

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2208265	(X3) Date Survey Completed 10/18/2022
Name of Provider or Supplier Huntsville Mens Clinic	Street Address, City, State 250 Chateau Drive Sw, Suite 150, Huntsville, AL	
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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the 2021 - 2022 API (American Proficiency Institute) proficiency testing (PT) records, and an interview with the Clinic Manager, the surveyor determined the laboratory failed to ensure signed attestation statements and program forms were retained for at least two years for two of four surveys reviewed. The findings include: 1. A review of the API PT records revealed missing records for the following Chemistry / Endocrinology surveys: A) 2021 Event #3 had no program (results) forms, and no signature by the Laboratory Director on the attestation statement. B) 2022 Event #1 had no program forms, and no signed attestation statement. 2. A review of the instructions on the attestation statement revealed, "SIGNATURES REQUIRED - For all PT results, an attestation statement must be signed by the testing personnel and the laboratory director, and retained for two years". 3. In an interview on 10/18/2022 at 12:35 PM, the Clinic Manager reviewed and confirmed the above findings. .</p>
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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 a review of environmental records and an interview with the Clinic Manager, the laboratory failed to ensure room temperature, room humidity, and refrigerator temperatures were monitored and documented for four of nineteen months reviewed from March 2021 through September 2022. The findings include: 1. A review of environmental records revealed the laboratory failed to monitor and document room temperature, room humidity, and refrigerator temperatures from March 2021 through June 2021. 2. During and interview on 10/18/2022 at 2:24 PM, the Clinic Manager confirmed the previous Testing Personnel (no longer employed) had not recorded any environmental parameters in the laboratory. .

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on a review of maintenance records for the FastPack IP System Qualigen 1 (Serial Number 0978) and an interview with the Clinic Manager, the laboratory failed to ensure maintenance was performed and documented as per the frequency required by the manufacturer for five of nineteen months reviewed from March 2021 through September 2022. The findings include: 1. A review of FastPack IP System Qualigen 1 maintenance records revealed the laboratory failed to perform and document the daily and weekly maintenance as required by the manufacturer from March 2021 through July 2021. 2. During and interview on 10/18/2022 at 2:24 PM, the Clinic Manager confirmed the previous Testing Personnel (no longer employed) had not performed and documented the Qualigen maintenance. .

D5439

CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test

system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on a review of the FastPack IP System Qualigen 1 (Serial Number 0978) and Qualigen 2 (SN0192) records and an interview with the Clinic Manager, the laboratory failed to ensure calibration verification (C-V) was performed every six months as required by the laboratory policy. The surveyor noted three of three C-V's performed in 2021 - 2022 exceeded the six-month timeframe. The findings include: 1. A review of records for PSA (Prostatic Specific Antigen) and Testosterone performed on the FastPack IP System Qualigen 1 and 2 revealed the tests are calibrated with two calibrators, A and B. Analytes calibrated with less than three calibrators must have a calibration verification every six months. 2. A review of the C-V records for the two Qualigen instruments revealed the following: A) Qualigen 1: 1) 3/1/2021-PSA and Testosterone validation 2) Eight months later on 11/22/2021 the laboratory performed a C-V on PSA and Testosterone 3) Ten and a half later on 10/7/2022 the laboratory performed a C-V on Testosterone B) Qualigen 2: 1) 11/22/2021- PSA validated 2) Ten and a half later on 10/7/2022 the laboratory performed a C-V on PSA 3. A review of the procedure "Calibration and Calibration Verification" revealed, C-V "... performed minimally every six months, utilizing 3 or more calibrators across the reportable range". 4. During an interview on 10/18/2022 at 2:10 PM, the Clinic Manager confirmed the C-V's were late, and should be performed every six months. .

D5481

CONTROL PROCEDURES

CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a review of Quality Control (QC) records for the FastPack IP System Qualigen 1 (Serial Number 0978) and an interview with the Clinic Manager, the laboratory failed to ensure QC was performed and documented before patient testing four of nineteen months reviewed from March 2021 through September 2022. The findings include: 1. A review of FastPack IP System Qualigen 1 QC records revealed the following months of PSA (Prostatic Specific Antigen) and Testosterone patient testing when the laboratory failed to performed and document QC: A) March 2021; 135 patients affected B) April 2021; 171 patients affected C) May 2021; 157 patients affected D) June 2021; 215 patients affected 2. The laboratory provided a "Corrective Action Statement" for each month dated 8/30/2021, however the Laboratory Director failed to sign the statements to indicate his approval. The surveyor further noted the

same beginning statement for all four months, March, April, May and June 2021, "1. Two levels of controls were not run for Testosterone and PSA for the month of March 2022. This affected 135 patients. ...". [No one in the laboratory had noted the April-June 2021 statements contained the wrong year, the incorrect month and number of affected patients.] 3. During and interview on 10/18/2022 at 2:24 PM, the Clinic Manager confirmed the previous Testing Personnel (no longer employed) failed to perform and document the Qualigen QC March - June 2021. .

