

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2302307	(X3) Date Survey Completed 03/31/2025
Name of Provider or Supplier Cleveland Men's Health Group	Street Address, City, State 6500 Rockside Road, Suite 180, Independence, 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
D5391	<p>PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a)</p> <p>(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 preanalytic systems specified at 493.1241 through 493.1242.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interviews with the Practice Consultant (PC) #1, PC #2 and Testing Personnel (TP) #1, the laboratory failed to establish and follow their own written policies and procedures and accurately document all assessment activities of the ongoing mechanism to monitor, assess, and correct problems identified in the preanalytic test systems. This deficient practice had the potential to affect five out of five patient prostate specific antigen (PSA) and testosterone (Testo) tests performed on 03/28/2025, the date testing began. Findings Include: 1. Review of the laboratory's Form CMS-116, approved by the Laboratory Director via signature and date on 03/28/2025 and provided on the date of the inspection revealed the laboratory performed PSA and Testo testing procedures. 2. Review of the manufacturer's "Quality Assurance Manual", approved by the Laboratory Director on 02/07/2025 and provided on the date of the inspection, found the following statement under the "Quality Assurance Assessment Program" section: "Our laboratory assesses the QA plan monthly, using the QA Assessment, which (1) evaluates and monitors the overall quality of our testing; (2) helps evaluate how well our policies and procedures are working; and (3) minimizes the possibility of recurrent problems." 3. The Inspector requested the laboratory's 2025 quality assessment documentation from TP#1. TP#1 provided the laboratory's February (dated 02/28/2025) and March (dated 03/25/2025) "Quality Assurance Assessment" worksheets that indicated a "Y" by a preanalytic monitor that was not applicable as the laboratory did not begin patient testing until 03/28/2025. See below: "Patient specimens were collected and handled according to our protocol." 4. The Inspector, on 04/08/2025 at 4:26 PM, had a telephone conversation</p>

with PC#1 and PC#2. PC#1 and PC#2 confirmed the laboratory began patient testing on 03/28/2025 and stated the laboratory must have been confused on how to complete their quality assessments.

D5405

PROCEDURE MANUAL

CFR(s): 493.1251(c)

(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory.

This STANDARD is not met as evidenced by:

Based on record review and an interview with Testing Personnel (TP) #1, the laboratory failed to ensure that written competency assessment, prostate specific antigen (PSA) and testosterone (Testo) and Qualigen FastPack IP maintenance and service policies and procedures were established, to include instructions not provided by the manufacturer and were available to the laboratory personnel for the testing conducted in the subspecialties of Routine Chemistry and Endocrinology. This deficient practice had the potential to affect five out of five patient PSA and Testo tests performed on 03/28/2025, the date testing began. Findings Include: 1. Review of the laboratory's Form CMS-116, approved by the Laboratory Director via signature and date on 03/28/2025 and provided on the date of the inspection revealed the laboratory performed PSA and Testo testing procedures. 2. Review of the laboratory's policies and procedures provided on the date of the inspection did not find any competency assessment, PSA, Testo and Qualigen FastPack IP maintenance and service policies and procedures. 3. The Inspector requested the laboratory's competency assessment, PSA, Testo and Qualigen FastPack IP maintenance and service policies and procedures, approved by the Laboratory Director via signature and date from TP#1. TP#1 provided the manufacturer's "Quality Assurance Manual", approved by the Laboratory Director on 02/07/2025 and the manufacturer's "QA Manual" and package inserts for "PSA" and "Testo", all unapproved by the Laboratory Director. TP#1 confirmed the laboratory did not establish their own written competency assessment, PSA, Testo, Qualigen FastPack IP maintenance and service policies and procedures to include all of the required components not provided by the manufacturer and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 03/31/2025 at 1:35 PM.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(b)

