Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0966751	02/12/2019
Name of Provider or Supplier	**Street Address, City, State**	
A To Z Pediatrics	4804 Rowan Rd, New Port Richey, FL	

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
D0000	A recertification survey was conducted at the facility on 02/12/2019 . Based on the survey findings, an Immediate Jeopardy situation was identified under D5400 Analytic Systems and the laboratory was notified at 4:30 PM on 02/12/2019. The laboratory failed to perform throat cultures with bacitracin discs according to manufacturer's instructions. The laboratory failed to verify and update the procedure manual to be consistent with laboratory testing. The following conditions were not met: D5400 Analytical Systems 493.1250 and D6000 Moderate Complexity Laboratory Director 493.1403.
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on American Proficiency Institute (API) proficiency record review, procedure manual review, patient log review and interview with Testing Personnel #C, the laboratory failed to test Microbiology (throat culture with bacitracin disc) proficiency testing samples(2017 - 2nd, 3rd Testing Events and 2018 1st, 2nd, and 3rd Testing Events) the same manner as patient specimens. Findings included: Review of American Proficiency Institute (API) proficiency records revealed that for 2017 2nd and 3rd Events and 2018 1st, 2nd, and, 3rd Events, the API Attestation Statement section for "Person(s) Performing the Test" was signed by Testing Personnel #B and

	Testing Personnel #C. Review of the standard operating procedure, dated 06/11/2008 "Throat Cultures for Streptococcus" indicated the procedure was to setup one culture with one patient throat swab. Review of the "Patient Test Order Log" for 2017-2018 showed that throat culture proficiency testing sample setup was completed in duplicate, however patient samples were setup individually. Proficiency testing was done by both Testing Personnel #B and #C. Plates for proficiency then were read by Testing Personnel #C. Patient sample throat culture setup was performed once by either Testing Personnel #C or #D. Patient cultures then were read by Testing Personnel #D. Interview on 02/12/2019 at 11:00 AM, Testing Personnel # C confirmed that two testing personnel performed throat culture setup on each Microbiology (throat culture with bacitracin disc) proficiency samples and this was not how patients were tested.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of CMS 209- Laboratory Personnel Report, review of patient logs, review of American Proficiency Institute (API) proficiency testing, and interview with the Testing Personnel #C, the laboratory failed to have all testing people rotate through the testing of Microbiology (throat culture with bacitracin disc) proficiency testing for 2017 2nd, and 3rd Testing Events and 2018 1st, 2nd, and 3rd Testing Events. Findings Included: Review of the CMS 209 (signed and dated by the Laboratory Director 02/12/2019) the laboratory had 3 testing people listed (#B, #C, and #D). Review of the API Attestation Statement for 2017 2nd and 3rd Testing Events and 2018 1st, 2nd, and 3rd Testing Events showed 2 Testing Personnel (#B and #C) signed the attestation statements. Review of the "Patient Test Order Log" revealed that Testing Personnel #C and #D were performing patient testing. Interview on 02/12/2019 at 11:15 AM, Testing Personnel #C confirmed that Testing Personnel #D did perform throat cultures with bacitracin disc for 2017 and 2018 and did not perform proficiency testing.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review, and interview with Testing Personnel #C and Laboratory Director, the laboratory failed to document the initial use of procedure and discontinuance of procedure in the procedure manual for throat cultures(See D5409), and failed to follow manufacturer's instructions for throat cultures(See D5411).

