

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  46D2214836	<b>(X3) Date Survey Completed</b>  12/09/2021
<b>Name of Provider or Supplier</b>  Prime Labs Llc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2000</b>	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of proficiency testing (PT) records for 2021 and confirmed by interview with the general supervisor and testing personnel on 12/09/2021 @ 1:30 PM, the laboratory failed to enroll in an approved PT program in the subspecialties of bacteriology, mycology, and virology which would include organisms the laboratory could potentially identify and report which are listed in subpart I and are performed as part of the Wound (CLCS Version 3) Panel, the Foot Fungus (CLCS Version 2) Panel, the UTI (CLCS Version 2) Panel, the STI (CLCS Version 2) Panel, the Women's Health (CLCS Version 1) Panel, and the Resp (Using Thermo Version 6) Panel as described by the Prime Labs CLCS Panel Summary. At the time of the survey, the laboratory reported performing 50,000 tests annually.</p>
<b>D3000</b>	<p>FACILITY ADMINISTRATION CFR(s): 493.1100</p> <p>Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure</p>

that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.

This CONDITION is not met as evidenced by:  
Based on record review and interview with the general supervisor, the laboratory failed to report SARS-CoV-2 negative test results from April 2021 through December 2021. Findings include: 1. In an interview with the general supervisor on 12/09/2021 at 10:45 AM, confirmed that negative SARS-CoV-2 test results were not reported to the state health department. 2. Laboratory procedure failed to include instructions for reporting negative SARS-CoV-2 test results to the state health department. 3. The laboratory performed approximately 3000 SARS-CoV-2 tests annually using the Thermo QuantStudio 12K PCR assay. 4. The technical supervisor confirmed the findings on 12/09/2021 at 1:00 PM.

**D5413**

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT  
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:  
Based on direct observation, and interview with testing personnel, the laboratory failed to store TaqPath COVID-19 controls at a temperature consistent with the manufacturer's instructions. Findings include: 1. TaqPath COVID-19 controls requires to be stored at a temperature colder than -70 C. 2. Direct observation revealed that controls were stored in a freezer that was at a temperature of -21 C. 3. The laboratory performed approximately 3000 SARS-CoV-2 tests annually using the Thermo QuantStudio 12K PCR assay. 4. In an interview on 12/09/2021 at approximately 1:15 PM, the general supervisor confirmed that controls were not store at a temperature colder than -70 C.

**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 records review and interview with the laboratory staff, the laboratory failed to ensure the twice a year evaluation of the two Kingfisher Duo Prime, one Kingfisher Flex, and three QuantStudio 12K Flex test instruments that compared the relationship between instruments. 1. The laboratory quality assessment procedure failed to include a system that twice a year evaluates and defines the relationship between test results using different instruments. 2. The laboratory records review failed to include instrument to instrument comparison. 3. The laboratory performs approximately 50,000 Thermo Fisher TaqMan PCR wound, foot fungus, urinary tract infection, women's health, sexually transmitted infections, and respiratory molecular panel tests per year. 4. In an interview conducted on 12/19/2021 at 12:20 AM, testing personnel stated the laboratory did not have a system in place that twice a year evaluates and defines the relationship between test results using different instruments.

**D6076**

**LABORATORY DIRECTOR**  
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:  
Based on record review, direct observation, and interview with laboratory staff, the laboratory director failed to provide management and direction to the laboratory by failure to ensure that the physical plant and environmental conditions of the laboratory are appropriate for uni-directional workflow for molecular testing. (See D6083); failure to ensure that test systems had established performance specifications before reporting patient test result (See D6086); and the failure to ensure that quality control procedures are followed to assure the quality of laboratory services provided (See D6093).

**D6083**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(2)

The laboratory director must ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed.

This STANDARD is not met as evidenced by:  
Based on direct observation and interview with the general supervisor, the laboratory failed to provide uni-directional workflow for molecular testing such as specimen preparation, amplification, and reagent preparation. Findings include: 1. The laboratory performs approximately 50,000 Thermo Fisher TaqMan PCR wound, foot fungus, urinary tract infection, women's health, sexually transmitted infections, and respiratory molecular panel tests per year. 2. Laboratory record review revealed a lack of a log or procedure for contamination checks, including wipe checks. 3. Direct laboratory observation on 12/09/2021 at approximately 10:54 AM, found that the PreAMP Reaction Mix was made in same room as patient specimens were extracted which can lead to contamination of the patient specimens. 4. In an interview on 12/09

/2021 at approximately 11:00 AM, the general supervisor confirmed that no checks for contamination, including wipe checks, were performed and that the PreAMP Reaction Mix was made in same room as patient specimens were extracted.

**D6086**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(3)(ii)

The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.

This STANDARD is not met as evidenced by:

Based on record review and interview with the technical supervisor, the laboratory director failed to ensure that test systems had established performance specifications before reporting patient test results. Findings include: 1. The laboratory performs approximately 50,000 Thermo Fisher TaqMan PCR wound, foot fungus, urinary tract infection, women's health, sexually transmitted infections, and respiratory molecular panel tests per year. 2. In an interview on 12/09/2021 at approximately 1:00 PM the technical supervisor confirmed that the laboratory began reporting patient test results on 04/01/2021. 3. Record review of test system performance specifications revealed that the wound test system was approved by the laboratory director on 12/08/2021, the COVID-19 test system was approved by the laboratory director on 12/07/2021, and the foot fungus was approved by the laboratory director on 12/07/2021. 4. In an interview on 12/09/2021 at approximately 1:00 PM the technical supervisor confirmed that patient test results were reported before the laboratory director ensured that test systems had established performance specifications.

**D6093**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on record review and interview with the general supervisor, the laboratory failed to follow the procedure for running quality controls for the Thermo Fisher TaqMan PCR test panels. Findings include: 1. The "Laboratory Operations Manual for rDNA/RNA Based Pathogen Testing" procedure manual stated that every amplification plate must have an external positive control and must pass for the plate to be valid. 2. Record review of quality controls logs revealed the laboratory did not have an external positive control on every amplification plate. 3. The laboratory performs approximately 50,000 Thermo Fisher TaqMan PCR wound, foot fungus, urinary tract infection, women's health, sexually transmitted infections, and respiratory molecular panel tests per year. 4. In an interview on 12/09/2021 at approximately 12:15 PM, the general supervisor confirmed the laboratory failed to follow the procedure manual by not including an external positive control on every amplification plate.