

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 32D0537331	(X3) Date Survey Completed 06/04/2019
Name of Provider or Supplier De Baca Family Practice Clinic	Street Address, City, State 546 N 10th St, Fort Sumner, NM	
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	During a recertification survey completed on 06/04/19 for 42 CFR part 493 Laboratory Requirements, the facility was found out of compliance with the following condition: 42 CFR Part 493.1403 Laboratory Director, moderate complexity.
D5213	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)</p> <p>The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on the review of 2018-2019 proficiency testing records and interviews with laboratory staff, the laboratory failed to evaluate TSH (Thyroid Stimulating Hormone) results not graded by the proficiency testing agency for 2 (1st event 2018 and 1st event of 2019) of 4 test events. Findings are: A. Review of 2018-2019 revealed the laboratory failed to self-grade TSH results not graded by the proficiency agency for 2 of 4 test events. Each upgraded result was marked with "#" and indicated "This method was not graded due to an insufficient number of peer respondents. No appropriate default grouping was available. The listed range should provide a reasonable guide to your performance. However, exercise caution in evaluating your results." 1. Review of the TSH results for the 1st event of 2018 (02/08/18) indicated 3 (#3 - #5) of the 5 samples were not graded and were not within the acceptable range. The laboratory received a score of 100% but the actual score would have been 40 %. The laboratory performed corrective actions for the urobilinogen failure on 04/03/18 and whole blood glucose on 04/10/18 but no indication that the laboratory identified the failed TSH results. The Laboratory Director signed the report on 04/10/18. #1 = 2.5 acceptable range 1.9 - 3.3 #2 = 0.3 acceptable range 0.1 - 1.0 #3 = 4.3 acceptable range 4.7 - 11.6 #4 = 2.0 acceptable range 2.4 - 5.5 #5 = 2.9 acceptable range 3.3 - 7.6 2. Review of the 1st event of 2019 (02/08/19) TSH results revealed the laboratory did</p>

not self-grade 3 samples (#1, #3, #4) and were not within the acceptable range. The laboratory received a score of 100%. The actual score would have been 40%. The Laboratory Director signed the report on 04/17/19. #1 = 1.1 acceptable range 1.6 - 3.6 #2 = 2.6 acceptable range 2.0 - 3.3 #3 = 2.1 acceptable range 2.9 - 6.2 #4 = 3.4 acceptable range 3.7 - 9.7 #5 = 0.2 acceptable range 0.2 - 0.7 B. During interview on 06/03/19 at 3:15 pm, the Laboratory Supervisor confirmed the laboratory had not reviewed and graded the TSH results for the 1st events of 2018 and 2019.

D5441

CONTROL PROCEDURES
CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on the review of 2018-2019 proficiency test records, manufacturer instructions, 2018 chemistry quality control, calibration, and interview with laboratory staff, the laboratory failed to have quality control procedures that monitored accuracy and precision over time. Findings are: A. Review of 2018-2018 proficiency test records revealed failures for TSH (Thyroid Stimulating Hormone) for 2 of 4 test events and no documentation of quality control review as part of the corrective actions. See D5213 B. Review of the manufacturer's instructions for the Cliniqua Liquid QC Immunoassay Control indicated, "The assigned mean values were derived from analysis of vials representative of the entire lot. Analyte values were obtained from laboratories of the instrument manufacturer, manufacturers of instrument specific reagents, or from reference laboratories. The Expected Range of the Mean is provided to assist the laboratory until it has established its own mean and standard deviation." C. Review of the quality control records for 2018-May 2019 did not indicate any review or revision of the quality control ranges for the current lot of quality control materials. The laboratory adopted the manufacturer's Range of Means as its acceptable range. D. Review of the 2018-2019 quality control documentation did not indicate any assessment of the accuracy or precision through the use of statistical methods such as calculation of the Coefficient of Variation (precision) or plotting the results in a graph against the established ranges (accuracy). Lot 1706090B expiration date 02/2021 in use by the laboratory as of 04/06/18 1. Level 1 The manufacturer Range of Means for TSH 0.72 - 1.61 uIU/mL (micro International Units/milliliter) with a mean of 1.16. The calculated range (using the laboratory's first 30 days of quality control data) 0.9 - 1.34 with a mean of 1.12 and a calculated CV (Coefficient of Variation) of 10.23%. 2. Level 2 The manufacturer Range of Means for TSH 8.38 - 15.65 uIU/mL with a mean of 12.01. The calculated range (using the laboratory's first 30 days of quality control data) 8.75 - 13.23 with a mean of 10.99 and a calculated CV (Coefficient of Variation) of 10.2%. 3. Review of the FREND immunoassay analyzer instructions revealed the expected between-day precision for clinical samples as follows: Mean of 0.496 = 3.4% Mean of 5.948 = 0.5% Mean of 11.989 = 1.3% Mean of 23.763 = 0.0% E.

