Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D1058440	03/17/2022
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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on a review of proficiency testing records, and interviews with the Laboratory Director, the surveyor determined the laboratory failed to enroll in proficiency testing (PT) with an HHS (Health and Human Services)-approved PT provider for regulated tests for the first two events in 2020 and the first two events in 2021. This affected two of three Microbiology PT survey events in 2020, and two of three Hematology and Microbiology PT survey events in 2021. The findings include: 1. During the entrance tour at 9:00 AM on 3/17/2022 the Laboratory Director stated moderate-complexity testing included a Molecular Respiratory Pathogen Panel performed on the BioFire Film Array (in use since the previous survey on 6/18/2019), and CBC's (Complete Blood Counts) performed on the Medonic M Series Hematology analyzer (in use for patient testing since 3/16/2021.) 2. A review of laboratory records revealed no documentation of proficiency testing. At approximately 9:20 AM on 3/17/2022 the Laboratory Director explained most of the laboratory records were retained electronically, and only the Clinic Administrator had access to the PT records. 3. At approximately 2:00 PM on 3/17/2022 the surveyor was provided two surveys, as follows: A) WSLH (Wisconsin State Laboratory of Hygiene) Proficiency Testing Off-Schedule Set A Hematology PT performed on 10/20/2021, and B) API (American

	Proficiency Institute) Remedial PT Event 72R for BioFire testing performed on 9/1 /2021 4. At approximately 2:10 PM on 3/17/2022, the surveyor requested the rest of the PT records, including BioFire PT (Event 3-2019, Events 1, 2 and 3-2020) and the 2021 PT for Hematology and Microbiology. The Laboratory Director explained there were no records for 2019 since these were already packed away. The Director further stated she noticed she had not received any PT scores in July 2021, and after investigation determined Administration had failed to place the API PT order for 2021; only API Event 3-2021 surveys were available when the order was received by API in August 2021. In addition, the Laboratory Director ordered remedial or off-cycle PT surveys from other PT providers. [Only the records for the two remedial surveys listed in #3 above were available on the day of the survey.] 5. On 3/21/2022 at 7:52 AM the laboratory submitted via e-mail the following surveys for moderate-complexity testing: A) API 2020-Event #3-Microbiology performed on 10/13/2020 B) API 2020-Event #3 SARS-CoV2 performed on 11/3/2020 C) API 2021-Event #3-Microbiology performed on 9/29/2021 D) API 2021-Event #3-Hematology performed on 11/12/2021 E) AAFP (American Academy of Family Physicians) Reinstatement PT for Virology performed 9/2 - 9/3/2021 F) API 2022-Event #1-Microbiology performed on 2/18/2022 6. On 3/30/2022 the surveyor reviewed the above records and noted no 2020-Event #1 and #2 PT surveys for Microbiology (performed on the BioFire). The surveyor further noted the CMS (Center for Medicare and Medicaid Services) CASPER Report 0096D Proficiency Testing Scores report listed no scoring for Event #1 and #2 in 2020; this indicated the laboratory failed to order Microbiology PT in early 2020. [A review of BioFire Quality Control records revealed the instrument was in use for patient testing in 2020 for all months except February, May and August.] 7. In a phone interview on 3/30/2022 at 1:00 PM, the surveyor asked the Laboratory Director about Microbiology PT for 2020. The Laboratory Director stated she submitted to CLIA everything the Administrator had e-mailed to her. The Director stated she knew the laboratory was performing patient testing despite some BioFire reagent supply shortages in 2020, however the laboratory did not notify her about any problems regarding PT. The Director stated she may have noted a lack of PT and written this up in QA (Quality Assessment) reports. The surveyor stated none of this documentation was provided during the survey, and noted the laboratory failed to order PT Event #1 and #2 surveys in 2020 and 2021. .
