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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 26D2164792 | (X3) Date Survey Completed 09/08/2022 |
| Name of Provider or Supplier Precision Labs Llc | Street Address, City, State 15320 Conway Rd, Chesterfield, MO | |
| 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 |
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| D5545 | <p>HEMATOLOGY CFR(s): 493.1269(b)(d)</p> <p>(b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory procedures, Sysmex CA-500 analyzer quality control (QC), patient results and interview with the technical consultant (TC), the laboratory failed to include two levels of control material each 8 hours of operation for prothrombin time (PT). Findings: 1. Review of laboratory procedure "Prothrombin Time (PT) seconds" states, " Controls should be tested at the initiation of testing, upon reagent changes, and at least once each 8 hour shift." 2. Review of Sysmex CA-500 analyzer QC for August 2022 showed two levels of PT QC was not performed on August 10, 2022. 3. Review of patient results showed 24 patient PT results were reported without QC being performed on August 10, 2022. 4. Interview with the TC on August 29, 2022 at 3:30 PM confirmed the laboratory failed to perform two levels of PT QC each 8 hours of operation.</p> |