Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0271843	02/23/2021
Name of Provider or Supplier	**Street Address, City, State**	
Benton Pediatrics, Inc	5612 Nw 43rd St, Gainesville, 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	At the time of the announced, on-site recertification survey, Benton Pediatrics, Inc. was found to be not in compliance with the CLIA laboratory requirements of 42 CFR 493.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to document annual competency assessment in 2020 on six out of nine testing personnel. The findings include: Review of the competency records showed that the laboratory failed to have documentation of annual competency assessments for six out of nine testing personnel for 2020. Testing Persons #A, B, C, D, E, F had a competency assessment on 7/25/19 and 2/8/21. During an interview with Testing Person A on 2/23/21 at 12:00PM, it was confirmed that personal competency had not been performed in 2020 for the six testing personnel.
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 record review and staff interview, the laboratory failed to perform Bacteriology throat culture quality controls (QC) weekly resulting in 12 days of patient testing in 2019 and 2020 without QC. Findings Include: Review of Throat Culture QC (Quality Control) policy and procedure revealed that QC is to be performed weekly. Review of the "Throat Culture Worksheet and Quality Control" documentation showed one patient was tested each day on 9/25/19, 9/27/19, and 9/28 /19. There was no documentation of QC performed the week of 9/23/19 or on 9/28/19. One patient was tested on 4/20/20 with no documentation of QC performed the week of 4/20/20. Two patients were tested on 4/30/20 and one patient tested on 5/1/20 with no documentation of QC for the week of 4/27/20. One patient was ran on 8/4/20 with no documentation of QC the week of 8/3/20. One patient was tested each day 9/28/20, 10/1/20, 10/5/20, and 10/7/20 with no documentation of QC performed between 9/21 /20 and 10/8/20. During an interview on 2/23/21 at 12:00 PM Testing Person #A confirmed that QC was missing.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on record review and staff interview, the facility's quality assessment procedure failed to detect omissions in the quality control testing for 5 weeks of testing in 2019 and 2020. The findings include: The record review of the "Monthly Lab Audit" for 8 /22/19-10/3/19 stated "throat culture controls handled appropriately". Review of quality control documentation showed QC was missing 9/25/19, 9/27/19, and 9/28/19. The record review of the "Monthly Lab Audit" for 3/7/20-6/1/20 stated "throat culture controls handled appropriately". Review of the quality control (QC) documentation showed QC was missing 4/13/20, 4/20/20, and 5/1/20. The record review of the "Monthly Lab Audit" for 6/2/20 - 8/18/20 stated "T/C (throat culture) controls handled appropriately." Review of the quality control documentation showed QC was missing 8/4/20. The record review of the "Monthly Lab Audit" for 8/18/20-10/22/20 stated "t/c controls zone not within range 3x". Review of the quality control (QC) documentation showed QC was missing 9/28/20, 10/1/20, 10/5/20, and 10/7/20. The interview with Testing Person A on 2/23/21 at 12:00pm, confirmed the QA program failed to detect the missing QC.