

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2231905	(X3) Date Survey Completed 07/25/2023
Name of Provider or Supplier Ohmc, Pc DbA Columbus Mens Clinic	Street Address, City, State 1507 Chambers Road, Suite 208, Columbus, OH	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and an interview with the Senior Director of Clinical Operations in Compliance (SDCOC), the laboratory failed to establish and follow written policies and procedures to assess the competency of the Technical Consultant (TC) based on the responsibilities of the position and at a frequency determined by the laboratory. This deficient practice had the potential to affect 600 patients tested under the subspecialty of Endocrinology performed from 01/13/2022 to 07/25/2023. Findings Include: 1. Review of the laboratory's Form CMS-209 on 07/25/2023, approved by the Laboratory Director on 06/21/2023, revealed one individual listed and qualified by the Laboratory Director to function as a TC. 2. Review of the laboratory's "Staff Orientation Training and Competency" policy and procedure, signed and dated by the Laboratory Director on 12/02/2022 found no mention of instructions for assessing TC competency assessment. 3. The Inspector requested a TC competency assessment policy and procedure, and TC competency assessment documentation based on the responsibilities of the position from the SDCOC. The SDCOC confirmed the laboratory did not have a TC competency assessment policy and procedure, did not perform a TC competency assessment, and was unable to provide the requested information. The interview occurred on 07/25/2023 at 1:30 PM.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the</p>

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 record review and an interview with the Senior Director of Clinical Operations in Compliance (SDCOC), the laboratory failed to follow their Calibration /Calibration Verification policy and procedure. This deficient practice had the potential to affect 600 patients tested under the subspecialty of Endocrinology from 01 /13/2022 to 07/25/2023. Findings Include: 1. Review of the "Calibration/Calibration Verification" policy and procedure signed and dated by the Laboratory Director on 12 /02/2022 and provided on the date of the inspection, found the following statements: "Calibration Verification For analyzers and analytes that are not calibrated with a minimum of three calibrators verifying the low, midpoint and high end of the reportable range, calibration verification must be performed every six months to substantiate the continued accuracy of the monitors throughout the reportable range, after initial validation studies are performed with the setup of the analyzer." "Calibration verification is performed every six months, as stated in current CLIA and State regulations" 2. The inspector requested the calibration verification documentation for 2022 and 2023 from the SDCOC. 3. The SDCOC confirmed the laboratory did not perform any calibration verification for 2022 and 2023 as required, and was unable to provide the requested documentation. The interview occurred on 07 /25/2023 at 3:10 PM.

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on record review and an interview with the Senior Director of Clinical Operations in Compliance (SDCOC), the laboratory failed to include in their policies and procedures the reportable range for testosterone test results for the Qualigen FastPack system. This deficient practice had the potential to affect 600 patients tested under the subspecialty of Endocrinology from 01/13/2022 to 07/25/2023. Findings

Include: 1. Review of the laboratory's policies and procedures titled "Reportable Ranges" signed and dated by the Laboratory Director on 11/18/2021 failed to find a policy and procedure that included the reportable range of testosterone test results for the Qualigen FastPack system. 2. The inspector requested a policy and procedure for the reportable range of testosterone test results for the Qualigen FastPack system from the SDCOC. The SDCOC confirmed there was no procedure that included the reportable range of testosterone test results and was unable to provide the requested documents. The interview occurred on 07/25/2023 at 1:20 PM.

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 record review and an interview with the Senior Director of Clinical Operations in Compliance (SDCOC), the laboratory failed to follow the manufacturer's instructions for the calibration of the solo pipette utilized for testosterone testing procedures and result reporting. This deficient practice had the potential to affect 600 patients tested under the subspecialty of Endocrinology from 01/13/2022 to 07/25/2023. Findings Include: 1. Review of the policy and procedure titled "General Maintenance" under the section titled "Pipettes" found the following statement: "Pipette accuracy is required to be verified annually or more frequently if required by the manufacturer." 2. Review of the manufacturer's instructions titled "Gilson Guide to Pipetting" found the following statements: "Since accuracy and precision have a direct influence on the quality of analytical results it is imperative that the performance of individual pipettes compared regularly with the manufacturer's specifications. Frequency Action Annually Adjustment - Calibration." 3. The inspector requested all calibration records for the solo laboratory pipette from the SDCOC. 4. The SDCOC confirmed the laboratory did not follow the manufacturer's instructions or the policy and procedure for the annual pipette calibration and was unable to provide the requested documents. The interview occurred on 07/25/2023 at 2:15 PM.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
Based on record review and an interview with the Senior Director of Clinical Operations in Compliance (SDCOC), the laboratory failed to follow written policies and procedures and document all assessment activities of the ongoing mechanism to monitor, assess, and correct problems identified in the analytic systems. This deficient practice had the potential to affect 600 patients tested under the subspecialty of

Endocrinology from 01/13/2022 to 07/25/2023. Findings Include: 1. Review of the laboratory's "Quality Assessment Plan, Monthly Checklist, Analytic" sheets found the following statements: "Items for review Review of instrument maintenance logs for completeness and corrections Calibration verifications up to date?" 2. Further review of the laboratory's "Quality Assessment Plan, Monthly Checklist, Analytic" sheets approved via signature and date by the Laboratory Director on 11/15/2021, revealed the above-mentioned "Items for Review" not annotated for May 2022, November 2022, and marked as completed for May 2023. 3. Review of instrument maintenance sheets provided on the date of inspection did not find any calibration records for the laboratory's solo pipette used for during testosterone testing. 4. Review of calibration verification did not find any records for the Qualigen FastPack system used for testosterone testing. 5. The inspector requested completed quality assessment checklists from the SDCOC. The SDCOC confirmed the laboratory did not document all assessment activities and could not provide the requested information. The interview occurred on 07/25/2023 at 3:20 PM.

D5893

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1299(b)(c)

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

This STANDARD is not met as evidenced by:
Based on record review and an interview with the Senior Director of Clinical Operations in Compliance (SDCOC), the laboratory failed to ensure a post analytic quality assessment program was maintained to assure the quality of laboratory services provided, and to identify failures in laboratory quality. This deficient practice had the potential to affect 600 patients tested under the subspecialty of Endocrinology from 01/12/2022 to 07/25/2023. Findings Include: 1. Review of the laboratory's policy and procedure manual titled, "Quality Assessment Plan", signed and dated by the Laboratory Director on 11/18/2021 revealed the following statements: "Purpose ... Annual review of the system is incorporated into the QA process. Following annual review, or at any time as deemed necessary, updates and/or modification, deletion or addition of criteria may occur." Goals ...All QA activities will be documented in the appropriate format." 2. Review of six out of 11 quality assessment documents found "Quality Assessment Plan Unexpected Event" worksheets attached with 07/17/2023 as the date of review and as the date of the LD signature. The worksheets contained the following information: Problem or Event Description August 2022 QA packet missing September 2022 QA packet missing No calibration verification since November 2021 No calibration verification May 2022 No calibration verification November 2022 No calibration verification April 2023 3. The Inspector requested documentation of the annual review as stated in the "Quality Assessment Plan" for 2022 and 2023. The SDCOC confirmed there was no annual review or documentation of the quality assessment system as stated in the laboratory policy and procedure and was unable to provide the requested information. The interview occurred on 07/25/2023 at 3:00 PM.