

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2200510	(X3) Date Survey Completed 09/01/2021
Name of Provider or Supplier Florida Medical Laboratory Group Inc	Street Address, City, State 224 Eglin Pkwy Ne Ste E, Fort Walton Beach, 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
D0000	An announced CLIA initial survey was conducted at Florida Medical Laboratory Group Inc. on 9/01/2021. The laboratory is not in compliance with the 42 CFR Part 493, Requirements for Laboratories.
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 record review and staff interview, the facility failed to have a passing proficiency test score for the analytes "Sodium" and "Chloride" during the 1st Chemistry testing event in 2021. The findings include: The record review on 9/1/21 of the American Proficiency Institute 1st Chemistry event of 2021 showed a score of 0% for the analyte "Sodium" and a score of 0% for the analyte "Chloride". The 9/1/21 interview with the Technical Supervisor at 12:15pm confirmed the failure in proficiency testing.</p>
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the facility failed to retain laboratory temperature records and instrument maintenance logs for December 2020. The</p>

	<p>findings include: 1. The laboratory was unable to provide documentation that showed laboratory instrumentation maintenance was performed according to manufacturer instructions for the month of December 2020. The instruments in use: Beckman Coulter AU480, Clinitek Advantus, Sysmex XN-500, and Beckman Coulter Access 2. 2. The laboratory was unable to provide documentation that showed the temperature of the laboratory, the refrigerator, or the freezer was being monitored in December 2020. During the interview with the Technical Supervisor on 9/1/21 at 10:53am, it was confirmed the temperature and maintenance records were missing.</p>
<p>D5209</p>	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Laboratory Director, the laboratory had not performed competency assessment on the Technical Supervisor/Technical Consultant since the laboratory opened in 2020. The findings include: Record review of competency records revealed that competency evaluations had not been performed for the Technical Supervisor/Technical Consultant. During the interview on 9/1/21 at 11:05am, the Technical Supervisor/Technical Consultant acknowledged they had not received a competency evaluation from the Laboratory Director.</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 record review and staff interview, the laboratory failed to ensure the accuracy of Thyroglobulin Antibodies and Thyroid Peroxidase Antibodies testing at least twice a year for 2020 - 2021 for the subspecialty of Immunology. The findings include: Review of proficiency testing documentation for 2020 and 2021 showed that Thyroglobulin Antibodies and Thyroid Peroxidase Antibodies were not included in the proficiency testing records. During the interview on 9/1/21 at 12:05 PM, the Technical Supervisor confirmed that the laboratory did not enroll the analytes for proficiency testing or verify twice annually to confirm accuracy.</p>
<p>D5427</p>	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(c)</p> <p>(c) Documentation. The laboratory must document all activities specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the facility failed to retain documentation that showed how the accuracy, precision, and reportable range was determined for the</p>

Clinitek Advantus urinalysis instrument. The findings include: The laboratory was unable to provide raw documentation that showed how the Clinitek Advantus was validated prior to patient testing. During and interview on 9/1/21 at 9:20am, the Technical Supervisor confirmed the documentation was missing.

D5783

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:

Based on record review and interview with testing personnel, the laboratory failed to identify, initiate corrective action, and document for quality control (QC) outside the acceptable two standard deviation (2SD) multiple days in a row for fifteen chemistry analytes in July 2021. The findings include: Record review of the General Quality Control policy states if the results obtained are outside of the acceptable 2SD limit, corrective action must be initiated and a pop up window will appear in the laboratory information system (LIS) for corrective action documentation. Record review of daily chemistry QC for the month of July revealed QC failures with no corrective action documentation for the following analytes and dates: QC Level one: Parathyroid Hormone, Intact mean is 26.92 pg/mL (picograms per milliliter) with a 2SD limit of 5.85 pg/mL. The high limit is 32.77 pg/mL and the low limit is 21.07 pg/mL. On 7/7/21 level one control was above the high limit at 36 pg/mL. One patient was tested and reported. On 7/13/21 level one control was above the high limit at 33 pg/mL. Two patients were tested and reported. On 7/17/21 level one control was above the high limit at 33 pg/mL. One patient was tested and reported. On 7/27/21 level one control was above the high limit at 34 pg/mL. Three patients were tested and reported. On 7/28/21 level one control was above the high limit at 33 pg/mL. One patient was tested and reported. Thyroglobulin Antibodies mean is 65.78 IU/mL (international units per milliliter) with a 2SD limit of 17.40 IU/mL. The high limit is 83.18 IU/mL and the low limit is 48.38 IU/mL. On 7/10/21 level one control was below the low limit at 48 IU/mL. Two patients were tested and reported. On 7/28/21 level one control was below the low limit at 47 IU/mL. One patient was tested and reported. Thyroid Peroxidase Autoantibodies mean is 19.90 IU/mL with a 2SD limit of 4.10 IU/mL. The high limit is 24 IU/mL and the low limit is 15.8 IU/mL. On 7/8/21 level one control was below the low limit at 15 IU/mL. One patient was tested and reported. On 7/10/21 level one control was below the low limit at 14 IU/mL. Two patients were tested and reported. On 7/28/21 level one control was below the low limit at 14 IU/mL. One patient was tested and reported. On 7/30/21 level one control was below the low limit at 15 IU/mL. One patient was tested and reported. On 7/31/21 level one control was below the low limit at 15 IU/mL. Two patients were tested and reported. Urea Nitrogen mean is 15.04 mg/dL (milligrams per deciliter) with a 2SD limit of 1.68 mg/dL. The high limit is 16.72 mg/dL and the low limit is 13.36 mg/dL. On 7/27/21 level one control was above the high limit at 17 mg/dL. One patient was tested and reported. Creatinine, Serum mean is 0.73 mg/dL with a 2SD of 0.05 mg/dL. The high limit is 0.78 mg/dL and the low limit is 0.68 mg/dL. On 7/30/21 level one control was above the high

