Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	02D0640552	08/29/2022
Name of Provider or Supplier	**Street Address, City, State**	
Independence Park Medical Services Inc	9500 Independence Drive, Ste 400, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 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. This CONDITION is not met as evidenced by: Based on surveyor review of proficiency testing records and an interview with the laboratory director, the laboratory failed to enroll in an approved proficiency testing program for the specialty Microbiology, subspecialty Virology for the Xpert Xpress CoV-2, Influenza A and B, and Respiratory Syncytial Virus assays. Findings include: 1. The laboratory began using the cartridges for patient testing on 12/16/2020. 2. The laboratory reports performing approximately 430 CoV-2/Flu/RSV per year. 3. The laboratory director stated she was unaware the cartridges were non-waived and required proficiency testing when used with the laboratory's Cepheid Xpert Xpress analyzer. 4. The laboratory director confirmed these findings by interview on 8/29/22 at 16:00 pm.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) 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. This STANDARD is not met as evidenced by: Based on review of patient records, the Manual Urine Microscopic Examination Procedure, and interview with the laboratory director, the laboratory failed to include all the required elements for reporting urine microscopic test results in five (5) of five (5) urine microscopic results reviewed (#25223, 10317, 28814, 29792, 29763). Findings include: 1. The Manual Urine Microscopic Examination Procedure dated 12 /21/2020, lists six required elements (WBC, RBC, Epithelial Cells, Bacteria, Mucus /Yeast, and Casts/Crystals) for inclusion on the patient report. 2. Five of five urine microscopy reports reviewed lacked all six elements: a. #25223: missing WBC, Epithelial Cells, Bacteria, Mucus/Yeast, and Casts/Crystals b. #10317: missing Mucus /Yeast, and Casts/Crystals c. #28814: missing Mucus/Yeast, and Casts/Crystals d. #29792: missing WBC, Epithelial Cells, Bacteria, Mucus/Yeast, and Casts/Crystals e. #29463: missing WBC, Epithelial Cells, Bacteria, Mucus/Yeast, and Casts/Crystals 3. The laboratory reports performing 87 urine microscopic examinations annually. 4. The laboratory director confirmed these findings by interview on 8/29/22 at 16:00 pm.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on surveyor record review and an interview with the laboratory director, the laboratory failed to verify the performance specifications of the Cepheid CoV-2/Flu /RSV assay cartridges prior to reporting patient test results. Findings include: 1. The laboratory's verification records did not include data for the Cepheid CoV-2/Flu/RSV assay cartridges. 2. The laboratory began using the cartridges for patient testing on 12 /16/2020. 3. The laboratory reports performing approximately 430 CoV-2/Flu/RSV tests per year. 4. The laboratory director stated she was unaware the cartridges were non-waived and required verification of performance when used with the laboratory's Cepheid Xpert Xpress analyzer. 5. The laboratory director confirmed these findings by interview on 8/29/22 at 16:00 pm.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The

	laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor record review and interview with the laboratory director, the laboratory failed to perform control procedures each day patient specimens are tested for the Cepheid CoV-2/Flu/RSV assay. Findings include: 1. The laboratory began using the cartridges for patient testing on 12/16/2020. 2. The laboratory reports performing approximately 430 CoV-2/Flu/RSV per year. 3. The laboratory director stated she was unaware the cartridges were non-waived and required daily control procedures when used with the laboratory's Cepheid Xpert Xpress analyzer. 4. The laboratory director confirmed these findings by interview on 8/29/22 at 16:00 pm.