

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 02D0640642	(X3) Date Survey Completed 08/18/2026
Name of Provider or Supplier Alaska Urology, Llc	Street Address, City, State 3841 Piper Street, Suite T300, Anchorage, AK	
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
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review of daily checks logs, quality checklists and forms, and an interview with the General Supervisor (GS), the laboratory failed to document corrective actions taken when Diazyme DZ-lite c270 reagent carousel temperature and testing room humidity are outside the defined range for three (3) of three (3) months when TrueUA testing was performed. Findings include: 1. Review of the Laboratory Daily/Weekly Checks log showed the Diazyme DZ-lite c270 reagent carousel temperature was out of range 17 of 20 times in May 2026 with no corrective actions documented. 2. Review of the Laboratory Daily/Weekly Checks log showed the humidity was out of range for 12 out of 42 days in January and March of 2026 with no corrective actions documented. 3. Review of the Monthly Quality Audit Checklist and Quality Assessment Review Form showed other corrective actions listed but no documentation for reagent carousel temperature or room humidity deviations. 4. In an interview on 8/18/26 at 12:00 P.M., the GS stated the Diazyme DZ-lite c270 instrument was replaced, correcting the reagent carousel temperature deviations and confirmed no corrective actions were documented prior to replacement. 5. The laboratory reports performing 12,500 Urinalysis tests annually.