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on a lack of proficiency testing records on the day of the survey, and interviews with the Laboratory Director, the laboratory failed to retain PT records in a format allowing review by the surveyor during the survey period. This affected six of eight PT records from Event #3-2019 thru Event #1-2022. The findings include: 1. During the entrance tour at 9:00 AM on 3/17/2022 the Laboratory Director stated moderate-complexity testing included a Molecular Respiratory Pathogen Panel performed on the BioFire Film Array (in use since the previous survey on 6/18/2019), and CBC's (Complete Blood Counts) performed on the Medonic M Series Hematology analyzer (in use for patient testing since 3/16/2021.) 2. A review of laboratory records revealed no documentation of proficiency testing. At approximately 9:20 AM on 3/17/2022 the Laboratory Director explained most of the laboratory records were retained electronically, and only the Clinic Administrator had access to the PT records. 3. At

	approximately 2:00 PM on 3/17/2022 the surveyor was provided two surveys, as follows: A) WSLH (Wisconsin State Laboratory of Hygiene) Proficiency Testing Off-Schedule Set A Hematology PT performed on 10/20/2021, and B) API (American Proficiency Institute) Remedial PT Event 72R for BioFire testing performed on 9/1 /2021 4. At approximately 2:10 PM on 3/17/2022, the surveyor requested the rest of the PT records, including Microbiology PT (Event 3-2019, Events 1, 2 and 3-2020) and the 2021 PT for Hematology and Microbiology. The Laboratory Director explained there were no records for 2019 since these were already packed away. The surveyor explained the 2019-Event #3 survey results were not reviewed during the previous CLIA survey on 6/18/2019, and the laboratory should have retained the results for review during this CLIA survey. 5. As the interview continued on 3/17 /2022, the Director further stated Administration had failed to place the API PT order for 2021; only API Event 3-2021 surveys were available and performed by the laboratory. In addition, the Laboratory Director ordered remedial or off-cycle PT surveys from other PT providers. Only the records for the two remedial surveys listed in #3 above were available on the day of the survey; no other PT records were available for review. .
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) 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. This STANDARD is not met as evidenced by: Based on a review of proficiency testing and personnel records, the Quality Assessment [QA] Plan and an interview with the Laboratory Director, the laboratory failed to follow their procedures to monitor, assess and correct problems identified in the laboratory processes and procedures. The findings include: I) Proficiency Testing 1. A review of the Quality Assessment Plan under "Proficiency Testing"(PT), on page 9 of 13 revealed, "...Standards ...All regulated analytes are enrolled in an approved PT program. ... All documentation is kept on file for at least two years. ...". 2. A review of proficiency testing records revealed the laboratory failed to enroll in proficiency testing (PT) with an HHS (Health and Human Services)-approved PT provider for regulated tests for the first two events in 2020 (Microbiology) and the first two events (Hematology and Microbiology) in 2021. (Refer to D2000.) The laboratory further failed to implement a system to retain PT records for six of eight survey events (Event #3-2019 thru Event #1-2022) in a format allowing review of the records during the on-site CLIA survey. (Refer to D3037.) 3. During an interview at approximately 9:20 AM on 3/17/2022 the Laboratory Director explained most of the laboratory records were retained electronically, and only the Clinic Administrator had access to the PT records. During a later interview at 2:10 PM, the Laboratory Director confirmed Administration had failed to order 2021 PT until August 2021, by which time only 2021-Event 3 was available. The surveyor further confirmed via the CMS (Center for Medicare and Medicaid Services) CASPER Report 0096D Proficiency Testing Scores report which had no scores for Event #1 and #2 in 2020, indicating the laboratory failed to order Microbiology PT in early 2020. During a phone interview on 3/30/2022 at 1:00 PM the Laboratory failed to forward any PT for these events, and did not notify her of any problems. II) Personnel 1. A review of the Quality Assessment Plan under "Personnel", on page 3 of 13 revealed, "...Standards ... Each personnel file shall

	contain: ...Documentation of highest level of education ... Documentation of new hire training...". The surveyor also noted under "Corrective Actions", "Modifications to job descriptions, hiring practices and training, as needed or when required.". 2. A review of the personnel files of testing personnel revealed Testing Personnel (TP) #3 (the Clinic Administrator) was not listed on the previous Form CMS-209 (Laboratory Personnel Report), but was on the current Form CMS-209. Annual competencies were performed in 2020 and 2021, however there were no education or training documents for TP #3 on file. (Refer to D6065 and D6066.) 3. During an interview on 3/17/2022 at 11:10 AM, the Laboratory Director confirmed the above noted findings, stating TP #3 transferred to this location in 2019. 4. A review of Hematology records revealed 35 days in 2021 when quality controls were unacceptable. During an interview on 3/17 /2022 at 12:15 PM the Laboratory Director stated in 2021 there were new testing personnel who were not performing the QC correctly. The testing personnel were not mixing the QC, not allowing the QC vials to reach room temperature, not running the QC in the correct mode on the Medonic, not reviewing expiry dates, and not "looking" at the results to ensure QC was in acceptable ranges. However, the surveyor noted no modifications to job descriptions, hiring practices or modified training emphasizing the areas noted to be a problem, as per the QA procedure. .