	<p>During interview on 06/03/19 at 4:00 pm, the Laboratory Supervisor stated that the new LIS (Laboratory Information System) is capable of monitoring quality control but it had not been set up. She further stated that there was no other method such as an interlaboratory quality assessment program for monitoring quality control.</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: Based on the review of 2018-2019 proficiency test records, manufacturer's instructions, 2018 chemistry quality control records, and interview with laboratory staff, the Laboratory Director failed to provide overall direction and management of the laboratory. Findings are: A. The Laboratory Director failed to ensure an effective quality control policy was established and maintained. See D6020 B. The laboratory director failed to ensure proficiency results were reviewed and corrective actions performed by the appropriate staff. See D6018 C. The Laboratory Director failed to ensure a comprehensive corrective action plan was followed for proficiency testing failures for 2 consecutive test events in 2018. See D6019</p>
<p>D6018</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)</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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;</p> <p>This STANDARD is not met as evidenced by: Based on the review of 2018-2019 proficiency testing records and interviews with laboratory staff, the Laboratory Director failed to ensure proficiency results were reviewed and corrective actions performed by the appropriate staff. Findings are: A. The laboratory failed to evaluate TSH (Thyroid Stimulating Hormone) results not graded by the proficiency testing agency for 2 (1st event 2018 and 1st event of 2019) of 4 test events. See D5213 B. Review of the 2018-2019 proficiency testing records revealed no reviews or corrective actions performed by the Technical Consultant. C. During interview on 06/03/19 at 3:15 pm, the Laboratory Supervisor confirmed the laboratory had not reviewed and graded the TSH results for the 1st events of 2018 and 2019.</p>
<p>D6019</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv)</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</p>

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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

Based on the review of 2018-2019 proficiency testing records and interviews with laboratory staff, the Laboratory Director failed to ensure a comprehensive corrective action plan was followed for proficiency testing failures for 2 consecutive test events in 2018. Findings are: A. Review of 2018-2019 proficiency records revealed the laboratory failed to self-grade TSH results not graded by the proficiency agency for 2 of 4 test events. See D5213 1. Each upgraded result was marked with "#" and indicated "This method was not graded due to an insufficient number of peer respondents. No appropriate default grouping was available. The listed range should provide a reasonable guide to your performance. However, exercise caution in evaluating your results." 2. During interview on 06/03/19 at 3:15 pm, the Laboratory Supervisor confirmed the laboratory had not reviewed and graded the TSH results for the 1st events of 2018 and 2019. B. Review of the TSH results for the 2nd event of 2018 (05/10/18) indicated 4 (#1- #3, #5) of the 5 samples were not graded and not within the acceptable range. The laboratory received a score of 100% but the actual score would have been 40 %. The Laboratory Director signed the report on 07/25/18. #1 = 1.3 acceptable range 2.6 - 5.6 #2 = 0.7 acceptable range 0.9 - 2.9 #3 = 2.3 acceptable range 3.4 - 8.4 #4 = 0.6 acceptable range 0.5 - 1.8 #5 = 2.1 acceptable range 3.3 - 7.6 1. Review of corrective actions dated 07/24/18 indicated the laboratory repeated all samples but samples #2 and #3 were still not acceptable. There was no documentation of any other actions such as review of maintenance, calibration, quality control and patient records. C. Review of the TSH results for the 3rd event of 2018 (09/14/18) revealed the laboratory failed with a score of 40%. Sample #2 was not graded and did not fall within the acceptable range which would have changed the score to 20%. The Laboratory Director signed the report on 11/30/18. #1 = 0.6 acceptable range 0.6 - 2.0 #2 = 2.2 acceptable range 2.7 - 6.7 #3 = 3.7 acceptable range 3.8 - 9.4 #4 = 1.2 acceptable range 1.6 - 4.6 #5 = 2.5 acceptable range 3.0 - 8.0 1. Review of the laboratory's corrective actions dated 11/30/18 indicated the laboratory retested the samples but 2 (#2 and #4) were still not acceptable. There was no indication that sample #1 was retested and there was no documentation of any other actions such as review of maintenance, calibration, quality control and patient records.

D6020

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

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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on the review of 2018-2019 proficiency test records, manufacturer instructions, 2018 chemistry quality control records, the Laboratory Director failed to ensure an

effective quality control policy was established and maintained. Findings are: A. The laboratory failed to establish quality control ranges as required by the manufacturer of the quality control material. See D5441 B & C B. The laboratory failed to monitor the precision and accuracy of the TSH test method using statistical evaluation of quality control results. See D5441 D & E