels of external quality control each day of patient testing or develop an Individualized Quality Control Plan (IQCP) to modify the frequency of QC testing for the FertiPro

	<p>SpermMar IgG and IgA latex test for the detection of sperm antibodies. Refer to D5445 II 6. The laboratory failed to have an alternate mechanism to detect immediate errors when commercial control materials were not available. Refer to D5485</p>
<b>D6076</b>	<p><b>LABORATORY DIRECTOR</b> CFR(s): 493.1441</p> <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.</p> <p>This CONDITION is not met as evidenced by: I. Based on review of the laboratory records and staff interview, it was revealed the laboratory director failed to provide overall management for the laboratory. Refer to D6086 II. Based on review of the laboratory's quality control records and staff interview, it was revealed the laboratory director failed to ensure quality control programs were established and maintained to ensure the quality of laboratory services provided and to identify failures in quality as they occur. Refer to 6093 III. Based on review of the laboratory's quality assurance records and staff interview, it was revealed the laboratory director failed to ensure quality assurance programs was established and maintained to ensure the quality of laboratory services provided and to identify failures in quality as they occur. Refer to 6094</p>
<b>D6086</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(3)(ii)</p> <p>The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.</p> <p>This STANDARD is not met as evidenced by: I. Based on direct observation, review of the laboratory's records and confirmed in staff interview, it was revealed the laboratory director failed to ensure verification studies for the Hamilton Thorn IVOS semen analyzer system. Refer to D5421 II. Based on review of the Food and Drug Administration (FDA) database for approved tests, review of patient test records from 2018 through 09/18/2019, and staff interview, it was revealed the laboratory director failed to ensure establishment studies were performed prior to testing patient samples for a non-FDA approved test system. Refer to D5423.</p>
<b>D6093</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control records and staff interview, it was revealed the laboratory director failed to ensure a quality control program was</p>

	<p>established and maintained to ensure the quality of laboratory services provided and to identify failures in quality as they occur. Refer to D5441, D5445, and D5485.</p>
<p><b>D6094</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b>  CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by:  Based on review of the laboratory's quality assurance records and staff interview, it was revealed the laboratory director failed to ensure quality assurance programs were established and maintained to ensure the quality of laboratory services provided and to identify failures in quality as they occur. Refer to D5793</p>
<p><b>D6127</b></p>	<p><b>TECHNICAL SUPERVISOR RESPONSIBILITIES</b>  CFR(s): 493.1451(b)(9)</p> <p>The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by:  Based on review of CMS 209 form, personnel records, and interview with staff, the Technical Supervisor (TS) failed to evaluate and document performance of 2 of 2 Testing Persons responsible for high complexity testing at least semiannually during the first year that testing persons analyze patient specimens. Findings included: 1. Review of the submitted CMS 209 form revealed Testing Persons #1 and #2 listed to perform high complexity testing. 2. Review of personnel records from 2015 through 2019 revealed the following: a. Testing Person #1 Training documentation: 04/2015 No other documentation of semiannual evaluation during the first year of patient testing was provided. b. Testing Person #2 Training documentation: 03/2017 No other documentation of semiannual evaluation during the first year of patient testing was provided The TS failed to evaluate and document performance at least semiannually during the first year of patient testing. 3. In an interview on 09/18/2019 at 1230 1045 hours in the breakroom, the TS was asked to provide documentation of semiannual competency assessment for Testing Persons #1 and Testing Person #2 that was performed at this location. No documentation was provided. This confirmed the above findings.</p>
<p><b>D6128</b></p>	<p><b>TECHNICAL SUPERVISOR RESPONSIBILITIES</b>  CFR(s): 493.1451(b)(9)</p> <p>The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.</p>

This STANDARD is not met as evidenced by:  
 Based on review of Centers for Medicare and Medicaid (CMS) 209 form, personnel records, and interview with staff, the Technical Supervisor (TS) failed to perform the annual competency evaluations for 1 of 1 testing persons for the high complexity testing in the specialty of hematology for 2017 and 2018. Findings included: 1. Review of the submitted CMS 209 form revealed Testing Person (TP) #1 listed to perform high complexity testing. 2. Review of laboratory personnel records revealed TP#1 training documentation from 04/2015. The laboratory was asked to provide documentation of annual competency evaluations. 3. In an interview on 09/18/2019 at 1045 hours in the facility breakroom, the Technical Supervisor (TS) was asked to describe how annual competency assessment was performed. He stated that testing persons from this laboratory and the Bedford, Texas laboratory came together at the Bedford location and competency assessment was performed on testing persons from both facilities at the same time. The TS was asked to provide annual competency assessment for this facility's testing persons performed at this facility location for 2017 and 2018. No documentation was provided. This confirmed the above findings.

**D6168**

**TESTING PERSONNEL**  
 CFR(s): 493.1487

The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.

This CONDITION is not met as evidenced by:  
 Based on review of the CMS-209 form and personnel records, it was revealed the laboratory failed to have documentation that 1 of 2 testing persons (TP#1) met the qualifications required to perform high complexity testing. (Refer to D6171)

**D6171**

**TESTING PERSONNEL QUALIFICATIONS**  
 CFR(s): 493.1489(b)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could

have qualified as a technologist under 493.1491 on or before February 28, 1992; (b) (4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6) (i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Based on review of the Centers for Medicare and Medicaid (CMS) 209 form and review of the laboratory's personnel records revealed the laboratory failed to have documentation that 1 of 2 testing persons (TP#1) met the qualifications required to perform high complexity testing. Findings included: 1. Review of the CMS-209 form included Testing Person #1 and Testing Person #2 listed to perform moderated complexity testing. 2. Review of personnel records revealed Testing Person (TP) #1 had a Bachelor of Science degree in Animal Science. The academic record revealed TP#1 did NOT have a Bachelor of Science degree in a biological, chemical, physical or clinical laboratory science. 3. The above findings were confirmed by the Technical Supervisor in an interview on 09/18/2019 at 1045 hours in the breakroom.