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on reviews of the Hematology quality control (QC) records and the Laboratory Director's QC review reports, and an interview with the Laboratory Director, the laboratory: I) failed to ensure at least two levels of quality control were acceptable, prior to analyzing patient specimens and reporting the results. The surveyor noted 35 days of patient CBC (Complete Blood Count) testing in 2021 and two days in 2022 when QC failures occurred; and II) failed to ensure testing personnel did not use expired QC on six days of patient CBC testing in April 2021; and III) failed to retain QC records documenting Hematology QC shifts and trends in a format allowing review by the surveyor during the survey period. This affected Hematology QC records from January 2021 through February 2022. The findings include: 1. Refer to D5481. 2. Refer to D5417. 3. Refer to D5441. .
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on reviews of the Hematology quality control (QC) records, the Laboratory

	Director's QC review report, and an interview with the Laboratory Director, the laboratory failed to ensure testing personnel did not use expired QC on six days of patient CBC (Complete Blood Count) testing in April 2021. The findings include: 1. A review of the 2021 Hematology QC records (the Laboratory Director's QC review report) revealed six days (4/23 - 4/30/2021) of patient CBC testing when the testing personnel used expired QC. 2. A review of corrective action for the six days revealed the Laboratory Director noted the QC was in even though it was expired; there was no evidence the patient CBCs run 4/23/2021 and 4/26 - 4/30/2021 were reviewed to ensure patient care was not compromised. 3. During an interview on 3/17/2022 at 12: 15 PM, the surveyor reviewed and confirmed the above noted findings with the Laboratory Director. .
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on missing Quality Control (QC) records on the day of the survey, and interviews with the Laboratory Director, the laboratory failed to retain QC records documenting Hematology QC shifts and trends in a format allowing review by the surveyor during the survey period. This affected Hematology QC records from January 2021 through February 2022. The findings include: 1. A review of Hematology records revealed no mechanism to monitor for shifts and trends over time. Only electronic copies of the instrument QC print-outs and the Laboratory Director's QC Review reports were available for review on the day of the survey. 2. During an interview on 3/17/2022 at 12:15, the Laboratory Director explained she usually monitored the Hematology electronically on the Muxim LIS (Laboratory Information System). She had intended to print the QC records (January 2021 through February 2022) when she arrived on 3/16/2022, however the computer had "crashed" and the records were not available. The Director was able to show the surveyor Levey-Jennings charts for only one parameter on her computer screen; records were only retained electronically and were not available on the day of the survey. .
