

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1050183	(X3) Date Survey Completed 05/02/2019
Name of Provider or Supplier Gruene Lake Medical	Street Address, City, State 948 Gruene Road, #140, New Braunfels, TX	
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	<p>The laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCIES: D6000 - 42 C.F.R. 493.1403 Condition: Laboratory Director; moderate complexity D6033 - 42 C.F.R. 493.1409 Condition: Technical Consultant; moderate complexity D6063 - 42 C.F.R. 493.1421 Condition: Testing Personnel; moderate complexity Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representative was given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider /supplier, the State Survey Agency (SA) should be notified immediately.</p>
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute's proficiency testing records from 2017, 2018, and 2019, and staff interview, it was revealed the laboratory failed to have documentation of testing personnel signing 5 of 7 attestation statements. The findings were: 1. A review of the laboratory's American Proficiency Institute's Hematology proficiency testing records from 2017 (events 1, 2, and 3), 2018 (events 1, 2, and 3) and 2019 (event 1) revealed the laboratory failed to have documentation of testing personnel signing 5 of 7 attestation statements. They were:</p>

2017 event 3 2018 event 1 2018 event 2 2018 event 3 2019 event 1 2. The laboratory was asked to provide documentation of testing personnel signing the attestation statements as required. No documentation was provided. 3. An interview with the office manager on 05/02/2019 at 1444 hours in the break room - after her review of the records- confirmed the findings. NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEYS CONDUCTED 06/03/2015 AND 02/01/2017

D5413

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

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on review of the manufacturer's instructions for the Boule Con-Diff Tri-Level hematology controls, review of the laboratory refrigerator temperature records from June 2018 to April 2019, and staff interview, it was revealed the laboratory failed to have documentation of monitoring the correct refrigerator temperature for the storage of the controls. The findings were: 1. A review of the manufacturer's instructions of the Boule Con-Diff Tri-Level hematology controls (201043L R03.31.15) under the section titled "Storage and Stability" revealed: "When stored at 2 - 10C, sealed vials are stable at least until the expiration date shown on the TABLE OF EXPECTED RESULTS" The temperature range equates to 35.6 - 50.0F. 2. A review of the laboratory's refrigerator temperature records from June 2018 to April 2019 revealed the laboratory's documented acceptable temperature range for the refrigerator to be 33 - 45F. 3. Further review of the temperature records from January 2019 to March 2019 revealed the following days where the documented refrigerator temperature was outside the manufacturer's required range: a) January 2019 Date Temperature 1/02 34F 1/03 33F 1/04 33F 1/07 34F 1/08 35F 1/09 35F 1/11 34F 1/14 35F 1/15 32F 1/16 35F 1/18 34F 1/21 33F 1/22 34F 1/23 34F 1/24 35F 1/25 35F 1/28 34F 1/31 35F b) February 2019 Date Temperature 2/01 33F 2/06 33F 2/08 35F 2/09 34F 2/10 33F 2/13 33F 2/18 35F 2/19 35F 2/20 33F 2/21 34F 2/22 33F 2/26 33F 2/27 34F c) March 2019 Date Temperature 3/01 32F 3/05 33F 3/06 33F 3/07 34F 3/11 33F 3/13 34F 3/15 32F 3/19 33F 3/20 31F 3/22 33F 3/23 32F 3/24 35F 3/25 35F 3/26 32F 4. The laboratory was asked to provide documentation of monitoring the correct temperature range as defined by the manufacturer. No documentation was provided. 5. An interview with the office manager on 05/02/2019 at 1444 hours in the break room - after her review of the records - confirmed the findings.

D5437

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)

(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:

Based on review of the manufacturer's instructions of the Medonic M-series hematology analyzer, review of the laboratory's calibration records from 2017 and 2018, and staff interview, it was revealed the laboratory failed to have documentation of calibrating the analyte hemoglobin every six months. The findings were: 1. A review of the manufacturer's instructions for the Medonic M-series hematology analyzer (November 2012, Article No. 1504283) under the section titled "Calibration" revealed: "Calibration must be performed upon setup of the instrument and then at a minimum of every six months." 2. A review of the laboratory's calibration records from 2017 and 2018 revealed the laboratory performed calibrations: June 2017 December 2017 July 2018 December 2018 3. Further review of the calibration records revealed the analyte hemoglobin was not calibrated during the calibration performed in July 2018. Thus, calibration of hemoglobin was not performed for a complete year (December 2017 to December 2018). 4. The laboratory was asked to provide documentation of calibrating hemoglobin as part of the calibration performed in July 2017. No documentation was provided. 5. An interview with testing personnel number 3 as listed on Form CMS 209 on 05/02/2019 at 1320 hours in the front office revealed she was unaware calibration of hemoglobin was not performed as part of the calibration performed in July 2018. She stated calibrations were only performed at the identified times. This confirmed the findings.