(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on record review and an interview with Testing Personnel (TP)#1, the laboratory failed to define criteria, monitor and document maintenance and service activities of the Qualigen FastPack IP test system utilized for prostate specific antigen (PSA) and testosterone (Testo) tests performed in the subspecialties of Routine Chemistry and Endocrinology. This deficient practice had the potential to affect five out of five patient PSA and Testo tests performed on 03/28/2025, the date testing began. Findings Include: 1. Review of the laboratory's Form CMS-116, approved by the Laboratory Director via signature and date on 03/28/2025 and provided on the date of the inspection revealed the laboratory performed PSA and Testo testing procedures. 2. Review of the laboratory's policies and procedures provided on the date of the inspection did not find any maintenance and service policies and procedures for the Qualigen FastPack IP analyzer. 3. The Inspector requested the laboratory's maintenance and service policies and procedures, approved by the Laboratory Director via signature and date, and their 2025 Qualigen FastPack IP maintenance and service documentation from TP#1. TP#1 confirmed the laboratory did not establish and define maintenance and service policies and procedures, did not monitor and document maintenance for their Qualigen FastPack IP analyzer in 2025 and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 03/31/2025 at 1:45 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.

This STANDARD is not met as evidenced by:
Based on record review and interviews with the Practice Consultant (PC) #1, PC #2 and Testing Personnel (TP) #1, the laboratory failed to establish and follow their own written policies and procedures and accurately 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 five out of five patient PSA and Testo tests performed on 03/28/2025, the date testing began. Findings Include: 1. Review of the laboratory's Form CMS-116, approved by the Laboratory Director via signature and date on 03/28/2025 and provided on the date of the inspection revealed the laboratory performed prostate specific antigen (PSA) and testosterone (Testo) testing procedures. 2. Review of the manufacturer's "Quality Assurance Manual", approved by the Laboratory Director on 02/07/2025 and provided on the date of the inspection, found the following statement under the "Quality Assurance Assessment Program" section: "Our laboratory assesses the QA plan monthly, using the QA Assessment, which (1) evaluates and monitors the overall quality of our testing; (2) helps evaluate how well our policies and procedures are working; and (3) minimizes the possibility of recurrent problems." 3. The Inspector requested the laboratory's 2025 quality assessment documentation from TP#1. TP#1 provided the laboratory's February (dated 02/28/2025) and March (dated 03/25/2025) "Quality Assurance Assessment" worksheets that indicated a "Y" by monitors that were not applicable as the laboratory was not enrolled in a proficiency testing (PT) program until 03/31/2025 and no patient testing was performed until 03/28/2025. See below: "Proficiency tests were handled in the same manner as patient specimens." "Proficiency test results were evaluated, failures were investigated, and remedial action was taken." "Each day, all environmental elements are checked, logged and are

within normal ranges." "Each QC event, two levels of quality control were tested and were within acceptable ranges before patients were tested." "The system is operating optimally." 4. On 04/08/2025 at 4:26 PM, the Inspector had a telephone conversation with PC#1 and PC#2. PC#1 and PC#2 confirmed the laboratory began patient testing on 03/28/2025, the laboratory did not enroll with a PT provider until 03/31/2025 and stated the laboratory must have been confused on how to complete their quality assessments.

D5805

TEST REPORT
CFR(s): 493.1291(c)

(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 review and an interview with Testing Personnel (TP) #1, the laboratory failed to ensure the laboratory had test reports that indicated the correct laboratory location and the specimen source (when appropriate) for the prostate specific antigen (PSA) and testosterone (Testo) tested performed in the subspecialties of Routine Chemistry and Endocrinology. This deficient practice had the potential to affect five out of five patient PSA and Testo tests performed on 03/28/2025, the date testing began. Findings Include: 1. Review of the laboratory's Form CMS-116, approved by the Laboratory Director via signature and date on 03/28/2025 and provided on the date of the inspection revealed the laboratory performed PSA and Testo testing procedures. 2. Review of five out of five patient PSA and Testo final test reports performed on 03/28/2025 revealed an incorrect facility name (Precise Men's Medical Center) of where the testing was performed and did not find the specimen source (only indicated as "blood draw"). 3. TP#1, on 03/31/2025 at 2:30 PM, confirmed the patient PSA and Testo final test reports indicated Precise Men's Medical Center as the laboratory location where the testing was performed and the specimen source as "blood draw".

