

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 28D0455518	(X3) Date Survey Completed 06/24/2022
Name of Provider or Supplier Dr Np Patel Md, Pc	Street Address, City, State 110 N 37th St Ste 101, Norfolk, NE	
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
D0000	A routine recertification CLIA survey was conducted at Urology Services on 6/8/2022 with survey exit date 6/24/2022 by the Nebraska Department of Health and Human Services. Immediate Jeopardy was identified related to the following conditions: D2000 - Enrollment and testing of samples 493.801 D5400 - Analytic systems 493.1250 D6000 - Moderate complexity laboratory director 493.1403
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor review of the laboratory's list of tests performed and interview with the lab director and technical consultant the laboratory failed to enroll in an approved proficiency testing program for moderate complexity testing for the specialties of bacteriology, chemistry, and hematology for 2021. Findings are: 1. Review of the laboratory's list of tests revealed the laboratory performs moderate complexity testing for bacteriology, chemistry, and hematology. Regulated analytes include urine colony count, ALT(SGPT), Albumin, Total Bilirubin, Chloride, Total Cholesterol, HDL Cholesterol, Creatinine, Glucose, Potassium, Sodium, Total Protein, Triglycerides, BUN, Cell Identification or White Blood Cell Differential, Red Blood Cell (RBC), Hematocrit (HCT), Hemoglobin (HGB), White Blood Cell (WBC), and Platelets. 2. Interview with the lab director and technical consultant on 6/6/2022 at 11:50 AM</p>

	<p>confirmed the laboratory failed to enroll in proficiency testing for the specialties of bacteriology, chemistry, and hematology for 2021. Regulated analytes include bacteriology - urine colony count, ALT(SGPT), Albumin, Total Bilirubin, Chloride, Total Cholesterol, HDL Cholesterol, Creatinine, Glucose, Potassium, Sodium, Total Protein, Triglycerides, BUN, Cell Identification or White Blood Cell Differential, Red Blood Cell (RBC), Hematocrit (HCT), Hemoglobin (HGB), White Blood Cell (WBC), and Platelets.</p>
<p>D2015</p>	<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 lack of documentation and interview with the technical consultant, the laboratory failed to maintain a copy of all proficiency testing records for 2020. Findings are: 1. The laboratory failed to provide documentation of all proficiency testing records for 2020. 2. Interview with the technical consultant on 6/6/2022 11:30 AM confirmed the laboratory did not have a copy of all proficiency testing records for 2020.</p>
<p>D5217</p>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's list of tests performed, lack of documentation, and interview with the laboratory director and technical consultant, the laboratory failed to have a system for verifying the accuracy of the testing for prostate specific antigen (PSA), testosterone, urine microscopy, and post-vasectomy sperm presence for 2021. Findings are: 1. Review of the laboratory's list of tests performed revealed the laboratory had performed testing for prostate specific antigen (PSA), testosterone, urine microscopy, and post-vasectomy sperm presence in 2021. 2. Interview with the laboratory director and technical consultant 6/6/2022 at 11:30 AM confirmed the laboratory had not performed accuracy verification at least twice annually for the analytes protein specific antigen (PSA), testosterone, urine microscopy, and post-vasectomy sperm presence.</p>
<p>D5400</p>	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p>

Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:

Based on observation of regents, review of documentation, and interview, the laboratory had expired media (Refer to D5417); failed to perform instrument function checks (Refer to D5431); failed to perform calibration verification (Refer to D5439); and failed to perform control procedures (Refer to D5477).

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on surveyor observation of media, review of policy, and interview, the laboratory had expired Trypticase Soy Agar with 5% Sheep Blood media. Findings are: 1. Surveyor observation of media in the refrigerator revealed an expiration date of 6/3/2022 for the Trypticase Soy Agar with 5% Sheep Blood media. 2. Review of the laboratory's policy "Urology Clinic Quality Assurance Program" showed "When the reagent material is expired it will be discarded." 3. Interview with the technical consultant on 6/6/2022 at 11:10 AM confirmed the laboratory had expired media available for use.

