Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D1058440	06/18/2019
Name of Provider or Supplier	**Street Address, City, State**	
Prime Med	1970 Andrews Avenue, Ozark, AL	

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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on a review of the Laboratory Personnel Report for CLIA (CMS form #209), a review of the personnel and proficiency testing records, a review of the Quality Assessment Plan (8.0 Proficiency Testing) and quality assurance records, and an on-site interview with the representative for the laboratory and the Laboratory Director, via the telephone, the surveyor determined the laboratory failed to ensure the proficiency testing samples were tested on a rotational basis by all personnel who routinely perform patient testing. This affected five of five proficiency testing events. The findings include: 1. The Laboratory Personnel Report, signed by the Laboratory Director, included three testing personnel (one new personnel, since the previous survey in August of 2017. 2. A review of the personnel records revealed Testing Personnel (TP) #1 and #2 had previously qualified to perform moderate complexity testing and were trained in March of 2017. Further review revealed TP #1 and TP #2 were competent to perform testing in the laboratory, including the Bioray Film Array analyzer for respiratory panels. This is the only non-waived testing performed at the laboratory. 3. A review of the API (American Proficiency Institute) proficiency testing records revealed TP #1 had signed the attestation statements (indicating she was the testing personnel) for Event #3, 2017; all three events for 2018, and Event #1, 2019 for Molecular Bacteriology and Virology testing, performed on the Bioray. 4. In an interview on June 18, 2019 at 12:50 PM, with the Laboratory Director (via telephone) and a representative for the laboratory, who was on-site for the survey process, the surveyor inquired why testing personnel #1 had been the only participant with the proficiency testing. The Laboratory Director confirmed TP #1 had performed

	all of the proficiency testing. The Laboratory Director stated it was discussed with TP #1 the need to rotate the proficiency testing, as late as yesterday (June 17). There was no documentation of this discussion. The Laboratory Director further stated TP #2 was a nurse, who performed patient testing. The representative, sent by the Laboratory Director to be onsite for the survey process, confirmed the nurse, TP #2, did perform testing on patient samples and was trained to do so. 5. A review of the quality assurance records revealed a note, dated 8/30/18: "...need to rotate testing staff." 6. The section, titled 8.0 Proficiency Testing of the Quality Assessment Plan, included the following: "...The laboratory test PT samples using the same procedure /methodologies used for patient testing and qualified testing personnel test the PT specimens on rotational schedule..."
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of Quality Control (QC) and Quality Assurance (QA) records, a review of the policy and procedure manual, and an interview with the on-site technical representative, sent by the Laboratory Director (LD) to assist with the survey process, and a telephone interview with the LD, the surveyor determined the laboratory failed to test an external positive and negative with each lot number or shipment of reagent packs for respiratory panels, prior to testing patients specimens and reporting the results. The laboratory's manual contained two QC plans, which were contradictory. Although, the laboratory indicated in an IQCP (Individualized Quality Control Plan), the external positive and negative controls would be tested with each change and shipment of reagent packs, the laboratory failed to test both controls on the same day or within the same timeframes of using the reagent packs for patient testing. The findings include: 1. The laboratory's policy and procedure manual contained two QC plans, which were contradictory. a) A review of the manual revealed instructions under Quality Control, for QC testing on the Biofire to test a positive and negative control with the reagent pack number and/or shipment; and to verify external and internal control results are acceptable, prior to patient testing with the reagent lot, shipment, and following month. b) Further review of the policies and procedures revealed an IQCP with the following instructions for quality control testing: "...daily (Internal), + (positive)/= (negative) with change and shipment of lot per manufacturer's recommendations..." 2. A review of the QC records revealed the following: a) In 2017, the laboratory tested external positive and negative controls: April 14 (lot #471717), June 22 (lot #534117), Aug 25 (lot#595617), and November 27 (lot #678317). On December 19, the laboratory staff documented a positive external control was run with reagent lot #650017, but a negative was not tested until December 26 for this lot number of reagent. b) On January 24, 2018 the staff documented an external negative control was tested for lot number 778017, and the positive was tested on January 25, 2018. c) On February 27, 2018, the staff