D5813

TEST REPORT
CFR(s): 493.1291(g)

(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values.

This STANDARD is not met as evidenced by:
Based on record review and an interview with Testing Personnel (TP) #1, the laboratory failed to establish a policy and procedure to notify the individual responsible for using the prostate specific antigen (PSA) and testosterone (Testo) test results performed in the subspecialties of Routine Chemistry and Endocrinology, when they were abnormal. This deficient practice had the potential to affect five out

of five patient PSA and Testo tests performed on 03/28/2025, the date testing began. Findings were as follows: 1. Review of the laboratory's Form CMS-116, approved by the Laboratory Director via signature and date on 03/28/2025 and provided on the date of the inspection revealed the laboratory performed PSA and Testo testing procedures. 2. Review of the manufacturer's "Quality Assurance Manual", approved via signature and date by the Laboratory Director on 02/07/2025 and provided on the date of the inspection found the following: "Procedures for Reporting Abnormal Patient Test Results Examples of acceptable ways to handle abnormal results are circling them in red ink or notifying the caregiver verbally within a few minutes. If your lab reports abnormal results differently than normal results, indicate below how abnormal results are reported." A hand written note by the laboratory stated "We verbally notify the patient of abnormal test results." 3. TP#1 confirmed that the laboratory notifies the patient of abnormal test results and stated the patient's paper chart is provided to the ordering provider for their review and charting needs. The interview occurred on 03/31/2025 at 1:50 PM.

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1299(a)

(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 postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:
Based on record review and interviews with the Practice Consultant (PC) #1, PC #2 and Testing Personnel (TP) #1, the laboratory failed to establish and follow their own written policies and procedures and accurately document all assessment activities of the ongoing mechanism to monitor, assess, and correct problems identified in the post analytic systems. This deficient practice had the potential to affect five out of five patient prostate specific antigen (PSA) and testosterone (Testo) tests performed on 03/28/2025, the date testing began. Findings Include: 1. Review of the laboratory's Form CMS-116, approved by the Laboratory Director via signature and date on 03/28/2025 and provided on the date of the inspection revealed the laboratory performed PSA and Testo testing procedures. 2. Review of five out of five patient PSA and Testo final test reports, performed on 03/28/2025 found an incorrect facility name (Precise Men's Medical Center) where the testing was performed and there were no indications of the specimen source, 3. Review of the manufacturer's "Quality Assurance Manual", approved by the Laboratory Director on 02/07/2025 and provided on the date of the inspection, found the following statement under the "Quality Assurance Assessment Program" section: "Our laboratory assesses the QA plan monthly, using the QA Assessment, which (1) evaluates and monitors the overall quality of our testing; (2) helps evaluate how well our policies and procedures are working; and (3) minimizes the possibility of recurrent problems." 4. The Inspector requested the laboratory's 2025 quality assessment documentation from TP#1. TP#1 provided the laboratory's February (dated 02/28/2025) and March (dated 03/25/2025) "Quality Assurance Assessment" worksheets that indicated a "Y" by post-analytic monitors that were not applicable as the laboratory was not enrolled in a proficiency testing (PT) program until 03/31/2025 and no patient testing was performed until 03/28/2025. See below: "Proficiency test results were evaluated, failures were investigated, and remedial action was taken." "All lab reports contain correct information." 5. On 04/08/2025 at 4:26 PM, the Inspector had a telephone conversation with PC#1 and PC#2. PC#1 and PC#2 confirmed the final test reports did not contain the correct facility name where

the testing was performed and there were no indications of the specimen source. PC#1 and PC#2 further confirmed the laboratory began patient testing on 03/28/2025, the laboratory did not enroll with a PT provider until 03/31/2025 and stated the laboratory must have been confused on how to complete their quality assessments.