D5431

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(2)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

Based on review of the laboratory procedure manual, review of instrument maintenance, and interview with the technical consultant, the laboratory failed to verify centrifuge speed and timer annually for accuracy. Findings are: 1. Review of the procedure used by this laboratory for the examination of urine sediment revealed testing personnel were to spin an aliquot of urine for 5 minutes at 1200 to 1500 revolutions per minute (RPM). 2. Review of the laboratory's policy "Urology Clinic Quality Assurance Program" revealed "Centrifuge speed and timer will be verified annually for accuracy." 3. Review of maintenance records for the centrifuge used for spinning urine revealed the last tachometer check for proper RPMs and timer check had been performed on 2/8/2019. 4. Interview with the technical consultant on 6/6

/2022 at 11:33 AM confirmed the speed and time on the centrifuge in use had not been checked since the documented date, 2/8/2019.

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 review of manufacturer's instructions, review of calibration verification records, and interview with the technical consultant, the laboratory failed to perform calibration verification every 6 months for prostate specific antigen (PSA) and testosterone. 1. Manufacturer's instructions indicate "Every 6 months, verify calibration of the FastPack IP System using the FastPack Total PSA and the FastPack Testo Method Verification Kit to verify that calibration is accurate to the limits of the reportable range specified by Qualigen, Inc." 2. Surveyor review of the calibration verification records revealed calibration verification was performed on 8/4/2020 for PSA and 9/16/2020 for testosterone. 3. Interview with the technical consultant on 6/6/2022 at 11:10 AM confirmed the laboratory failed to perform calibration verification every six months.

D5477

CONTROL PROCEDURES
CFR(s): 493.1256(e)(4)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

	<p>Based on the laboratory's Individualized Quality Control Plan and Risk assessment for Commercially Prepared Media, lack of documentation, and interview with the technical consultant, the laboratory failed to document the condition of Trypticase Soy Agar with 5% Sheep Blood media and MacConkey agar media when received. 1. The laboratory's Individualized Quality Control Plan and Risk assessment for Commercially Prepared Media indicate the laboratory needs to "examine [media] for obvious defects including cracked or damaged plates, obvious contamination... upon receipt and before inoculation with patient specimens." 2. The laboratory failed to document the condition of the Trypticase Soy Agar with 5% Sheep Blood media and MacConkey agar media since January 2020. 3. Interview with the technical consultant on 6/6/2022 at 11:10 AM confirmed the laboratory failed to document the condition of the media received since January 2020.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: The laboratory director failed to ensure the laboratory is enrolled in an approved proficiency testing program (Refer to D6015); failed to assure competencies were performed (Refer to D6030); failed to have an approved procedure manual (Refer to D6031); and failed to have duties/responsibilities of each person involved in testing (Refer to D6032).</p>
<p>D6015</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)</p> <p>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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.</p> <p>This STANDARD is not met as evidenced by: The laboratory director failed enroll the laboratory in an approved proficiency testing program (Refer to D2000).</p>
<p>D6030</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</p> <p>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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to</p>

process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on review of testing personnel listed on the CMS-209 and interview with the technical consultant, the laboratory director failed to assure competencies were performed on testing personnel #1, as listed on the CMS 209. 1. Testing personnel #1, as listed on the CMS-209, started working in the laboratory on March 2021. 2. Interview with the technical consultant confirmed testing personnel #1, as listed on the CMS-209, did not have competencies performed.

D6031

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(13)

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

This STANDARD is not met as evidenced by:

Based on surveyor review and interview with the technical consultant and laboratory director, the laboratory failed to have a procedure manual for the chemistry analytes: protein specific antigen (PSA) and testosterone. 1. Surveyor review of procedure manual revealed no procedure was available for PSA and testosterone. 2. Interview with the technical consultant and laboratory director on 6/6/2022 at 11:50 AM confirmed the laboratory failed to have a procedure for PSA and testosterone.

D6032

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(14)

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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on lack of documentation and interview with the technical consultant, the laboratory director failed to have, in writing, the duties and responsibilities of each person involved in testing. 1. The laboratory failed to have documentation in writing the duties and responsibilities of each person involved in testing. 2. Interview with the technical consultant on 6/10/2022 at 10:05 AM confirmed the laboratory director

failed to specify in writing the duties and responsibilities of each person involved in testing.