

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  36D2231905	<b>(X3) Date Survey Completed</b>  02/12/2026
<b>Name of Provider or Supplier</b>  Ohmc, Pc DbA Columbus Mens Clinic	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5805</b>	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p> <p>This STANDARD is not met as evidenced by: Based on record reviews and an interview with the Practice Manager (PM), the laboratory failed to include the reportable range and the reference range for testosterone, established within their performance specifications, on three out of three final test reports. This deficient practice had the potential to affect 1488 out of 1488 patients tested in the subspecialty of Endocrinology from 07/25/2023 through 02/12/2026. Findings Include: 1. Review of the Policies and Procedures manual titled, "General Laboratory Policy and Procedure Manual", approved via signature and date by the current Laboratory Director on 06/06/2025 found the following: "Qualigen Fastpack Reportable Range IP System Testosterone 16-1600 ng/dL" a. Review of three out of three patient final test reports for testosterone results did not find any reportable range listed. b. On 02/12/2026 at 12:15 PM the PM confirmed the laboratory did not include the reportable range for patient testosterone test results on the final test report. 2. Review of the Policies and Procedures manual titled, "General Laboratory Policy and Procedure Manual", approved via signature and date by the current Laboratory Director on 06/06/2025 found the following: "Qualigen Fastpack Reference Range IP System Testosterone 20-49 yrs; 214-1009 ng/ml &gt;50 yrs; 216-1004 ng/ml" a. Review of three out of three patient final test reports for testosterone</p>

results found the following: "Testo Ref. Range 400-1000 ng/dL" b. On 02/12/2026 at 12:15 PM the PM confirmed the laboratory did not include the correct reference range for patient testosterone test results on the final test report. ng/dL; nanograms per deciliter ng/mL; nanograms per milliliter

**D6031**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(13)

(e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and

This STANDARD is not met as evidenced by:  
Based on record review and an interview with the Practice Manager (PM), the LD failed to ensure that an approved policy and procedure manual was available to all laboratory personnel responsible for any aspect of the moderate complexity testosterone testing procedures in the subspecialty of Endocrinology. This deficient practice had the potential to affect 183 out of 183 patient tests performed on 09/01/2024 through 06/06/2025. Findings Include: 1. Review of the form CMS 116 found a new Laboratory Director as of 09/01/2024. 2. Review of the laboratory's policies and procedures manual titled, "General Laboratory Policy and Procedure Manual", found a review page titled, "Manual Review", with the new Laboratory Director approval date of 06/06/2025. 3. An interview on 02/12/2026 at 12:30 PM with the PM confirmed that the LD failed to provide an approved policy and procedure manual to all laboratory personnel for moderately complexity testosterone testing.