Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0664211	02/06/2018
Name of Provider or Supplier	**Street Address, City, State**	
Prime Care Medical Center	710 East Main St, Adamsville, TN	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Assurance Program procedure and interview with testing personnel number one, the laboratory failed to establish written policies to assess testing personnel competency as specified in the personnel requirements in subpart M. The findings include: 1. Review of the laboratory's policy titled "Quality Assurance Program" revealed the following statement "Personnel are evaluated annually or when new methodologies are incorporated." Required competency assessment elements and appropriate frequency were not included in the policy. Required competency assessment elements and frequencies as specified in the personnel requirements in subpart M include: Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; Monitoring the recording and reporting of test results; Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; Direct observation of performance of instrument maintenance and function checks; Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and Assessment of problem skills; and Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. thereafter, evaluations must be performed at least annually. 2. Review of six of six testing personnel competency assessments for 2017 and 2018 revealed problem solving was not included as part of competency assessment. 3. Interview with testing personnel number one on February 6, 2018 at 10:00 am confirmed that the

	laboratory's policy for testing personnel competency did not include all elements as specified in subpart M. _____
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's Medical Laboratory Evaluation (MLE) proficiency testing reports for 2016, the policy titled "Quality Assurance Program" and interview with testing personnel number one, the laboratory failed to follow policy for evaluation of proficiency testing results in 2016. The findings include: 1. Review of the 2016 MLE proficiency testing reports revealed the following events with unacceptable results for urine sediment: Event MLE-M1-Specimen US-2; Event MLE-M3-Specimen US-5. Both reports were signed by the laboratory director with no corrective action for unacceptable results. 2. Review of the laboratory's policy titled "Quality Assurance Program" revealed the following statement: "PT failures are investigated and remedial action taken." 3. Interview with testing personnel number one on February 6, 2018 at 10:30 am confirmed the laboratory failed to follow policy for evaluation of proficiency testing in 2016. _____
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: Citation number one: Based on observation of the laboratory, review of the calibration

	records for the Ortho Vitros 250, and interview with testing personnel number one, the laboratory failed to perform calibration verification to include at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range for the sodium (Na), potassium (K) and chloride (Cl) analytes in 2016 and 2017. The findings include: 1. Observation of the laboratory on February 6, 2018 at 8:00 am revealed the Ortho Vitros 250 chemistry instrument in use for patient testing. 2. Review of the calibration records for the Ortho Vitros 250 revealed calibration of the Na, K, and Cl analytes using two calibration points in 2016 and 2017. 3. Interview with testing personnel number one on February 6, 2018 at 1:00 pm confirmed the laboratory calibrates the Ortho Vitros 250 analytes Na, K, and Cl using two calibration points and failed to verify the calibration using at least a minimal, mid and maximum value in 2016 and 2017. _____ Citation number 2: Based on observation of the laboratory, review of the calibration records for the Ortho Vitros 250, the laboratory's procedure manual, and interview with testing personnel number one, the laboratory failed to perform calibration verification at least every six months for the analytes carbon dioxide (CO2), blood urea nitrogen (BUN), high-density lipoprotein (HDL), albumin, alkaline phosphatase and triglyceride in 2017 and 2018. The findings include: 1. Observation of the laboratory on February 6, 2018 at 8:00 am revealed the Ortho Vitros 250 chemistry instrument in use for patient testing. 2. Review of the calibration records for the Ortho Vitros 250 revealed the following: CO2 calibration performed 12-20-16, next calibration 1-31-18; BUN performed 9-28-16, next calibration 6-7-17; HDL calibration performed 1-13-17, next calibration 9-13-17; albumin calibration performed 7-28-16, next calibration 3-8-17; alkaline phosphatase calibration performed 5-23-17, no additional calibrations have been performed; triglyceride calibration performed 2-3-17, next calibration 10-2-17. 3. Review of the laboratory's procedure manual revealed no policies or procedures related to calibration verification. 4. Interview with testing personnel number one on February 6, 2018 at 1: 00 pm confirmed the laboratory failed to verify calibration at least every 6 months for the analytes CO2, BUN, HDL, albumin, alkaline phosphatase and triglyceride in 2017 and 2018. _____