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 review of patient reports and an interview with the Clinic Manager, the laboratory failed to ensure two of five required parameters were included on a test report. The findings include: 1. During the post analytical review on 10/18/2022 at 3:05 PM, the surveyor requested a patient test report. The Clinic Manager provided two patient reports printed from the Advanced MD EHR (Electronic Health Record), as follows: A) Patient #1 dated 10/7/2021: The report failed to include the name of the facility performing the test or the units of measurement for Testosterone. B) Patient #2 dated 10/18/2022: The report failed to include the name and address of the facility performing the test or the units of measurement for Testosterone and PSA (Prostatic Specific Antigen). 2. During and interview on 10/18/2022 at 3:10 PM, the Clinic Manager confirmed the above findings. .

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 a review of the FastPack IP System Qualigen 1 (Serial Number 0978) and Qualigen 2 (SN0192) records and an interview with the Clinic Manager, the Laboratory Director failed to document his review / approval (as indicated by his signature and date) of the manufacturer's performance specification for one of two tests validated on Qualigen 1, and one of one tests validated on Qualigen 2 before patient testing began. The findings include: 1. A review of the installation records for

the two Qualigen instruments revealed the following: A) Qualigen 1: On 3/1/2021 the laboratory documented precision, accuracy and reportable range for PSA (Prostatic Specific Antigen) and Testosterone, however the Laboratory Director had failed to document his approval of the Testosterone validation procedures. Patient testing on the instrument began on 3/1/2021. B) Qualigen 2: On 11/22/2021- PSA precision, accuracy and reportable range were validated on the new Qualigen 2, however the Laboratory Director had failed to document his approval of the validation procedures. Patient testing on the instrument began 11/22/2021. 2. During an interview on 10/18 /2022 at 1:55 PM, the Clinic Manager stated the Laboratory Director had signed his approval of the validations, however the laboratory was unable to provide any substantiating documentation during the survey. .

D6017

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(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)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program.

This STANDARD is not met as evidenced by:
Based on a review of the American Proficiency Institute (API) proficiency testing (PT) records and an interview with the Clinic Manager, the Laboratory Director failed to ensure the laboratory submitted results within the timeframe specified by the proficiency testing provider. This was noted for one out of four 2021 to 2022 API events reviewed. The findings include: 1. A review of the API records revealed the 2022 API Chemistry / Endocrinology Event #2 survey received a score of zero percent due to "Failure to Participate". Instrument printouts revealed the laboratory performed the survey on 5/26/2022, and the deadline for submission was 6/8/2022, according to the API website 2. A review of the "Quality Assessment Plan" PT Corrective Action form for the 2022 API Chemistry / Endocrinology Event #2 survey revealed, "Results not entered into the API Data Base". 3. During an interview on 10 /18/2022, at 12:33 PM, the Clinic Manager confirmed the laboratory failed to submit results by the due date. .

D6036

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413

The technical consultant is responsible for the technical and scientific oversight of the laboratory.

This STANDARD is not met as evidenced by:
Based on reviews of API (American Proficiency Institute) proficiency testing (PT) records, environmental logs, FastPack IP System Qualigen 1 (Serial Number 0978) and Qualigen 2 (SN0192) records and an interview with the Clinic Manager, the surveyor determined the Technical Consultant failed to provide technical and scientific oversight of the laboratory resulting in deficiencies which occurred from March 2021 through May 2022. The findings include: 1. A review of laboratory records revealed no documentation of the Technical Consultant's reviews and

scientific oversight, as follows: A) No evidence of review to ensure all required API PT records were available (Refer to D2015.) B) No monitoring of the timeframes to ensure the calibration verification on the two FastPack IP System Qualigen instruments was performed every six months as per the procedure (Refer to 5439.) C) No technical supervision to ensure environmental parameters, and FastPack IP System Qualigen maintenance, and QC was performed and documented March - June 2021 (Refer to D2015, 5429, and 5481.) D) No technical supervision to ensure new instrument installation procedures validated the manufacturer's performance specification and were reviewed and approved (as indicated by signature and date) before patient testing began. (Refer to D6013.) 2. During the exit summation interview with the Clinic Manager on 10/18/2022 at 3:25 PM, the surveyor reviewed the above deficiencies and the lack of technical oversight and supervision.
SURVEYOR ID 332558 Licensure and Certification Surveyor