Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D2231905	01/13/2022
Name of Provider or Supplier	**Street Address, City, State**	
Ohmc, Pc Dba Columbus Mens Clinic	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
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 record review and an interview with the Clinic Manager (CM), the laboratory failed to follow their General Maintenance policy and procedure for monitoring and documenting room temperature and humidity conditions for reliable Qualigen FastPack IP testing procedures. All Qualigen FastPack IP testing procedures performed in this laboratory from 12/01/2021 to 01/13/2022 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the "FastPack IP System Product Specifications" document provided on the date of the inspection, found the following statements: "Ambient Operating Temperature: 15C (59F) to 32C (90F)" "Operating Humidity: 10% to 80% relative humidity" 2. Review of the laboratory's policy and procedure manual titled "General Laboratory Policy and Procedure Manual", signed and dated by the LD on 11/18/2021 found the following statement: "3. Read and record each day of operation the room temperature and humidity for the laboratory." 3. The Inspector requested the laboratory's temperature and humidity documentation from 12/01/2021 to 01/13/2022 from the CM. The CM confirmed the laboratory did not document laboratory temperatures and humidity conditions consistent with the manufacturer's instructions and was unable to provide the requested documentation on the date of the inspection. The interview occurred 01 /13/2022 at 10:45 AM. C; degrees Celsius F; degrees Fahrenheit
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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 quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and an interview with the Clinic Manager (CM), the laboratory failed to, each day of patient testing, perform and document quantitative testosterone quality control (QC) procedures, to include two levels of QC material of different concentrations. This deficient practice had the potential to affect two out of two patients tested under the sub-specialty of endocrinology. Findings Include: 1. Review of the laboratory's policy and procedure manual titled "General Laboratory Policy", signed and dated by the LD on 11/18/2021 found the following statement: "Quality Control Assessment Immunoassay (Qualigen FastPack) 1. Two valid levels of quality control results must be obtained by running Qualigen Control 1 & 2 control prior to running patient samples and after any daily maintenance has been performed. Because this test is FDA classified as moderately complex, two levels of control are required each day of patient testing." 2. Review of the laboratory's December 2021 "Quality Control Chart", provided on the date of the inspection, found the laboratory did not perform and document two levels of testosterone QC material on the Qualigen FastPack IP system on 12/09/2021 and 12/30/2021. 3. The Inspector requested documentation of two levels of testosterone QC material on the Qualigen FastPack IP system for 12/09/2021 and 12/30/2021 from the CM. The CM confirmed the laboratory did not test and document two levels of testosterone QC materials on the Qualigen FastPack IP system as required, and was unable to provide the requested documentation on the date of the inspection. The interview occurred 01/13/2022 at 11: 00 AM.
D5805	TEST REPORT CFR(s): 493.1291(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. This STANDARD is not met as evidenced by: Based on record reviews and an interview with the Clinic Manager (CM), the laboratory failed to include on the final test report the units of measure for patient testosterone results. This deficient practice had the potential to affect 300 out of 300 patients tested from 12/08/2021 to 01/13/2022 under the sub-specialty of endocrinology. Item 1 Findings Include: 1. Review of one out of one of the laboratory's final test reports for patient results did not find any units of measure or cutoff values. 2. The CD confirmed the laboratory did not include any units of measure for any patient testosterone test results on the final test report. The interviews

	occurred on 01/13/2022 at 11:30 AM. Based on record reviews and an interview with the Clinic Manager (CM), the laboratory failed to include on the final test report the test result for testosterone. This deficient practice had the potential to affect 300 out of 300 patients tested from 12/08/2021 to 01/13/2022 under the sub-specialty of endocrinology. Item 2 Findings Include: 1. Review of one out of one of the laboratory's final patient test reports did not find a testosterone result for the ordered test. 2. The CM confirmed the laboratory did not include results for patient testosterone on the final test report. The interview occurred 01/13/2022 at 11:30 AM.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on record review and an interview with the Clinic Manager (CM), the Laboratory Director (LD) failed to ensure one out of one Testing Personnel (TP) was trained and had demonstrated they could perform testing procedures reliably to provide and report accurate results prior to performing patient testing. This deficient practice had the potential to affect 300 out of 300 patients tested from 12/08/2021 to 01/13/2022 under the sub-specialty of endocrinology. Findings Include: 1. Review of the laboratory's policies and procedures, approved and signed by the LD on 11/18 /2021, and provided on the date of the inspection, found the following statement: "Initial Training Initial training on individual analyzers, equipment, test methods and kits must be documented. Document initial training competency at the completion of each training activities. Document all initial instrument orientation on the Personnel Training Checklist and the New Employee Checklist." 2. The Inspector requested the laboratory's "Personnel Training Checklist" and the "New Employee Checklist" for Testing Personnel (TP) #1 from the CM. The CM confirmed the laboratory did not document training or initial demonstration of competency in order to reliably provide and report accurate results prior to patient testing for TP #1 and was unable to provide the requested documentation on the date of the inspection. The interview occurred 01 /13/2022 at 10:24 AM.