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:
Based on record review and interviews with the Practice Consultant (PC) #1, PC #2 and Testing Personnel (TP) #1, the Laboratory Director failed to provide overall management and direction in accordance with 493.1407 of this subpart for prostate specific antigen (PSA) and testosterone (Testo) testing procedures performed in the subspecialties of Routine Chemistry and Endocrinology. This deficient practice had the potential to affect five out of five patient PSA and Testo tests performed on 03/28/2025, the date testing began. Findings Include: 1. The Laboratory Director failed to ensure that a quality assessment program was established and maintained to assure the quality of prostate specific antigen (PSA) and testosterone (Testo) testing procedures performed in the subspecialties of Routine Chemistry and Endocrinology and to identify failures in quality as they occur. (Refer to D6020) 2. The Laboratory Director failed to ensure the laboratory had test reports that indicated the correct laboratory location and the specimen source (when appropriate) for the prostatic specific antigen (PSA) and testosterone (Testo) tested performed in the subspecialties of Routine Chemistry and Endocrinology. The Laboratory Director also failed to establish a policy and procedure to notify the individual responsible for using the PSA and Testo test results, performed in the subspecialties of Routine Chemistry and Endocrinology, when they were abnormal. (Refer to D6026) 3. The Laboratory Director failed to ensure that an approved procedure manual was available to all laboratory personnel responsible for any aspect of the prostate specific antigen (PSA), testosterone (Testo) testing processes in the subspecialties of Routine Chemistry and Endocrinology and to include instructions not provided by the manufacturer. (Refer to D6031)

D6020

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

This STANDARD is not met as evidenced by:
Based on record review and interviews with the Practice Consultant (PC) #1, PC #2 and Testing Personnel (TP) #1, the Laboratory Director failed to ensure that a quality assessment program was established and maintained to assure the quality of prostate specific antigen (PSA) and testosterone (Testo) testing procedures performed in the subspecialties of Routine Chemistry and Endocrinology and to identify failures in quality as they occur. This deficient practice had the potential to affect five out of five patient PSA and Testo tests performed on 03/28/2025, the date testing began. Findings

Include: 1. Review of the laboratory's Form CMS-116, approved by the Laboratory Director via signature and date on 03/28/2025 and provided on the date of the inspection revealed the laboratory performed PSA and Testo testing procedures. 2. Review of the manufacturer's "Quality Assurance Manual", approved by the Laboratory Director on 02/07/2025 and provided on the date of the inspection, found the following statement under the "Quality Assurance Assessment Program" section: "Our laboratory assesses the QA plan monthly, using the QA Assessment, which (1) evaluates and monitors the overall quality of our testing; (2) helps evaluate how well our policies and procedures are working; and (3) minimizes the possibility of recurrent problems." 3. The Inspector requested the laboratory's 2025 quality assessment documentation from TP#1. TP#1 provided the laboratory's February (dated 02/28/2025) and March (dated 03/25/2025) "Quality Assurance Assessment" worksheets that indicated a "Y" by monitors that were not applicable as the laboratory was not enrolled in a proficiency testing (PT) program until 03/31/2025 and no patient testing was performed until 03/28/2025. See below: "Patient specimens were collected and handled according to our protocol." "Proficiency tests were handled in the same manner as patient specimens." "Proficiency test results were evaluated, failures were investigated, and remedial action was taken." "Each day, all environmental elements are checked, logged and are within normal ranges." "Each QC event, two levels of quality control were tested and were within acceptable ranges before patients were tested." "The system is operating optimally." "Proficiency test results were evaluated, failures were investigated, and remedial action was taken." "All lab reports contain correct information." 4. On 04/08/2025 at 4:26 PM, the Inspector had a telephone conversation with PC#1 and PC#2. PC#1 and PC#2 confirmed the laboratory began patient testing on 03/28/2025, the laboratory did not enroll with a PT provider until 03/31/2025 and stated the laboratory must have been confused on how to complete their quality assessments.

