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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>53D0703107          | <b>(X3) Date Survey Completed</b><br><br>04/27/2023 |
| <b>Name of Provider or Supplier</b><br><br>Cheyenne Obstetrics And Gynecology, Inc Pc                                      | <b>Street Address, City, State</b><br><br>2301 House Avenue Suite 400, Cheyenne, WY |   |
| 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>  |
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| <b>D2000</b>              | <p><b>ENROLLMENT AND TESTING OF SAMPLES</b><br/>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:<br/>Based on review of the Becton Dickinson Affirm VP III (system used to detect vaginal pathogens) patient testing log, lack of documentation, and staff interview, the laboratory failed to enroll in an approved proficiency testing program for the regulated bacteriology (<i>Gardnerella vaginalis</i>) and mycology (<i>Candida</i> species) test system for approximately 2 months of patient testing (2/15/23 through 4/25/23). The laboratory performed 104 Affirm VP III patient tests. The findings were: 1. Review of the Affirm VP III patient testing log showed 104 patients tests for <i>Gardnerella vaginalis</i> and <i>Candida</i> species were performed from 2/15/23 through 4/25/23. Review of the laboratory's documentation showed no evidence the laboratory was enrolled in proficiency testing. 2. Interview with the laboratory manager on 4/27/23 at 12:17 PM confirmed the laboratory had not enrolled in a proficiency testing program.</p> |
| <b>D5002</b>              | <p><b>BACTERIOLOGY</b><br/>CFR(s): 493.1201</p> <p>If the laboratory provides services in the subspecialty of Bacteriology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1261, and</p>   |

493.1281 through 493.1299.

This CONDITION is not met as evidenced by:

Based on observation, lack of documentation, review of the Affirm VP III patient testing log, review of the manufacturer's instructions for use, and staff interview, the laboratory failed to establish a policy and procedure for the Affirm VP III test system (D5401), failed to follow manufacturer's instructions (D5411), failed to ensure the Affirm VP III was verified for precision and accuracy prior to testing patient samples (D5421), and failed to perform quality control on the Affirm VP III test system each day of patient testing (D5449).

**D5006**

MYCOLOGY  
CFR(s): 493.1203

If the laboratory provides services in the subspecialty of Mycology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1263, and 493.1281 through 493.1299.

This CONDITION is not met as evidenced by:

Based on observation, lack of documentation, review of the patient testing log, review of the Affirm VP III manufacturer's instructions for use, and staff interview, the laboratory failed to establish a policy and procedure for the Affirm VP III test system (D5401), failed to follow manufacturer's instructions (D5411), failed to ensure the Affirm VP III was verified for precision and accuracy prior to testing patient samples (D5421), failed to ensure potassium hydroxide was checked for positive and negative reactivity prior to use (D5471) and failed to perform quality control on the Affirm VP III test system each day of patient testing (D5449).

**D5008**

PARASITOLOGY  
CFR(s): 493.1204

If the laboratory provides services in the subspecialty of Parasitology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1264, and 493.1281 through 493.1299.

This CONDITION is not met as evidenced by:

Based on observation, lack of documentation, review of the patient testing log, review of the Affirm VP III manufacturer's instructions for use, and staff interview, the laboratory failed to establish a policy and procedure for the Affirm VP III test system (D5401), failed to follow manufacturer's instructions (D5411), failed to ensure the Affirm VP III was verified for precision and accuracy prior to testing patient samples (D5421), and failed to perform quality control on the Affirm VP III test system each day of patient testing (D5449).

**D5209**

PERSONNEL COMPETENCY ASSESSMENT POLICIES  
CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:  
Based on review of the CMS-209 Laboratory Personnel Report, lack of documentation, and staff interview, the laboratory failed to ensure policies and procedures were established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure they were competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently. The findings were: 1. Review of the CMS-209 Laboratory Personnel Report showed the laboratory listed 7 physicians and 2 nurse practitioners who performed provider performed microscopy. In addition, the laboratory listed 10 testing personnel who performed moderately complex patient testing. 2. Review of the laboratory's documentation failed to show a policy and procedure to monitor each individual's competency had been developed. 3. Interview with the laboratory manager on 4/27/23 at 12:17 PM confirmed the laboratory had not developed a policy to ensure the competency of testing personnel, the physicians, or the nurse practitioners.

