

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 28D0455518	(X3) Date Survey Completed 01/06/2020
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
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on review of the demonstration of performance specifications and an interview with the technical consultant the laboratory failed to demonstrate the accuracy for a new chemistry instrument and a new hematology instrument. Findings are: NOTE: This deficiency was previously cited on 11/16/2017. 1. Review of the validation of performance specifications for a new instrument used for prostate specific antigen (PSA) testing (started on 7/26/2018) and testosterone testing (started on 8/7/2018) revealed no checks for accuracy had been included in the instrument validation. 2. Review of the validation of performance specifications for a new instrument used for complete blood count (CBC) testing (started on 3/30/2018) revealed no checks for accuracy had been included in the instrument validation. 3. Interview with the technical consultant on 12/17/2019 at 12:58 PM, confirmed a test comparison with another laboratory or instrument had not been performed prior to patient testing.</p>
D6041	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(3)</p> <p>(b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services</p>

offered;

This STANDARD is not met as evidenced by:

Based on review of testing performed, review of the CMS 96 report, proficiency testing for 2018, proficiency testing for 2019, and an interview with the technical consultant, the laboratory was not properly enrolled in proficiency testing for chemistry. Findings are: NOTE: This deficiency was previously cited on 11/16/2017. 1. Review of the testing performed revealed 16 regulated and 1 non regulated analytes tested on the chemistry instrument. 2. Review of the CMS 96 report (indicating proficiency testing scores for regulated analytes) revealed only the hematology analytes and no chemistry analytes present. 3. Review of proficiency testing for 2018 and 2019 indicated the laboratory had participated in all of the chemistry analytes, but were enrolled in the waived testing evaluations. 4. Interview with the technical consultant on 12/17/2019 at 12:06 PM confirmed the laboratory had been performing non waived testing on this instrument since 5/23/2017 and only performed the waived proficiency testing for these analytes.

D6063

LABORATORY TESTING PERSONNEL
CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:

Based on lack of documentation the laboratory failed to have proof of education on testing personnel #3, as listed on the CMS-209, performing moderate complex testing. Refer to D6065.

D6065

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on lack of documentation and interview with technical consultant, on 12/17/2019 at 1:28 PM the laboratory failed to have proof of education on one out of three testing personnel performing moderate complexity testing. Findings are: 1. No proof

of education documentation for testing personnel #3, as listed on the CMS-209, performing moderate complex testing was presented. 2. Interview with technical consultant confirmed no documentation was available.