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by:

	Based on reviews of the Hematology quality control (QC) records and the Laboratory Director's QC review reports, and an interview with the Laboratory Director, the laboratory failed to ensure at least two levels of quality control were acceptable, prior to analyzing patient specimens and reporting the results. The surveyor noted 35 days of patient CBC (Complete Blood Count) testing in 2021 and two days in 2022 when QC failures occurred. The findings include: 1. A review of the 2021 Hematology QC records (daily instrument printouts and the Laboratory Director's QC review report) revealed 35 days of patient CBC testing when at least two levels of QC were unacceptable, as follows: A) 4/26 - 4/30/2021: 6 days of patient testing when expired QC was used [Refer to D5417.] B) 5/3 - 5/6/2021: 4 days when all three levels were unacceptable; the Director stated the controls were not run in the QC mode C) 5/17 /2021 D) 6/8/2021 E) 7/21/2021 F) August 2021: QC unacceptable 11 days due to QC outside acceptable ranges or failure to run in the QC mode G) September 2021: QC unacceptable five days (9/1, 9/2, 9/16, 9/21, and 9/24/2021) H) 10/14/2021 I) November 2021: QC unacceptable 4 days (11/1, 11/2, 11/3, and 11/29/2021) J) 12/8 /2021 2. A review of the 2022 Hematology QC records (the Laboratory Director's QC review report) revealed Hematology QC was unacceptable on 1/13/2022 and 2/16 /2022. 3. During an interview on 3/17/2022 at 12:15 PM, the surveyor reviewed the recurring QC failures with the Laboratory Director, who confirmed there were "many days" when QC was unacceptable when patients were tested. When asked if she had determined the cause of the problem, and if corrective actions were implemented, the Director stated in 2021 there were new testing personnel who were not performing the QC correctly. The testing personnel were not mixing the QC, not allowing the QC vials to reach room temperature, not running the QC in the correct mode on the Medonic, not reviewing expiry dates, and not "looking" at the results to ensure QC was in acceptable ranges. The Director stated testing personnel were retrained, and some were terminated employment; the provider also reviewed patient CBC reports. 4. As the interview continued on 3/17/2022, the surveyor noted the problem occurred 35 days in 2021, and has occurred again in 2022. The surveyor then asked if the laboratory had implemented any mechanism to ensure patient tests would only be performed when QC was acceptable; the Director answered as of 3/16/2022 (the day before the survey) testing personnel must send the QC results for review to the Laboratory Director before performing any patient testing. .
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) 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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of Hematology records, the Quality Assessment Plan and an interview with the the Laboratory Director, the laboratory failed to follow their procedures to monitor, assess and correct problems identified in the laboratory processes and procedures. The findings include: 1. A review of the Quality Assessment Plan, on page 5 of 13 under "Testing and Instrumentation Quality Control" revealed, "...NO PATIENT TESTING SHOULD TAKE PLACE WHEN CONTROLS ARE OUTSIDE THE EXPECTED RANGE. SPECIMENS SHOULD BE HELD UNTIL CORRECTIVE ACTIONS ALLEVIATES THE PROBLEM AND CONTROLS TEST WITHIN THE EXPECTED RANGES. ... Standards ... QC

	(Quality Control) is evaluated and determined to be in control prior to reporting patient test results... Corrective Action ... Ensure corrective actions addresses the problems and avoid recurrence. ...". 2. A review of the Hematology QC records and the Laboratory Director's QC review reports revealed 35 days of patient CBC (Complete Blood Count) testing in 2021 when QC was unacceptable. This included six days in April 2021 when testing personnel used expired QC. QC was also unacceptable limits on 1/13/2022 and 2/16/2022. (Refer to D5417 and D5481.) 3. During an interview on 3/17/2022 at 12:15 PM, the surveyor reviewed the recurring QC failures with the Laboratory Director, who confirmed there were "many days" when QC was unacceptable when patients were tested. The surveyor then asked if the laboratory had implemented any mechanism to ensure patient tests would only be performed when QC was acceptable; the Director answered as of 3/16/2022 (the day before the survey) testing personnel must send the results to the Laboratory Director before performing any patient testing. .