	documented an external positive control was tested for lot number 815218, but the negative was not run until March 7. d) On April 30, 2018, the staff documented an external positive control was run for lot number 889818, but the negative was not run until May 1, 2018. e) On November 28, 2018, the staff documented two negative external controls were run with lot number 256618. f) On March 6, 2019, the staff documented a negative control was run with lot number 441319. Using this same lot number of reagent packs, the laboratory documented a positive external control was run on April 15 and a negative was run on April 16. 3. A review of the QA notes revealed the same technical representative, on-site for the survey, documented that no positive quality control was tested for new lot number, started 3/6/19, and was unable to locate the instrument printout for documentation. On the QA note for 2/20/18 - 3/12 /18, the staff documented no patients were recalled and no harm to patients. There was no documentation of which patients were potentially affected or what might have been the clinical significance to the patients. There was no documentation of assessment by the clinicians for these patients, whose specimens were tested with reagent packs which quality control had not been appropriately verified. 4. At 12:06 PM on June 18, 2019, the laboratory representative stated the staff had been testing the quality control with each shipment of reagents, which usually coincided with each lot number. At 12: 29 PM, the representative stated she assumed no patients were done on January 24, 2018, because the QC was tested at 5:10 PM, and the office closes at 5:00 (PM). The surveyor inquired of the meaning of "no patients recalled." The laboratory representative stated this statement means no patients were called back to perform a re-test. At this time, the surveyor asked the staff to verify how many patients were tested between December 19-26, 2017; January 24 -25, 2018, February 27 - March 7, 2018; April 30 - May 1, 2018; November 28, 2018 (two negative controls were tested) - February 25, 2019 (when negative and positive external controls were tested); and March 6 - April 16, 2019. 5. In a telephone interview on 6/18/2019 at 12:50 PM, the LD confirmed the contradiction in the policies. The LD stated "In my world, everything is external unless I said internal. In the lab manual, I should have marked out, monthly. We changed that." The LD also stated the staff had pulled the patients' charts (which patients were not identified), and because of the patients' clinical histories, the patients had not been re-called for re-testing. The LD director confirmed there was no documentation of patient remediation in QA notes or otherwise. Again, the surveyor asked about the time frames given above to verify the patient testing. The on-site representative stated no patients were tested. The surveyor asked again, specifically about the instance in November when two negative controls were tested. The on-site representative stated she would have to check. 6. Further review of the QA reports revealed the laboratory's random chart reviews and checklists. The random patient chart reviews for February 1 - 7, 11, 12 19, 26, and 28 of 2018 indicated no problems were identified. The QA checklists indicated no problems were identified by the lab in the category, titled: QC performed per requirements, based on manufacturer's recommendations, CLIA requirements and lab policies. Corrective Actions have been documented, reviewed by laboratory director, technical supervisor or consultant and discussed with staff.
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 a review of the Policy and Procedure Manual, a review of the IQCP (Individualized Quality Control Plan) for the Biofire Film Array, and an interview with the Laboratory Director (LD) and the on-site representative sent by the LD to assist with the survey process, the surveyor determined the LD failed to ensure the testing personnel were provided with one concise, non-contradictory quality control plan for testing quality control (QC) on the Biofire. The laboratory's manual contained two QC plans, which were contradictory. The findings include: 1. A review of the laboratory's policy and procedure manual revealed instructions for QC testing on the Biofire to test a positive and negative control with the reagent pack number and/or shipment; and to verify external and internal control results are acceptable, prior to patient testing with the reagent lot, shipment, and following month. 2. Further review of the policies and procedures revealed an IQCP with the following instructions for quality control testing: "...daily (Internal), + (positive)/= (negative) with change and shipment of lot per manufacturer's recommendations..." 3. During a telephone interview on 6/18/2019 at 12:50 PM, the surveyor discussed the conflict in the two QC plans with the LD and the on-site representative. The LD stated "In my world, everything is external unless I said internal. In lab manual, I should have marked out, monthly. We changed that." During this interview, the surveyor also discussed the specifics of what should be included in a quality control policy and procedure, per the CLIA regulations.
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 a review of the policy and procedure manual, a review of Quality Control (QC) and Quality Assurance (QA) records, and an interview with the on-site technical representative, sent by the Laboratory Director (LD), to assist with the survey process, and a telephone interview with the LD, the surveyor determined the LD failed to ensure testing personnel were provided with quality control policies and procedures, which were concise and non-contradictory for testing on the Biofire Film Array. The LD failed to ensure a written revision of the policy and procedure was available to staff, when/if the contradiction was identified. The LD further failed to maintain a quality assurance policy and procedure to ensure problems were identified with the quality control testing on the Biofire, and failed to ensure corrective actions were implemented and documented when problems were identified in the analytic system (quality control testing). All quality control and quality assessment activities must be documented. The laboratory's manual contained two QC plans, which were contradictory. Although, the laboratory indicated in an IQCP (Individualized Quality Control Plan), the external positive and negative controls would be tested with each change and shipment of reagent packs, the laboratory failed to test both controls on

	the same day or within the same timeframes of using the reagent packs for patient testing. This affected the survey review period, September 2017 - June 18, 2019 (date of the current survey). 1. Refer to D5445 and D6020. 2. A review of the Quality Assessment Plan revealed the following: "The objective of this Quality Assessment Plan is to ensure the laboratory delivers accurate and reliable results, as well as high quality service. The Quality Assessment Plan intends to: Improve the overall quality and efficiency of the laboratory service. Assess the effectiveness of written procedures and policies. Identify problems in the laboratory and take appropriate corrective actions. ...Revise laboratory procedures and policies when necessary, to address issues and increase effectiveness." Under the section, titled, 1.3 Corrective Actions were the following the instructions: "If the quality assessment identifies any missing procedures (or policies), needed revisions, areas to increase efficiency or effectiveness, then corrective actions must be taken. Corrective actions may also occur outside the annual quality assessment review. Corrective actions must be documented." Also included in the plan: "4.0 Relationship of Patient Information to Patient Results... The laboratory must document all test result comparison activities." Additionally, "5.3 Corrective Action Identify QC problems. Ensure corrective actions address the problems and avoid recurrence. Systemic problems may require further training or procedural changes."