Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0664211	11/18/2019
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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of patient number eleven test report, the laboratory records and interview with the lead testing personnel, the laboratory failed to verify the accuracy of wet prep and potassium hydroxide (KOH) testing twice a year in 2018 and 2019. The findings include: 1) Observation of the laboratory on November 18, 2019 at 8:15 am revealed a microscope on the counter in use for patient testing for urine microscopy, wet prep and KOH. 2) Review of patient number eleven test report revealed patient testing for wet prep performed on 08.20.2019. 3) Review of the laboratory records revealed no documentation that verification of accuracy had been done for wet prep or KOH in 2018 or 2019. 4) Interview with the lead testing personnel on November 18, 2019 at 3:30 p.m. confirmed the laboratory performs testing for both wet prep and KOH and no records were present for verifying the accuracy twice a year in 2018 and 2019.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

	This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of verification of performance specifications studies (VoPS) for the Sysmex KX-21N complete blood count (CBC) instrument and interview with the lead testing personnel, the laboratory failed to verify the reportable range of the Sysmex KX-21N complete blood count (CBC) instrument in 2019. The findings include: 1) Observation of the laboratory on November 18, 2019 at 8:15 am revealed the Sysmex KX-21N (serial # F3396) on the counter in use for patient testing for CBC. This instrument was new since the last survey. 2) Review of the VoPS studies for the Sysmex KX-21N CBC instrument revealed no documents were present verifying the reportable range of the instrument. 3) Interview with the lead testing personnel on November 18, 2019 at 3:30 p.m. confirmed no reportable range verification study had been performed for the Sysmex KX-21N CBC instrument in 2019. Patient testing began on August 26, 2019.
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: The laboratory director failed to maintain compliance with previous plan of correction (Refer to D6004), failed to review proficiency testing records (Refer to D6018), failed to follow corrective action plan for unacceptable proficiency testing results (Refer to D6019), failed to ensure the quality control program was maintained (Refer to D6020), and failed to ensure the quality assurance plan was maintained for patient test management (Refer to D6021 Citation number one), the quality assurance plan was maintained for record retention (Refer to D6021 Citation number two), and the quality assurance plan was maintained for testing personnel training and competency assessment (Refer to D6021 Citation number three).
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of previous plan of correction from survey performed on 02.06.2018, laboratory records and interview with the lead testing personnel, the laboratory director failed to ensure the previous plan of correction for calibration verification was

	maintained in 2018 and 2019. The findings include: 1) Review of the previous plan of correction from survey performed on 02.06.2018 revealed that the laboratory would perform calibration verification to include 3 levels every six months for the Sodium, Potassium and Chloride analytes. Laboratory director/technical consultant would monitor every six months. 2) Review of laboratory records revealed calibration verification was not performed every six months as due in September 2018 and March 2019. 3) Interview with the lead testing personnel confirmed the laboratory director failed to ensure the previous plan of correction for calibration verification was maintained in 2018 and 2019.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records and interview with the lead testing personnel, the laboratory director failed to review proficiency testing scores in 2018. The findings include: 1) Review of the laboratory's proficiency testing records revealed that 2018 event one had not reviewed by the laboratory director. 2) Interview with the lead testing personnel on November 18, 2019 at 3:30 p.m. confirmed the lab director failed to review proficiency testing scores for 2018 event one.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, proficiency testing records and interview with the lead testing personnel, the laboratory director failed to ensure the corrective action plan for unacceptable proficiency testing scores was followed in 2019. The findings include: 1) Review of the laboratory's procedure manual revealed the following: "All socres less than 100% on proficiency testing must be reviewed and comment made as to why score is or may have been out of range. The director should review proficiency tests/scores biannually." 2) Review of the laboratory's proficiency testing records revealed the following unacceptable scores for 2019 event one: WBC-Sample HD-1; Red Blood Cell-Sample HD-5, Hemoglobin-Sample HD-5, Hematocrit-sample HD-5, Granulocytes/Neut % HD-1, Urine Sediment Identification-Sample US-

