Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0521701	04/15/2022
Name of Provider or Supplier	**Street Address, City, State**	
Ada Pediatrics Pa	650 N Cole Rd, Boise, ID	

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
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of microbiology media records and an interview with the office manager on 4/15/2022, the laboratory failed to check each lot of prepared plated medium for its ability to support growth and/or inhibit growth prior to reporting urine colony count results. The findings include: 1. A review of microbiology media records identified that the laboratory failed to perform and document quality control (QC) to show the ability of the Hardy Blood Agar/MacConkey Biplate to support growth for lot numbers 499553, 492447, 487839, 481005, 475333 and 47329 prior to releasing patient urine colony count results. 2. A review of microbiology media records identified that the laboratory failed to perform and document QC to show the ability of the MacConkey portion of the Hardy Biplate to inhibit growth for lot numbers 499553, 492447, 487839, 481005, 475333 and 47329 prior to releasing patient urine colony count results. 3. An interview with the office manager on 4/15/2022 at 10:03 am confirmed that the laboratory failed to perform QC on media before patient results were reported.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409

	The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on record review of the CMS-209 Personnel Report Form, personnel education documents and an interview with the office manager on 4/15/2022, the laboratory failed to have a qualified technical consultant (TC) that meets the educational requirements listed in the state operations manual subpart M. See D6035
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on record review of the CMS-209 Personnel Report Form, personnel education documents and an interview with the office manager on 4/15/2022, the laboratory failed to ensure that the employee listed as the technical consultant (TC) met one of the educational requirements listed in the state operations manual subpart M to qualify as technical consultant. The findings include: 1. A review of the CMS-209 and

	personnel education documents for the employee listed as the TC and fulfilling the TC responsibilities identified that the laboratory failed to have documentation of at least a Bachelor's degree in chemical, physical or biological science for the employee. 2 An interview with the office manager on 4/25/ 2022 at 9:21 am, confirmed that the laboratory failed to have a qualified TC.