

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0693972	(X3) Date Survey Completed 09/18/2018
Name of Provider or Supplier Lowell F Clark Md Pa	Street Address, City, State 212 S Florida St, Bushnell, FL	
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
D2087	<p>ROUTINE CHEMISTRY CFR(s): 493.841(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on American Proficiency Institute (API) proficiency record review and interview with the Testing Personnel, the laboratory did not attain a score of at least 80% for the following Routine Chemistry analytes: 2017 1st Event Cholesterol HDL, 2017 2nd Event Cholesterol Total, Total Protein, 2018 1st Event Creatinine, Sodium, and 2018 2nd Event Potassium. Findings included: 1. Record review of API Routine Chemistry proficiency records revealed that the laboratory had obtained a score of less than 80% for the following analytes: 2017 1st Event Cholesterol HDL - 20%, 2017 2nd Event Cholesterol Total - 0% and Total Protein - 0%, 2018 1st Event Creatinine - 60% and Sodium - 60%, and 2018 2nd Event Potassium - 60%. 2. Interview on 09/18 /2018 at 11:00 AM, the Testing Personnel on staff confirmed the unsatisfactory Routine Chemistry proficiency testing scores.</p>
D2098	<p>ENDOCRINOLOGY CFR(s): 493.843(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on American Proficiency Institute (API) proficiency testing record review and Testing Personnel interview, the facility failed to obtain an 80% proficiency test score for the 2nd event of 2017 for the specialty of Endocrinology. Findings included: 1.</p>

	<p>Record review of API Endocrinology proficiency testing results it was revealed that the laboratory received a score of 40% for Thyroid Stimulating Hormone for 2017 2nd Event API Endocrinology proficiency testing. 2. Interview on 09/18/18 at 11:00 AM the Testing Personal confirmed the laboratory's unsatisfactory Endocrinology proficiency testing results.</p>
<p>D2121</p>	<p>HEMATOLOGY CFR(s): 493.851(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency testing results and interview with Testing Personal, the laboratory had 1 testing event that had analytes that received less than 80% in the specialty of Hematology. Findings Included: 1. Review of API proficiency testing results found the 3rd testing event in 2016 had 67% for White Blood Differential, 60% for Hematocrit, 60% for Hemoglobin, 60% for White Blood Cells, and 60% for Platelets. 2. Interview on 09/18 /2018 at 10:30 AM Testing Personnel confirmed the proficiency testing failures.</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 American Proficiency Institute (API) proficiency record review and interview with Testing Personnel, the laboratory failed to verify the accuracy of Total Bile Acids testing for two out of two years (2016-2018). Findings included: 1. Record review of API proficiency testing records revealed that the laboratory had not performed proficiency testing for Total Bile Acids. 2. Interview on 09/18/2018 at 2:45 PM the Testing Personnel stated the laboratory was not enrolled in proficiency testing and had not verified the accuracy of Total Bile Acids for two out of two years (2016-2018).</p>
<p>D5221</p>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) Routine Chemistry and Chemistry Endocrinology proficiency testing records and interview with the Testing Personnel, the laboratory failed to have corrective action for unsatisfactory testing events on 4 out of 7 (3rd Event 2016, 1st, 2nd, 3rd Event 2017, and 1st, 2nd Event 2018) testing events reviewed and for unsuccessful for proficiency testing for Chemistry Miscellaneous Urine Creatinine 2016 2nd and 3rd Event, and 2017 Chemistry Endocrinology 1st and 2nd Event for Free triiodothyronine (T3) Findings</p>

Included: Review of API proficiency testing records revealed the following unsatisfactory results: Routine Chemistry - 2nd Event 2017 Routine Chemistry - 75% Albumin - 0%, Cholesterol Total 0%, and Total Protein - 0%, 3rd Event Albumin - 0%, 1st Event 2018 Cholesterol HDL - 60% and Sodium 60%, and 2nd Event 2018 Potassium - 60%. 2017 Chemistry Endocrinology 2nd Event Thyroid Stimulating Hormone (TSH) - 40%. Chemistry Miscellaneous 2017 1st Event microalbumin - 0%. No corrective action was documented. Review of API proficiency testing results revealed the following unsuccessful proficiency testing results: Chemistry Miscellaneous 2016 2nd Event Urine Creatine - 0%, 2016 3rd Event Urine Creatinine - 0% , and 2017 1st Event Urine Creatinine - 0%, Chemistry Endocrinology Free T3 2017 1st Event - 60% and 2nd Event - 40%. Interview on 09/18/2018 at 11:30 AM the Testing Personnel confirmed the lack of documented corrective action.

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 maintenance record review and interview with Testing Personnel, there was no documentation to indicate that all required maintenance had been performed on 1 out of 2 Chemistry analyzers and the Hematology analyzer for two out of two years (2016-2018) Findings included: 1. Record review of maintenance logs for the Chemistry analyzers and Hematology analyzer revealed that documentation for the weekly, monthly, 3 month maintenance for the Chemistry analyzer and the documentation for the waived Hematology 3 month maintenance was missing. 2. Interview on 09/18/2018 at 1:45 PM with the Testing Personnel confirmed that weekly maintenance for chemistry analyzer and the 3 month maintenance for the Hematology had been performed but not documented and the monthly and every 3 month maintenance for the Chemistry analyzer had not been performed.

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 Chemistry calibration verification record review and interview with Testing Personnel, the laboratory did not perform calibration verifications on the chemistry analyzer at least every six months. Findings included: 1. Review of calibration verification records for the Chemistry analyzer revealed that calibration verifications had not been performed since June 2016. 2. Interview on 09/18/2018 at 2:00 PM with Testing Personal confirmed that calibration verifications had not been performed since June 2016.

D5469

CONTROL PROCEDURES

CFR(s): 493.1256(d)(10)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on Chemistry and Hematology Quality Control record review and interview with Testing Personnel, the laboratory failed to monitor quality control results since 11 /2016. Findings included: 1. Review of Quality Control records revealed that Quality Control results were being printed and put in a binder but Quality Control results were not being reviewed for outliers, shifts, or trends for a defined time period. 2. Interview on 09/18/2018 at 1:30 PM with Testing Personnel confirmed that the laboratory had not printed out Levy Jennings reports to review Quality Controls over a period of time since 11/2016.

D5793

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(b)(c)

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on Quality Assurance record review and interview with the Testing Personnel,

the laboratory failed to perform and document analytic systems quality assessment activities from 11/2016 - 9/2018. Findings included: 1. Review of the laboratory's records for November 2016 through September 2018 showed that there was no documentation of analytic systems quality assessment activities. The last time Quality Assurance activities were performed and documented was in October of 2016. 2. Interview on 09/18/2018 at 1:00 PM with the Testing Personnel confirmed that the laboratory had no documentation of quality assessment activities for November 2016 through September 2018.