D6026

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(8)

(e)(8) Ensure that reports of test results include pertinent information required for interpretation;

This STANDARD is not met as evidenced by:
Based on record review and an interview with Testing Personnel (TP) #1, the Laboratory Director failed to ensure the laboratory had test reports that indicated the correct laboratory location and the specimen source (when appropriate) for the prostatic specific antigen (PSA) and testosterone (Testo) tested performed in the subspecialties of Routine Chemistry and Endocrinology. The Laboratory Director also failed to establish a policy and procedure to notify the individual responsible for using the PSA and Testo test results, performed in the subspecialties of Routine Chemistry and Endocrinology, when they were abnormal. This deficient practice had the potential to affect five out of five patient PSA and Testo tests performed on 03/28/2025, the date testing began. Findings Include: 1. Review of the laboratory's Form CMS-116, approved by the Laboratory Director via signature and date on 03/28/2025 and provided on the date of the inspection revealed the laboratory performed PSA and Testo testing procedures. 2. Review of five out of the five patient PSA and Testo final test reports performed on 03/28/2025 revealed an incorrect facility name (Precise Men's Medical Center) of where the testing was performed and did not find the specimen source (only indicated as "blood draw"). 3. Review of the manufacturer's "Quality Assurance Manual", approved via signature and date by the Laboratory

Director on 02/07/2025 and provided on the date of the inspection found the following: "Procedures for Reporting Abnormal Patient Test Results Examples of acceptable ways to handle abnormal results are circling them in red ink or notifying the caregiver verbally within a few minutes. If your lab reports abnormal results differently than normal results, indicate below how abnormal results are reported." A hand written note by the laboratory stated "We verbally notify the patient of abnormal test results." 4. On 03/31/2025 at 1:50 PM, TP#1 confirmed that the laboratory notifies the patient of abnormal test results and stated the patient's paper chart is provided to the ordering provider for their review and charting needs. TP#1, on 03/31/2025 at 2:30 PM, also confirmed that the patient PSA and Testo final test reports indicated Precise Men's Medical Center as the laboratory location where the testing was performed and the specimen source as "blood draw".

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 Testing Personnel (TP) #1, the Laboratory Director failed to ensure that an approved procedure manual was available to all laboratory personnel responsible for any aspect of the prostate specific antigen (PSA), testosterone (Testo) testing processes in the subspecialties of Routine Chemistry and Endocrinology and to include instructions not provided by the manufacturer. This deficient practice had the potential to affect five out of five patient PSA and Testo tests performed on 03/28/2025, the date testing began. Findings Include: 1. Review of the laboratory's Form CMS-116, approved by the Laboratory Director via signature and date on 03/28/2025 and provided on the date of the inspection revealed the laboratory performed PSA and Testo testing procedures. 2. Review of the laboratory's policies and procedures provided on the date of the inspection did not find any competency assessment, PSA, Testo and Qualigen FastPack IP maintenance and service policies and procedures that included components not provided by the manufacturer. 3. The Inspector requested the laboratory's competency assessment, PSA, Testo and Qualigen FastPack IP maintenance and service policies and procedures, approved by the Laboratory Director via signature and date that included instructions not provided by the manufacturer from TP#1. TP#1 provided the manufacturer's "Quality Assurance Manual", approved by the Laboratory Director on 02/07/2025 and the manufacturer's "QA Manual" and package inserts for "PSA" and "Testo", all unapproved by the Laboratory Director. TP#1 confirmed the laboratory did not establish their own written competency assessment, PSA, Testo, Qualigen FastPack IP maintenance and service and quality assessment policies and procedures to include all of the required components not provided by the manufacturer and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 03/31/2025 at 1:35 PM.