D5785

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(3)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's refrigerator temperature records from June 2018 to March 2019, and staff interview, it was revealed the laboratory failed to have documentation of performing corrective actions when temperatures were outside the laboratory's acceptable range. The findings were: 1. A review of the laboratory's refrigerator temperature records from October 2018 to March 2019 revealed the laboratory's acceptable range to be 33 - 46F. 2. Further review of the refrigerator temperature records revealed the following day where the documented temperature was outside the laboratory's acceptable range and the laboratory did not document corrective actions: a) October 2018 Date Temperature 10/29 31F 10/31 31F b) December 2018 Date Temperature 12/31 31F c) March 2019 Date Temperature 3/01 32F 3/15 32F 3/20 31F 3/23 32F 3/26 32F 3. The laboratory was asked to perform documentation of performing corrective actions for the identified temperatures. No documentation was provided. 4. An interview with the office manager on 05/02/2019 at 1447 hours in the break room - after her review of the records- confirmed the findings. NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEYS CONDUCTED 06/03/2015 AND 02/01/2017

<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 review of the laboratory's personnel records and staff interview, it was revealed the laboratory director failed to provide overall management and direction for the facility. The findings were: 1. The laboratory director failed to ensure testing personnel had documentation of education and training in order to perform testing (refer to D6029).</p>
<p>D6029</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records and staff interview, it was revealed the laboratory director failed to ensure testing personnel had the appropriate education and training to perform testing. The findings were: 1. The laboratory director failed to ensure 1 of 5 testing personnel had documentation of education to perform testing. (Refer to D6065) NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEYS CONDUCTED 06/03/2015 AND 02/01/2017 2. The laboratory director failed to ensure 1 of 5 testing personnel had documentation of training to perform testing (Refer to D6066)</p>
<p>D6033</p>	<p>TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409</p> <p>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on review of the laboratory's personnel records and staff interview, it was revealed the technical consultant failed to provide technical oversight for the laboratory. The findings were: 1. The technical consultant failed to ensure competency assessments were performed by evaluating the six required criteria (refer to D6046). THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 02/01/2017 2. The technical consultant failed to ensure competency</p>

assessments were performed twice within the first year of employment (refer to D6053). THIS IS A REPEAT DEFICIENCY FROM THE SURVEYS CONDUCTED 06/03/2015 AND 02/01/2017

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's personnel records, and staff interview, it was revealed the technical consultant failed to document the methods used assess the competency of 3 of 3 testing personnel in 2018. The findings were: 1. A review of the laboratory's personnel records revealed the technical consultant failed to document the methods used to assess the competency of testing personnel. The competency assessments reviewed revealed the instructions to follow were to document all methods used to assess competency. The methods identified were: a) DO - direct observation b) QC - QC performed c) PT - proficiency testing d) BT - blind testing e) WT - written test f) ROL - review of logs 2. For 3 of 3 testing personnel, the competency assessments performed in 2018 document the methods use. Each testing personnel were simply marked with a "YES" that they demonstrated competency. The identified testing personnel were (as listed on Form CMS 209) Testing personnel number 1 Testing personnel number 3 Testing personnel number 4 3. The laboratory was asked to provide documentation of the methods used to assessment the competency of the identified testing personnel in 2018. No documentation was provided. 4. An interview with the office manager on 05/02/2019 at 1455 hours in the break room - after her review of the records - confirmed the findings. NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEYS CONDUCTED 06/03/2015 AND 02/01/2017

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's personnel records, and staff interview, it was revealed the technical consultant failed to personnel twice annual competency assessments on 1 of 1 testing personnel within the first year of employment. The findings were: 1. A review of the laboratory's personnel records revealed testing personnel number 2 (as listed on Form CMS 209) date of hire with the facility was January 2018. Thus, two competency assessments were required by January 2019. 2. A review of testing personnel number 2's personnel records revealed the technical consultant performed a competency assessment on testing personnel number 2 in January 2019. The were not any other competency assessments in the personnel file. 3. The laboratory was asked to provide documentation of the technical consultant performing a second competency assessment on testing personnel number 2 within

her first year of employment. No documentation was provided. 4. An interview with the office manager on 05/02/2019 at 1445 hours in the break room - after her review of the records - confirmed the findings. NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEYS CONDUCTED 06/03/2015 AND 02/01/2017

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 review of the laboratory's personnel records and staff interview it was revealed the laboratory failed to ensure testing personnel were qualified. The findings were: 1. The laboratory failed to ensure 1 of 4 testing personnel had documentation of education to qualify to perform testing (refer to D6065) NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEYS CONDUCTED 06/01/2015 AND 02/01/2017 2. The laboratory failed to ensure 1 of 4 testing personnel had documentation of training on the Medonic M-series hematology analyzer (refer to D6066).

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 review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to ensure 1 of 5 testing personnel had documentation of education to perform testing. The findings were: 1. A review of the laboratory's submitted Form CMS 209 (signed by the laboratory director on 05/02/2019) revealed the laboratory identified 5 testing personnel. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of education to qualify 1 of 5 testing personnel to perform testing. The person was (as listed on Form CMS 209) : Testing personnel number 2 3. The laboratory was asked to provide documentation of education to qualify testing personnel number 2 to perform testing. No documentation was provided. 4. An interview with the office manager on 05/02/2019 at 1450 hours in the break room - after her review of the records- confirmed the findings. NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEYS CONDUCTED 06/01/2015 AND 02/01/2017.

D6066

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(b)(4)(ii)

Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to ensure 1 of 5 testing personnel had documentation of training on the Medonic M-series analyzer. The findings were: 1. A review of the laboratory's submitted Form CMS 209 (signed by the laboratory director on 05/02/2019) revealed the laboratory identified 5 testing personnel. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of training on the Medonic M-series on 1 of 5 testing personnel. The person was (as listed on Form CMS 209) : Testing personnel number 2 3. The laboratory was asked to provide documentation of training of testing personnel number 2. 4. An interview with the office manager on 05/02/2019 at 1450 hours in the break room - after her review of the records- confirmed the findings.