**D5401**

**PROCEDURE MANUAL**  
CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:  
Based on lack of documentation and staff interview, the laboratory failed to have written procedures for the Affirm VP III (molecular test system for the detection of Candida species, Gardnerella vaginalis, and Trichomonas vaginalis). In addition, the laboratory failed to have written procedures for the provider performed microscopy (PPM) tests which included direct wet mounts, potassium hydroxide (KOH) preparations, fern tests, and post-coital examinations of vaginal or cervical mucous. The laboratory performed approximately 373 PPM tests per year and 156 Affirm VP III patient tests from 2/15/23 to 4/25/23. The findings were: 1. Review of the laboratory's procedure manuals showed no evidence the laboratory and developed a policy and procedure for the Affirm VP III test system or the PPM tests performed. 2. Interview with the laboratory manager on 4/27/23 at 12:17 PM confirmed the laboratory did not have written procedures for the Affirm VP III test system or the PPM procedures.

**D5411**

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

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:  
Based on observation, lack of documentation, review of the patient testing log and the

Affirm VP III (molecular test system for the detection of *Candida* species, *Gardnerella vaginalis*, and *Trichomonas vaginalis*) instructions for use, and staff interview, the laboratory failed to follow the manufacturer's instructions to ensure the test kit, reagents, and probe analysis cards (PACs) were stored and the patient testing was performed at the appropriate temperature. In addition, the laboratory failed to verify the temperature of the MicroProbe Lysis Block was at the appropriate temperature prior to patient testing. The laboratory had performed 156 patient tests from 2/15/23 to 4/25/23. The findings were: 1. Observation on 4/27/23 at 11:15 AM showed an Affirm VP III test kit was located on a counter in the patient testing area. The reagent box was not labeled with an open date. 2. Review of the laboratory's documentation showed no evidence the temperature of the testing area was monitored or the temperature of the MicroProbe Lysis Block was at the appropriate temperature prior to patient testing. 3. Review of the Affirm VP III manufacturer's instructions showed the test kit was stable until the expiration date indicated on the kit box when stored at 2 to 8 degrees Celsius. Alternatively, the kit could be stored at room temperature (up to 30 degrees Celsius) for no more than 3 months. All reagents and PACs must be at 22 to 28 degrees Celsius prior to use. In addition, the manufacturer's instructions stated the laboratory must verify that the MicroProbe Lysis Block was at 85 plus or minus 5 degrees Celsius prior to patient testing. 4. Interview with the laboratory manager on 4/27/23 at 11:15 AM revealed the laboratory did verify the temperature of the MicroProbe Lysis Block prior to patient testing; however, the results were not documented. In addition, the laboratory manager confirmed the Affirm VP III test box was not labeled with an open date and the room temperature of the testing area was not monitored.

**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 lack of documentation and staff interview, the laboratory failed to verify the accuracy and precision of the Affirm VP III (molecular test system for the detection of *Candida* species, *Gardnerella vaginalis*, and *Trichomonas vaginalis*) test system prior to patient testing. The laboratory had performed 156 Affirm VP III patient tests from 2/15/23 to 4/25/23. The findings were: 1. Review of the laboratory's records showed no evidence a verification study had been completed for the Affirm VP III test system. 2. Interview with the laboratory manager and testing personnel #1 on 4/27/23 at 11:25 AM confirmed the verification study had not been completed.

**D5449**

**CONTROL PROCEDURES**  
 CFR(s): 493.1256(d)(3)(ii)(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--  
 At least once a day patient specimens are assayed or examined perform the following

for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of quality control (QC) records, patient testing logs, and staff interview, the laboratory failed to perform a positive and negative control each day of testing for the Affirm VP III (molecular test system for the detection of Candida species, Gardnerella vaginalis, and Trichomonas vaginalis) for approximately 2 months of patient testing. This failure affected 31 patient tests. The findings were: 1. Review of the QC records and patient testing logs for the Affirm VP III test system showed the following concerns: a. 1 patient test was performed on 2/15/23 with the last documented QC being performed on 2/13/23 b. 3 patient tests were performed on 2/28/23 with the last documented QC being performed on 2/27/23. c. 1 patient test was performed on 3/10/23 with the last documented QC being performed on 3/6/23. d. 9 patient tests were performed from 3/14/23 to 3/21/23 with the last documented QC being performed on 3/13/23. e. 4 patient tests were performed from 3/28/23 to 3/30/23 with the last documented QC being performed on 3/23/23. f. 5 patient tests were performed from 4/4/23 to 4/7/23 with the last documented QC being performed on 4/3/23. g. 4 patient tests were performed from 4/11/23 to 4/12/23 with the last documented QC being performed on 4/10/23. h. 5 patient tests were performed from 4/19/23 to 4/23/23 with the last documented QC being performed on 4/17/23. i. 6 patient tests were performed on 4/25/23 with the last documented QC being performed on 4/24/23. 2. Interview with the laboratory manager on 4/27/23 at 12:17 PM confirmed QC had not been performed each day of patient testing as required.