	1, Cholesterol-Sample CH-2, Cholesterol, HDL-Sample CH-5. The report was signed by the lab director with no corrective action performed. 3) Interview with the lead testing personnel on November 18, 2019 at 3:30 p.m. confirmed the lab director failed to ensure the proficiency testing corrective action plan was followed for unacceptable proficiency testing scores for 2019 event one for multiple analytes.
D6020	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 the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control plan, review of patient number one test report, quality control (QC) records and interview with the lead testing personnel, the laboratory director failed to ensure the laboratory's quality control plan was maintained in 2018 and 2019. The findings include: 1) Review of the laboratory's quality control plan revealed that quality control is done and documented each day of testing for non-waived tests and are within acceptable limits before patient testing is reported. 2) Review of patient number one test report revealed complete blood count (CBC) reported on 05.31.2018. 3) Review of the laboratory QC records revealed the following: No CBC QC records were present for 05.31.2018. No documented review of CBC QC lot numbers 9021, 9197, 9281 (in use March 2019, September 2019, and October 2019 respectively). No documented review of chemistry QC lot numbers B6272, C6274 (In use June 2018, December 2018, April 2019), and lots G6664 and F6662 in use September 2019. 4) Interview with the lead testing personnel on November 18, 2019 at 3:30 p.m. confirmed the lab director failed to ensure the quality control program was maintained in 2018 and 2019. There was no record of quality control performed on 05.31.2018 with patient testing performed, and no documented review of multiple lot numbers for both hematology and chemistry spanning 2018 to 2019.
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: Citation number one: Based on review of the laboratory's quality assurance plan, laboratory records, and interview with the lead testing personnel, the laboratory director failed to ensure the laboratory's quality assurance plan for patient test management was maintained in 2018 and 2019. The findings include: 1) Review of

	the laboratory's quality assurance plan revealed quarterly reviews of five patients will be performed to verify post-analytic processes. 2) Review of the laboratory's patient test management records revealed that no patient chart reviews were performed in 2018 and none the first quarter and second quarter of 2019. 3) Interview with the lead testing personnel on November 18, 2019 at 3:30 pm. confirmed the lab director failed to ensure the quality assurance plan for patient test management was maintained in 2018 and 2019. _____ Citation number two: Based on review of the laboratory's quality assurance plan, laboratory records and interview with the lead testing personnel, the laboratory director failed to ensure the laboratory's quality assurance plan for record retention was maintained in 2019. The finding include: 1) Review of the laboratory's quality assurance plan revealed that the laboratory will retain all laboratory records for 2 years. 2) Review of the laboratory's quality control records revealed lot number 9021 in use on 03.07.2019. No package insert was present in the quality control records. 3) Interview with the lead testing personnel on November 18, 2019 at 3:30 p.m. confirmed the lab director failed to ensure the quality assurance plan for record retention was maintained in 2019. _____ Citation number three: Based on review of the laboratory's quality assurance plan, testing personnel records and interview with the lead testing personnel, the laboratory director failed to ensure the laboratory's quality assurance plan for testing personnel training and competency assessment was maintained in 2019. The findings include: 1) Review of the laboratory's quality assurance plan revealed that personnel are trained for any tests they perform and are evaluated upon hire, at 6 months, and then annually or when new methodologies are incorporated. Evaluation of personnel includes direct observation of patient testing, maintenance, quality control and reporting results, blind testing and problem solving. All personnel are trained in the performance of tests they perform. 2) Review of testing personnel records revealed the following: Five of six testing personnel competency assessments for 2019 were not signed by the lab director/technical consultant. No evaluation of review of QC, preventative maintenance, blind testing or problem solving was included for four of six personnel who perform complete blood count testing on the Sysmex KX-21N (testing personnel numbers two, three, four and five). No initial training or competency assessment for the use of the new Sysmex KX-21N instrument for six of six personnel. 3) Interview with the lead testing personnel on November 18, 2019 at 3:30 p.m. confirmed the laboratory director failed to ensure the laboratory's quality assurance plan for personnel was followed in 2019 when there was no initial training or competency for use of the new complete blood count instrument, competency assessments for 2019 were not reviewed by the lab director, and all six elements were not included for four of six testing personnel who perform patient testing for complete blood count in 2019.