

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0482624	(X3) Date Survey Completed 09/08/2021
Name of Provider or Supplier Larry L Smith Md	Street Address, City, State 6757 Us Hwy 271 North, Gilmer, 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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, the laboratory's QS11 Temperature Logs for June 2019 to August 2021, and staff interview, it was revealed the laboratory failed to ensure the Advantik QS Cryostat temperature readings were within the laboratory's acceptable range listed in the Moh's Cutting Procedure for 12 of 15 days reviewed from June 2019 to August 2021. Findings include: 1. A review of the laboratory's policy titled 'Moh's Cutting Procedure' revealed the following: "To begin the Moh's procedure the cryostat needs to be turned to -20C to -25C." 2. Review of the QS11 Temperature Logs for June 2019 to August 2021 revealed the following 12 days where the temperature exceeded the laboratory policy's allowable range (-20C to -25C) : 6/27/19 -27 11/12/19 -30 11/14/19 -29 3/3/20 -32 3/5/20 -33 5/19/20 -33 6/4/20 -33 11/5/20 -31 12/1/20 -31 3/30/21 -29 4/13/21 -28 4/15/21 -29 3. A random</p>

review of patient records revealed the following 8 patient's specimens were resulted when the Advantik QS Cryostat's temperature was documented outside of the laboratory policy's acceptable range: Patient: M20-091 Patient: M20-092 Resulted: 5/18/20 Patient: M20-097 Patient: M20-098 Resulted: 6/4/20 Patient: M20-208 Patient: M20-209 Resulted: 11/5/20 Patient: M20-218 Resulted: 12/1/20 Patient: M21-086 Resulted 4/15/21 4. An interview with the office manager on 9/8/21 at 9:20 a.m. in the laboratory, after review of the records, confirmed the above findings.

D5781

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
Based on a review of the laboratory's policies, the laboratory's QS11 Temperature Logs for 2019 to 2021, a random review of patient test records, and staff interview, it was revealed the laboratory failed to have documentation of performing corrective action when the Advantik QS Cryostat temperature was documented outside the acceptable range for 12 of 15 days reviewed from June 2019 to August 2021. Findings include: 1. A review of the laboratory's policy titled 'Moh's Cutting Procedure' revealed the following: "To begin the Moh's procedure the cryostat needs to be turned to -20C to -25C." 2. A review of the laboratory's QS11 Temperature Logs for 2019 to 2021 revealed the acceptable temperature range for the Advantik QS Cryostat (Serial number: 58245) was listed as -22F to -26F. *Note: The policy states degrees Celsius (C) and the temperature logs state degrees Fahrenheit (F). Also, the acceptable ranges in the policy do not match the acceptable ranges on the temperature logs. 3. Further review of the QS11 Temperature logs revealed a notation at the bottom of the form that read "* Temperature was adjusted." 4. A review of the QS11 Temperature logs from June 2019 to August 2021 revealed the following 12 days when the Cryostat was documented outside of the acceptable range and there was no '*' indicating the temperature was adjusted: 6/27/19 -27 11/12/19 -30 11/14/19 -29 3/3/20 -32 3/5/20 -33 5/19/20 -33 6/4/20 -33 11/5/20 -31 12/1/20 -31 3/30/21 -29 4/13/21 -28 4/15/21 -29 5. A random review of patient records revealed the following 9 patient's specimens were resulted when the Advantik QS Cryostat was documented outside of the acceptable range: Patient: M19-220 Resulted: 10/17/19 Patient: M20-091 Patient: M20-092 Resulted: 5/18/20 Patient: M20-097 Patient: M20-098 Resulted: 6/4/20 Patient: M20-208 Patient: M20-209 Resulted: 11/5/20 Patient: M20-218 Resulted: 12/1/20 Patient: M21-086 Resulted 4/15/21 6. An interview with the office manager on 9/8/21 at 9:20 a.m. in the laboratory, after review of the records, confirmed the above findings.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's Monthly Quality Assurance Checklists, a review of the laboratory's policies, and staff interview, it was revealed that the laboratory's quality assurance plan failed to identify and correct problems in analytic systems for 26 of 26 months from June 2019 to August 2021. Findings include: 1. A review of the laboratory's Monthly Quality Assurance Checklists revealed the following: "-All required temperatures were taken and recorded. - Any necessary remedial action was performed and documented. Our Quality Assurance Program is monitored for compliance: - The above information has been reviewed to determine whether errors that occurred could have been prevented by changing our policies or procedures." 2. 1. A review of the laboratory's policy titled 'Moh's Cutting Procedure' revealed the following: "To begin the Moh's procedure the cryostat needs to be turned to -20C to -25C." 3. A review of the laboratory's QS11 Temperature Logs revealed an acceptable range of -22F to -26F. *Note: The policy states degrees Celsius (C) and the temperature logs state degrees Fahrenheit (F). Also, the acceptable ranges in the policy do not match the acceptable ranges on the temperature logs. 4. The laboratory failed to ensure the Advantik QS Cryostat temperature readings were within the laboratory's acceptable range listed in the Moh's Cutting Procedure. (Refer to D5413) 5. The laboratory failed to have documentation of performing corrective action when the Advantik QS Cryostat temperature was documented outside the acceptable range. (Refer to D5781) 6. An interview with the office manager on 9/8/21 at 9:20 a.m. in the laboratory, after review of the records, confirmed the above findings.