**D5471**

**CONTROL PROCEDURES**

CFR(s): 493.1256(e)(1)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on observation, lack of documentation, and staff interview, the laboratory failed to check each new lot number or shipment of potassium hydroxide (KOH) for positive and negative reactivity prior to patient testing. The laboratory performed approximately 20 KOH preparations per month. The findings were: 1. Observation on 4/27/23 at 11:45 AM showed a bottle of KOH was available for use with a lot number of 2202 and an expiration date of 7/21/24. 2. Review of the laboratory's documentation showed no evidence the KOH solution used to detect fungal elements had been checked for positive and negative reactivity prior to patient testing. 3. Interview with the laboratory manager on 4/27/23 at 12:17 PM revealed the providers performed approximately 20 KOH preparations per month. Further, the laboratory manager confirmed quality control had not been performed.

**D5990**

**PPM TESTING PERSONNEL**

CFR(s): 493.1361

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1363 to perform the functions specified in 493.1365 for the volume and complexity of testing performed.

This CONDITION is not met as evidenced by:  
Based on lack of documentation, review of the CMS-209 Laboratory Personnel Report, and staff interview, the laboratory failed to ensure health care providers who performed provider performed microscopy (PPM) procedures met the established qualifications (D5991).

**D5991**

**PPM TESTING PERSONNEL QUALIFICATIONS**  
CFR(s): 493.1363

Each individual performing PPM procedures must-- (a) Possess a current license issued by the State in which the laboratory is located if the licensing is required; and (b) Meet one of the following requirements: (b)(1) Be a physician, as defined in 493.2. (b)(2) Be a midlevel practitioner, as defined in 493.2, under the supervision of a physician or in independent practice if authorized by the State in which the laboratory is located. (b)(3) Be a dentist as defined in 493.2 of this part.

This STANDARD is not met as evidenced by:  
Based on lack of documentation, review of the CMS-209 Laboratory Personnel Report, and staff interview, the laboratory failed to ensure health care providers (7 physicians and 2 nurse practitioners) who performed provider performed microscopy (PPM) procedures met the established qualifications. The findings were: 1. Review of the CMS-209 Laboratory Personnel Report showed the laboratory listed 7 physicians and 2 nurse practitioners who performed provider performed microscopy. 2. Review of the laboratory's records failed to show evidence of the physicians' and nurse practitioners' State license and educational documentation. 3. Interview with the laboratory manager on 4/27/23 at 12:17 PM revealed she was unaware of the requirement.

**D6000**

**MODERATE COMPLEXITY LABORATORY DIRECTOR**  
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:  
Review of the CMS-209 Laboratory Personnel Report, review of the laboratory's records, review of the patient testing log, review of the Affirm VP III instructions for use, lack of documentation, and staff interview, the laboratory director failed to ensure the Affirm VP III test system was verified for accuracy and precision prior to patient testing (D6013); failed to ensure testing personnel followed the manufacturer's instructions (D6014); failed to ensure the laboratory enrolled in proficiency testing (D6015); failed to ensure a quality assurance plan had been developed (D6021); and

failed to ensure competency assessment policies and procedures were established for the testing personnel, the technical consultant, and the healthcare providers performing provider performed microscopy (D6030).

**D6013**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(3)(ii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

This STANDARD is not met as evidenced by:  
Based on lack of documentation and staff interview, the laboratory director failed to ensure the Affirm VP III (molecular test system for the detection of Candida species, Gardnerella vaginalis, and Trichomonas vaginalis) test system was verified for accuracy and precision prior to patient testing. The laboratory had performed 156 patient tests from 2/15/23 to 4/25/23. Refer to D5421.