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 a lack of proficiency testing (PT) records in early 2020 and 2021, reviews of personnel records, Hematology quality control (QC) records and the Laboratory Director's QC review reports and interviews with the Laboratory Director, the Laboratory Director: 1) failed to ensure the laboratory was enrolled in an HHS (Health and Human Services)-approved PT program for regulated tests for the first two events in 2020 and the first two events in 2021. This affected two of three Microbiology PT survey events in 2020, and two of three Hematology and Microbiology PT survey events in 2021; 2) failed to ensure patient tests were not performed on days when QC was unacceptable. The surveyor noted 35 days of patient CBC (Complete Blood Count) testing in 2021 and two days in 2022 when QC failures occurred; 3) failed to ensure records documenting Hematology QC shifts and trends were retained in a format allowing review by the surveyor during the on-site survey period. This affected Hematology QC records from January 2021 through February 2022; 4) failed to ensure the laboratory followed the procedures to monitor, assess and correct problems identified in the laboratory processes and procedures; and 5) failed to ensure education and training documentation was available for one of three new Testing Personnel (TP) performing moderate-complexity patient testing. The findings include: 1. Refer to D6015. 2. Refer to D6020. 3. Refer to D6021. 4. Refer to D6065 and D6066. .
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

	This STANDARD is not met as evidenced by: Based on a lack of proficiency testing (PT) records in early 2020 and 2021 and interviews with the Laboratory Director, the Laboratory Director failed to ensure the laboratory was enrolled in an HHS (Health and Human Services)-approved PT program for regulated tests for the first two events in 2020 and the first two events in 2021. This affected two of three Microbiology PT survey events in 2020, and two of three Hematology and Microbiology PT survey events in 2021. The findings include: 1. Refer to D2000. .
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 reviews of the Hematology quality control (QC) records and the Laboratory Director's QC review reports, and interviews with the Laboratory Director, the Director: 1) failed to ensure patient tests were not performed on days when QC was unacceptable. The surveyor noted 35 days of patient CBC (Complete Blood Count) testing in 2021 and two days in 2022 when QC failures occurred; and 2) failed to ensure records documenting Hematology QC shifts and trends were retained in a format allowing review by the surveyor during the on-site survey period. This affected Hematology QC records from January 2021 through February 2022. The findings include: 1. Refer to D5441. 2. Refer to D5481. .
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 reviews of proficiency testing, personnel records and Hematology records, the Quality Assessment Plan and interviews with the Laboratory Director, the Laboratory Director failed to ensure the laboratory followed the procedures to monitor, assess and correct problems identified in the laboratory processes and procedures. The findings include: 1. Refer to D5291. 2. Refer to D5791. .
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

	(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on a review of personnel files, and an interview with the Laboratory Director, the laboratory failed to ensure educational documentation was available for one of three new Testing Personnel (TP) performing moderate-complexity patient testing. The findings include: 1. A review of the personnel files of testing personnel revealed TP #3 (the Clinic Administrator) was not listed on the previous Form CMS-209 (Laboratory Personnel Report), but was on the current Form CMS-209. Annual competencies were performed in 2020 and 2021, however there were no educational documents for TP #3 on file. 2. During an interview on 3/17/2022 at 11:10 AM, the Laboratory Director confirmed the above noted findings, stating TP #3 transferred to this location in 2019. .
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on a review of personnel files, and an interview with the Laboratory Director, the laboratory failed to ensure initial training documentation was available for one of three new Testing Personnel (TP) performing moderate-complexity patient testing. The findings include: 1. A review of the personnel files of testing personnel revealed TP #3 (the Clinic Administrator) was not listed on the previous Form CMS-209 (Laboratory Personnel Report), but was on the current Form CMS-209. Annual competencies were performed in 2020 and 2021, however there were no initial training documents for TP #3 on file. 2. During an interview on 3/17/2022 at 11:10 AM, the Laboratory Director confirmed the above noted findings, stating TP #3 transferred to this location in 2019. SURVEYOR ID# 32558 Licensure and Certification Surveyor