Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D2214836	09/06/2023
Name of Provider or Supplier	**Street Address, City, State**	
Prime Labs Llc	10619 S Jordan Gateway Blvd Suite 125, South Jordan, UT	

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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on proficiency testing record review, lack of documentation, and interview with the technical supervisor (TS), the laboratory failed to review and evaluate proficiency testing results for 2 of 2 proficiency testing performance evaluations in 2023. Findings: 1. American Proficiency Institute (API) 2023 Chemistry - Core - 1st Event review found a performance of "unacceptable" for samples Myoglobin CM-04, CO2 CH-02, phosphorus CH-05, and cortisol CH-02. 2. API 2023 Chemistry - Core - 2nd Event review found a performance of "unacceptable" for sample HCG (serum-quant) HCG-06. 3. Record review failed to include documentation the laboratory reviewed and evaluated the unacceptable PT results from API 2023 Chemistry - Core - 1st and 2nd Event 4. In an interview on September 6, 2023 at 12:11 PM, the TS confirmed the laboratory failed to review and evaluate the unacceptable PT results. 5. The laboratory performed 20,000 chemistry test annually.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, direct observation, and interview with the Technical Supervisor (TS), the laboratory failed to follow their preanalytic procedure for the acceptability requirements for samples received by the laboratory. Findings: 1. Review of the laboratory's procedure manual revealed the procedure "09-Pre-Analytical" stated the patient sample container must have the patient name and a secondary unique identifier. 2. Direct observation of the laboratory samples on September 6, 2023 at 4:05 PM, found 6 of 22 patient samples that were being prepared to run on a QuantStudio 12K Flex Real-Time PCR System had no patient identification on the original sample tube. 3. In an interview on September 6, 2023 at 2:25 PM, the TS confirmed samples were accepted when they did not have the patients' name and a secondary unique identifier. 4. The laboratory performs 95,000 test annually.
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 procedure manual review, record review, and interview with the technical supervisor (TS), the laboratory failed to follow the procedure to repeat critical values. Findings: 1. The laboratory procedure "SOP 12 - Clinical Blood Testing" stated when a test result is critical, the sample will be immediately repeated to ensure the accuracy of the result. 2. Record review of the Beckman Coulter AU480 instrument sample result log revealed 2 of 3 patients that had critical values were not repeated. 3. In an interview on September 6, 2023 at 5:30 PM, the TS confirmed the laboratory did not repeat all critical values. 4. The laboratory performed 20,000 chemistry tests per year.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on laboratory record review and interview with the technical supervisor (TS), the laboratory failed to ensure the twice a year evaluation of two QuantStudio 12K Flex Real-Time PCR Systems that compared the relationship between instruments. Findings: 1. Laboratory record review failed to produce instrument to instrument comparison for the two QuantStudio 12K Flex Real-Time PCR Systems twice a year in 2022 and 2023. 2. In an interview conducted on September 6, 2023, at 2:20 PM, the TS confirmed the laboratory has not performed an evaluation that defines the

	relationship between the two QuantStudio 12K Flex Real-Time PCR Systems. 3. The laboratory performed 50,000 molecular tests per year.
D5777	COMPARISON OF TEST RESULTS CFR(s): 493.1281(b)(c) (b) The laboratory must have a system to identify and assess patient test results that appear inconsistent with the following relevant criteria, when available: (b)(1) Patient age. (b)(2) Sex. (b)(3) Diagnosis or pertinent clinical data. (b)(4) Distribution of patient test results. (b)(5) Relationship with other test parameters. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on review of laboratory procedure manual and interview with the Technical Supervisor (TS), the laboratory failed to have a system that assessed patient test results that appear inconsistent with relevant criteria, including previous results. Findings: 1. Laboratory procedure manual review failed to produce a system that assessed patient test results that appear inconsistent with relevant criteria, including previous results. 2. In an interview on September 6, 2023 at 5:45 PM, the TS confirmed the laboratory did not have a system that assessed patient test results that appear inconsistent with relevant criteria. 3. The laboratory performed 95,000 test annually.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of patient test reports, laboratory procedure manual, and an interview with technical supervisor (TS), the laboratory failed to include the correct reference ranges for chemistry tests. Findings: 1. Review of the patient reports revealed five of the six chemistry reference ranges did not match reference ranges for the chemistry test that were found in the procedure "14 AU480 SOP". 2. The procedure manual showed: Parameter Reference Range Iron 50 - 212 Lactate Dehydrogenase 140 - 271 Glucose 74 - 109 Magnesium 1.9 - 2.7 Phosphorous 3.7 - 7.2 3. The patient report showed: Parameter Reference Range Iron 35 - 145 Lactate Dehydrogenase 122 - 222 Glucose 70 - 105 Magnesium 1.7 - 2.3 Phosphorous 2.5 - 4.5 4. In an interview on September 6, 2023 at 5:50 PM, the TS confirmed the lab failed to provide the correct reference ranges on the test report. 5. The laboratory performed 20,000 chemistry tests per year.