Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 06D0513593	(X3) Date Survey Completed 02/07/2023
Name of Provider or Supplier Adventhealth Urology At Denver	**Street Address, City, State** 850 E Harvard Ave, Suite 305, Denver, CO	

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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on a routine desk review of the CMS-155 report for Proficiency Testing (PT) performance, review of PT reports and laboratory staff interview, the laboratory failed to achieve satisfactory performance scores from the American Proficiency Institute in the specialty of Hematology for two out of three PT events in 2022 (events 1 and 3). See D2131
D2131	HEMATOLOGY CFR(s): 493.851(g)

	Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a routine desk review of the CMS-155 report for Proficiency Testing (PT) performance, review of PT reports and laboratory staff interview, the laboratory failed to achieve satisfactory performance scores of 80% or greater from the American Proficiency Institute in the specialty of Hematology for two out of three PT events in 2022 (events 1 and 3). Findings: 1. A review of the CMS-155 Individual Laboratory Profile on 12.26.2022 revealed the API PT scores for the specialty of Hematology for the 2022 Event 1 was 73% and the 2022 Event 3 was 66%. 2. A review of the API PT results submitted to the laboratory was performed during the biennial recertification survey on February 7, 2022 by the State Agency. 3. Review of the API PT results submitted to the laboratory indicated unsatisfactory performance testing the analytes of Hematocrit (HCT) and Hemoglobin (HGB) for the 2022 Event 1 where a score of 60% was reported. 4. Review of the API PT results submitted to the laboratory indicated unsatisfactory performance testing the analyte of Protime (PT) for the 2022 Event 3 where a score of 0% was reported. 5. Review of the API PT results submitted to the laboratory did not indicate that unsuccessful performance was achieved in the specialty of Hematology. 6. The Technical Consultant stated during the onsite survey held on February 7, 2023 that they were aware of the unsatisfactory performance with the HCT, HGB and PT results for the two events, but were unaware that those scores resulted in unsuccessful participation for the specialty of Hematology.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Assurance (QA) policy, Proficiency Testing (PT) results, Accuracy Verification (AV) documentation and staff interview, the laboratory failed to test at least twice annually urine bacteriology RT-PCR samples in 2022 as specified in their established QA policy. Findings: 1. The laboratory's QA policy states that urine bacteriology samples tested on the Bio Rad CFX96 instrument using an RT-PCR method will be sent to a reference lab at least twice annually to perform and document Accuracy Verification activities. 2. Review of both PT and AV records during the biennial recertification survey conducted on February 7, 2023 revealed that no samples were sent during 2022. 3. The Technical Supervisor verified on February 7, 2023 at 3:00 pm that no urine bacteriology samples were sent for Accuracy Verification during 2022 as specified in the laboratory's QA policy.