D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). This STANDARD is not met as evidenced by: Based on review of procedure manual and interview with Testing Personnel #C, the laboratory failed to document the date of initial use and discontinuance of throat culture standard operating procedures. Findings included: Review of the procedure manual revealed the procedure manual included 2 procedures for throat cultures, "Strep Select Agar and Quality Control" which the Laboratory Director review was signed and dated 01/03/2008 and "Throat Cultures for Streptococcus" effective date was 06/11/2008 and Laboratory Director review and signed date was 06/11/2008. The procedure manual also included a package insert for manufacturer's instructions for a brand of bacitracin discs not used by the laboratory at time of survey. None of the throat culture procedures or package insert had a discontinued date. Interview on 02/12 /2019 at 11:50 AM, the Laboratory Director confirmed there were 2 procedures for throat cultures and 1 package insert with manufacturer's instructions in the procedure manual.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on record review of manufacturer's instructions, patient logs, and interview with Testing Personnel #C and Laboratory Director the laboratory failed to follow manufacturer's instructions for 2 of 2 years (2017-2018) for incubation time for throat cultures with bacitracin discs. Findings included: Review of the current box lot (DD0030S) of bacitracin discs manufacturer's instructions(did not have a date) revealed the throat culture with bacitracin disc incubation time was to be 18-24 hours. Review of the "Patient Test Order Log" logs for 2017 - 2018 showed the following incubation times for the throat cultures: 2017 Plates read at 48 hours Culture setup date - 05/04/2017 Read date - 05/06/2017 number of patients - 2 Culture setup date - 05/06/2017 Read date - 05/08/2017 number of patients - 1 Culture setup date - 05/08 /2017 Read date - 05/10/2017 number of patients - 1 Culture setup date - 05/09/2017 Read date - 05/11/2017 number of patients - 5 Culture setup date - 05/15/2017 Read date -0 5/17/2017 number of patients - 4 Culture setup date - 05/17/2017 Read date -0 5/19/2017 number of patients - 2 Culture setup date - 05/20/2017 Read date - 05/22 /2017 number of patients - 2 Culture setup date - 05/22/2017 Read date - 05/24/2017 number of patients - 1 Culture setup date - 05/23/2017 Read date - 05/25/2017 number of patients - 2 Culture setup date - 05/26/2017 Read date - 05/28/2017 number of patients - 10 Culture setup date - 05/30/2017 Read date - 06/01/2017 number of patients - 3 Culture setup date - 05/31/2017 Read date - 06/02/2017 number of patients -3 Culture setup date - 06/05/2017 Read date - 06/07/2017 number of patients - 3 Culture setup date - 06/06/2017 Read date - 06/08/2017 number of patients - 2

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D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance

	with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of API (American Proficiency Institute) proficiency testing records and interview with the Testing Personnel #C , the Laboratory Director failed to recognize that the laboratory was not rotating Testing Personnel to perform proficiency testing and testing proficiency testing samples in duplicate (See D6016). Based on record review of manufacturer's instructions, job descriptions, and interview with the Laboratory Director, the Laboratory Director failed to ensure the delegate was performing her duties described in her job description (See D6004).
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on record review and interview with the Laboratory Director the Laboratory Director failed to effectively oversee the laboratory and the Technical Consultant for 2 out of 2 years (2017-2018). Findings Included: 1. Review of the CMS 209 signed and dated 02/12/2019 by the Laboratory Director revealed 1 Technical Consultant. 2. Review of the Technical Consultant Job Description that the Laboratory Director signed and dated 03/03/2015 showed the Laboratory Director had assigned the responsibility of ensuring patient test results were not reported unless all criteria for test performance charatcteristics were acceptable. 3. See D5400 for failure to effectively oversee the laboratory.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on American Proficiency Institute (API) proficiency record review, patient logs and interview with Testing Personnel #C, the Laboratory Director failed to ensure that proficiency testing was performed in the same manner as patients for Microbiology throat culture with bacitracin disc 2017 2nd and 3rd Testing Events and 2018 1st, 2nd,

	and 3rd Events. Findings included: Review of the API proficiency attestation statements revealed the Laboratory Director had signed the Attestation Statement attesting throat culture proficiency testing samples were tested the same as patients for 2017 2nd and 3rd Event, and 2018 1st, 2nd, and 3rd Events. The attestation was also signed by two of the Testing Personnel (#B and #C). Included on the Attestation Statement was the Sample Set(s) Tested by the Person performing the test. Review of the Patient Test Order Log showed the API throat culture proficiency samples culture set up was performed by two testing personnel (#B and #C) and the plates were read by Testing Personnel #C. Patient specimens were cultured once. Interview on 02/12 /2018 at 11:00 AM, Testing Personnel #C stated the throat culture proficiency testing was performed in duplicate which was not how patients were tested.