**D6014**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(3)(iii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:  
Based on observation, review of the Affirm VP III (molecular test system for the detection of Candida species, Gardnerella vaginalis, and Trichomonas vaginalis) manufacturer's instructions, patient testing log, and staff interview, the laboratory director failed to ensure the testing personnel followed the manufacturer's instructions to ensure the test kit, reagents, and probe analysis cards (PACs) were stored and patient tests were performed at the appropriate temperature and failed to verify the temperature of the MicroProbe Lysis Block was at the appropriate temperature prior to patient testing. The laboratory had performed 156 patient tests from 2/15/23 to 4/25/23. Refer to D5411.

**D6015**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved

proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:

Based on review of the Becton Dickinson Affirm VP III (system used to detect vaginal pathogens) patient testing log, lack of documentation, and staff interview, the laboratory failed to enroll in an approved proficiency testing program for the regulated bacteriology (*Gardnerella vaginalis*) and mycology (*Candida* species) test system for approximately 2 months of patient testing (2/15/23 through 4/25/23). The laboratory performed 104 Affirm VP III patient tests. Refer to D2000.

**D6021**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on procedure manual review, lack of documentation and staff interview, the laboratory director failed to ensure the laboratory had established a quality assessment plan for general laboratory, pre-analytic, analytic, and post-analytic systems for provider performed microscopy (PPM) tests and the Affirm VP III (molecular test system for the detection of *Candida* species, *Gardnerella vaginalis*, and *Trichomonas vaginalis*). The findings were: 1. The laboratory procedure manual failed to include a quality assurance plan that included the items the laboratory reviewed, the frequency of the review, and the method used to document the review in the following areas: a. General laboratory tasks which include proficiency testing review, testing personnel competency procedures, and complaint documentation and resolution. b. Pre-analytic tasks which include specimen collection, patient identification verification, specimen labeling, storage, and transportation. c. Analytic tasks which include review of quality control, instrument preventive maintenance, reagent replacement and test record logs. d. Post-analytic tasks which include test report accuracy. 2. Interview with the laboratory manager on 4/27/23 at 12:17 PM revealed the laboratory had not established a quality assessment plan.

**D6030**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(12)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) 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;

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|                     | <p>This STANDARD is not met as evidenced by:<br/>Based on review of the CMS-209 Laboratory Personnel Report, lack of documentation, and staff interview, the laboratory director failed to ensure policies and procedures were established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure they were competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently. Refer to D5209.</p>   |
| <p><b>D6033</b></p> | <p><b>TECHNICAL CONSULTANT-MODERATE COMPEXITY</b><br/>CFR(s): 493.1409</p> <p>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.</p> <p>This CONDITION is not met as evidenced by:<br/>Based on lack of documentation and staff interview, the laboratory failed to employ one or more individuals who were qualified by education and either training or experience to provide technical consultation for moderate complexity laboratory testing (D6034).</p>   |
| <p><b>D6034</b></p> | <p><b>TECHNICAL CONSULTANT QUALIFICATIONS</b><br/>CFR(s): 493.1411</p> <p>The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on lack of documentation and staff interview, the laboratory failed to employ one or more individuals who were qualified by education and either training or experience to provide technical consultation for moderate complexity laboratory testing. The findings were: 1. Review of the laboratory's records failed to show evidence a technical consultant had been employed. 2. Interview with the laboratory manager on 4/27/23 at 12:17 PM revealed she was unaware of the requirement.</p> |
| <p><b>D6063</b></p> | <p><b>LABORATORY TESTING PERSONNEL</b><br/>CFR(s): 493.1421</p> <p>The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.</p> <p>This CONDITION is not met as evidenced by:<br/>Based on lack of documentation, review of the CMS-209 Laboratory Personnel</p>  |

Report, and staff interview, the laboratory failed to ensure testing personnel met the qualifications to perform moderate complexity laboratory testing (D6065).

**D6065**

**TESTING PERSONNEL QUALIFICATIONS**

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy 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; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on lack of documentation, review of the CMS-209 Laboratory Personnel Report, and staff interview, the laboratory failed to ensure 10 of 10 testing personnel met the qualifications to perform moderate complexity laboratory testing. The findings were: 1. Review of the CMS-209 Laboratory Personnel Report showed the laboratory listed 10 testing personnel who performed moderately complex patient testing. 2. Review of the laboratory's records failed to show evidence of the testing personnel's qualifications. 3. Interview with the laboratory manager on 4/27/23 at 12: 17 PM revealed she was unaware of the requirement.