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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>06D0981096      | <b>(X3) Date Survey Completed</b><br><br>06/04/2019 |
| <b>Name of Provider or Supplier</b><br><br>Prime Pathology Laboratories, Llc   | <b>Street Address, City, State</b><br><br>3757 Bucknell Dr, Highlands Ranch, CO |   |
| 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>  |
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| <b>D5291</b>              | <p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT<br/>CFR(s): 493.1239(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on the lack of a quality assessment (QA) plan and laboratory director interview, the laboratory failed to establish written policies and procedures for staff to follow since testing began in March 2019 for an ongoing mechanism to monitor, assess, and take corrective action as needed for the general laboratory systems to include confidentiality, specimen identification and integrity, complaint investigations, communications, personnel competency and evaluation of proficiency testing performance. Findings include: a. The laboratory director was unable to provide the surveyor an active QA plan with written policies for the general laboratory systems. b. The laboratory director confirmed the laboratory had not written policies to evaluate general quality issues in the laboratory.</p> |
| <b>D5391</b>              | <p>PREANALYTIC SYSTEMS QUALITY ASSESSMENT<br/>CFR(s): 493.1249(a)</p> <p>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 preanalytic systems specified at 493.1241 through 493.1242.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on the lack of a quality assessment (QA) plan and laboratory director interview,</p>   |

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|                     | <p>the laboratory failed to establish written policies and procedures for staff to follow since testing began in March 2019 to monitor, assess, and take corrective action as needed for the preanalytic laboratory systems to include complete and accurate test requisitions, and appropriate specimen submission, handling, and referral. Findings include: a. The laboratory director was unable to provide the surveyor an active QA plan with written policies for the preanalytic laboratory systems. b. The laboratory director confirmed the laboratory had not written policies to evaluate preanalytic quality issues in the laboratory.</p>  |
| <p><b>D5401</b></p> | <p><b>PROCEDURE MANUAL</b><br/>CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on a review of the procedure manual and staff confirmation, the laboratory failed to provide during the onsite survey, a written procedure for histopathology slide examinations for staff to follow in 2019.</p>   |
| <p><b>D5791</b></p> | <p><b>ANALYTIC SYSTEMS QUALITY ASSESSMENT</b><br/>CFR(s): 493.1289(a)(c)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on the lack of a quality assessment (QA) plan and laboratory director confirmation, the laboratory failed to establish written policies and procedures for staff to follow since testing began in March 2019 for an ongoing mechanism to monitor, assess, and take corrective action as needed for the analytic laboratory systems to include monitoring of test system requirements, and maintenance; control procedures; documentation of corrective actions; and review and retention of all test records. Findings include: a. The laboratory director was unable to provide the surveyor an active QA plan with written policies for the analytic laboratory systems. b. The laboratory director confirmed the laboratory had not written policies to evaluate analytic quality issues in the laboratory.</p> |
| <p><b>D5891</b></p> | <p><b>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT</b><br/>CFR(s): 493.1299(a)</p> <p>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 postanalytic systems specified in 493.1291.</p> <p>This STANDARD is not met as evidenced by:</p>   |

Based on the lack of a quality assessment (QA) plan and lab director confirmation, the laboratory failed to establish written policies and procedures for staff to follow since testing began in March 2019 for an ongoing mechanism to monitor, assess, and take corrective action as needed for the postanalytic laboratory systems to include protocols for appropriate test report information for proper patient identification and interpretation of results; corrected reports; the accuracy and timeliness of test reports; and record retention for interim, preliminary, corrected and final reports. Findings include: a. The laboratory director was unable to provide the surveyor an active QA plan with written policies for the postanalytic laboratory systems. b. The laboratory director confirmed the laboratory had not written policies to evaluate postanalytic quality issues in the laboratory.