

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D1056380	(X3) Date Survey Completed 03/01/2019
Name of Provider or Supplier Mountain Medical Services	Street Address, City, State 354 Broadway, Saranac Lake, NY	
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
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>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 general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor's review of the laboratory's Quality Assessment (QA) policies and procedures and confirmed in an interview with the testing person, at the time of this survey, the laboratory failed to follow their established QA policy and perform a QA review for the 2017 and 2018 calendar years. THIS IS A RECITED STANDARD DEFICIENCY FROM THE SURVEY CONDUCTED ON NOVEMBER 10, 2016.</p>
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>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</p>

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 the surveyor's review of the laboratory's calibration verification records for the Qualigen Fast Pack System and an interview with the laboratory testing person, the laboratory failed to perform calibration verification at least once every six months for the analytes Thyroid Stimulating Hormone (TSH), Free Thyroxine (FT4) and Prostate Specific Antigen (PSA) on the Qualigen Fast Pack System endocrinology analyzer. FINDINGS: The laboratory testing person confirmed on March 1, 2019 at approximately 10:30 AM, the surveyor's findings that the laboratory did not perform a required calibration verification from August 23, 2018 through February 21, 2019 for the three analytes noted above. Therefore, the analyzer was out of calibration for 6 months. Approximately 30 patient samples were tested and reported during this time-period. THIS IS A RECITED STANDARD DEFICIENCY FROM THE SURVEY CONDUCTED ON NOVEMBER 10, 2016.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

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.

This CONDITION is not met as evidenced by:
Based on surveyor's review of the laboratory's established policies & procedures, laboratory records and interview with the testing person, the laboratory director failed to provide overall management of the laboratory. FINDINGS: The laboratory director failed to ensure that the laboratory maintained the plan of correction from the survey conducted on November 10, 2016. a. maintained the laboratory's established QA program for all phases of laboratory testing, refer to D6021. THIS IS A RECITED CONDITION DEFICIENCY FROM THE SURVEY CONDUCTED ON NOVEMBER 10, 2016.

D6021

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 quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on surveyor's review of the laboratory's QA policy and interview with the with the testing person, the laboratory director failed to follow and maintain their QA policy to monitor, assess and when indicated correct problems identified in the general laboratory system for endocrinology in calendar year 2017 and 2018. Refer to D5291 and D5439. THIS IS A RECITED CONDITION DEFICIENCY FROM THE SURVEY CONDUCTED ON NOVEMBER 10, 2016.