limit at 0.79 mg/dL. Fifty seven patients were tested and reported. Total Protein mean is 3.75 g/dL (grams per deciliter) with a 2SD of 0.1380 g/dL. The high limit is 3.888 g/dL and the low limit is 3.612 g/dL. On 7/7/21 level one control was above the high limit at 3.9 g/dL. Sixty five patients were tested and reported. Albumin mean is 2.48 g/dL with a 2SD of 0.1120 g/dL. The high limit is 2.592 g/dL and the low limit is 2.368 g/dL. On 7/2/21 level one control was below the low limit at 2.32 g/dL. Forty two patients were tested and reported. On 7/3/21 level one control was below the low limit at 2.32 g/dL. Forty four patients were tested and reported. Total Bilirubin mean is 0.62 mg/dL with a 2SD of 0.16 mg/dL. The high limit is 0.78 mg/dL and the low limit is 0.46 mg/dL. On 7/28/21 level one control was above the high limit at 0.80 mg/dL. Sixty five patients were tested and reported. On 7/29/21 level one control was above the high limit at 0.80 mg/dL. Forty two patients were tested and reported. On 7/30/21 level one control was above the high limit at 0.80 mg/dL. Fifty patients were tested and reported. On 7/31/21 level one control was above the high limit at 0.80 mg/dL. Fifty eight patients were tested and reported. Alkaline Phosphatase mean is 30.38 U/L (Units per Liter) with a 2SD of 3.08 U/L. The high limit is 33.46 U/L and the low limit is 27.30 U/L. On 7/3/21 level one control was below the low limit at 26 U/L. Forty one patients were tested and reported. On 7/7/21 level one control was below the low limit at 26 U/L. Sixty five patients were tested and reported. On 7/14/21 level one control was below the low limit at 27 U/L. Fifty three patients were tested and reported. On 7/28/21 level one control was below the low limit at 27 U/L. Sixty patients were tested and reported. On 7/29/21 level one control was below the low limit at 26 U/L. Forty two patients were tested and reported. On 7/30/21 level one control was below the low limit at 26 U/L. Fifty patients were tested and reported. On 7/31/21 level one control was below the low limit at 27 U/L. Fifty eight patients were tested and reported. Unsaturated Iron Binding Capacity (UIBC) mean is 130.23 ug/dL with a 2SD of 29.52 ug/dL. The high limit is 159.75 ug/dL and the low limit is 100.71 ug/dL. On 7/28/21 level one control was above the high limit at 161 ug/dL. Five were tested and reported. On 7/29/21 level one control was above the high limit at 164 ug/dL. Four were tested and reported. On 7/31/21 level one control was above the high limit at 161 ug/dL. Six were tested and reported. Direct Bilirubin mean is 0.28 mg/dL with a 2SD of 0.03 mg/dL. The high limit is 0.31 mg/dL and the low limit is 0.25 mg/dL. On 7/13/21 level one control was below the low limit at 0.24 mg/dL. Eleven patients were tested and reported. QC Level three: Total Triiodothyronine (T3) mean is 307.57 ng/mL (nanograms per mililiter) with a 2SD of 31 ng/mL. The high limit is 338.57 ng/mL and the low limit is 276.57 ng/mL. On 7/3/21 level three control was below the low limit at 275.85 ng/mL. Two patients were tested and reported. On 7/7/21 level three control was below the low limit at 276.40 ng/mL. One patient was tested and reported. Total Protein mean is 6.26 g/dL with a 2SD of 0.3540 g/dL. The high limit is 6.614 g/dL and the low limit is 5.906 g/dL. On 7/28/21 level three control was above the high limit at 6.7 g/dL. Sixty patients were tested and reported. On 7/29/21 level three control was above the high limit at 6.7 g/dL. Forty two patients were tested and reported. Direct Bilirubin mean is 2.49 mg/dL with a 2SD of .4060 mg/dL. The high limit is 2.896 mg/dL and the low limit is 2.084 mg/dL. On 7/13/21 level three control was below the low limit at 2.07 mg/dL. Eleven patients were tested and reported. On 7/14/21 level three control was below the low limit at 2.06 mg/dL. Eleven patients were tested and reported. Alkaline Phosphatase mean is 318.23 U/L with a 2SD of 13.75 U/L. The high limit is 331.98 U/L and the low limit is 304.48 U/L. On 7/2/21 level three control was below the low limit at 298 U/L. Forty patients were tested and reported. On 7/3/21 level three control was below the low limit at 300 U/L. Forty one patients were tested and reported. On 7/7/21 level three control was below the low limit at 301 U/L. Forty two patients were tested and reported. On 7/30/21 level three control was below the low limit at 301 U/L. Fifty patients were tested

and reported. On 7/31/21 level three control was below the low limit at 303 U/L. Fifty eight patients were tested and reported. Calcium mean is 13.08 mg/dL with a 2SD of .6720 mg/dL. The high limit is 13.752 mg/dL and the low limit is 12.408 mg/dL. On 7/3/21 level three control was below the low limit at 12.4 mg/dL. Forty five patients were tested and reported. On 7/7/21 level three control was below the low limit at 12.4 mg/dL. Sixty five patients were tested and reported. On 7/8/21 level three control was below the low limit at 12.4 mg/dL. Seventy five patients were tested and reported. Creatinine Kinase, Total (CK Total) mean is 543.74 U/L with a 2SD of 49.82 U/L. The high limit is 593.56 U/L and the low limit is 493.92 U/L. On 7/14/21 level three control was below the low limit at 474 U/L. One patient was tested and reported. Magnesium mean is 3.93 mg/dL with a 2SD of 0.2980 mg/dL. The high limit is 4.228 mg/dL and the low limit is 3.632 mg/dL. On 7/16/21 level three control was above the high limit at 4.3 mg/dL. Two patients were tested and reported. On 7/17/21 level three control was above the high limit at 4.3 mg/dL. Two patients were tested and reported. On 7/27/21 level three control was above the high limit at 4.3 mg/dL. Three patients were tested and reported. On 7/30/21 level three control was above the high limit at 4.3 mg/dL. Two patients were tested and reported. On 7/31/21 level three control was above the high limit at 4.3 mg/dL. Five patients were tested and reported. Interview with Testing Personnel B at 12:12 pm on 9/01/2021 confirmed they were not aware consecutive 2SD QC failures could not be accepted without corrective action and documentation.