Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D0235474	04/26/2018
Name of Provider or Supplier	**Street Address, City, State**	
Rainelle Medical Center	176 Medical Center Drive, Rainelle, WV	

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
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 laboratory's calibration records and interview with the Laboratory Manager(LM)/Testing Personnel #1 (TP1), the laboratory failed to perform and document the calibration for the Coulter AcT Diff Analyzer in 2017. Record review was from June 2016 to April 2018. The findings include: 1. Review of the Coulter AcT diff Analyzer's calibration records for 2016 identified calibration performed on 10/13/16. 2. Review of the Coulter AcT diff Analyzer's calibration records for 2017 identified no calibrations performed in 2017. 3. Review of the Coulter AcT diff Analyzer's calibration records for 2018 identified calibration performed on 4/16/18. 4. On 4/26/18 at approximately 11:50 AM, the LM/TP1 stated that they had not performed calibration in 2017.
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:
A. Based on review of the laboratory's calibration/calibration verification records, the Vitros 350 manufacturer's instructions for use and interview with the Laboratory Manager (LM)/Testing Personnel #1 (TP), the laboratory failed to perform and document calibration verification every 6 months for Alanine Aminotransferase, Albumin, Alkaline Phosphotase, Amylase, Aspartate Aminotransferase, Bilirubin Direct, Blood Urea, Calcium, Chloride, Cholesterol, Creatinine, Creatine Kinase Total, Glucose, High Density Lipoprotein, Magnesium, Phosphorus, Potassium, Total Protein, Sodium, Total Thyroxine, Total Billirubin, Uric Acid, and Vitamin D performed on the Vitros 350. Record review was from June 2016 to April 2018. The findings include:. 1. The manufacturer's instructions for use for the Vitros 350 analytes states, " Calibrate: When the slide lot number changes. When critical system parts are replaced due to service or maintenance. When government regulations require. For example, in the USA, CLIA regulations require calibration or calibration verification at least once every six months" 2. Review of the Vitros 350 calibration /calibration verification records from June 2016 to April 2018 identified no calibration verification for Alanine Aminotransferase, Albumin, Alkaline Phosphotase, Amylase, Aspartate Aminotransferase, Bilirubin Direct, Blood Urea, Calcium, Chloride, Cholesterol, Creatinine, Creatine Kinase Total, Glucose, High Density Lipoprotein, Magnesium, Phosphorus, Potassium, Prostatic Specific Antigen, Total Protein, Sodium, Total Thyroxine, Total Billirubin, Thyroid Stimulating Hormone, Uric Acid, Vitamin B12, and Vitamin D performed on the Vitros 350 from June 2016 to April 2018. 3. On 4/26/18 at approximately 8:30 AM, the LM/TP1 confirmed the findings.
B. Based on review of the laboratory's calibration/calibration verification records, the Vitros ECI manufacturer's instructions for use and interview with the Laboratory Manager (LM)/Testing Personnel #1 (TP), the laboratory failed to perform and document calibration verification every 6 months for Thyroid Stimulating Hormone, Vitamin B12, Prostatic Specific Antigen, and Vitamin D performed on the Vitros ECI. Record review was from June 2016 to April 2018. The findings include:. 1. The manufacturer's instructions for use for the Vitros ECI analytes states, "Calibrate: When the slide lot number changes. When critical system parts are replaced due to service or maintenance. When government regulations require. For example, in the USA, CLIA regulations require calibration or calibration verification at least once

	every six months" 2. Review of the Vitros ECI calibration/calibration verification records from June 2016 to April 2018 identified no calibration verification for Alanine Aminotransferase, Albumin, Alkaline Phosphotase, Amylase, Aspartate Aminotransferase, Bilirubin Direct, Blood Urea, Calcium, Chloride, Cholesterol, Creatinine, Creatine Kinase Total, Glucose, High Density Lipoprotein, Magnesium, Phosphorus, Potassium, Prostatic Specific Antigen, Total Protein, Sodium, Total Thyroxine, Total Billirubin, Thyroid Stimulating Hormone, Uric Acid, Vitamin B12, and Vitamin D performed on the Vitros ECI from June 2016 to April 2018. 3. On 4/26 /18 at approximately 8:30 AM, the LM/TP1 confirmed the findings.