

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0909399	(X3) Date Survey Completed 09/05/2018
Name of Provider or Supplier Dawson Pediatrics Pc	Street Address, City, State 300 Dawson Commons Circle Suite 320, Dawsonville, GA	
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 Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on September ,05 2018. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor review of laboratory records and an interview with the clinic's laboratory coordinator (TP #1 CMS 209) and laboratory director , the laboratory failed to enroll in a CMS approved Proficiency Testing (PT) program for the speciality of Microbiology (Throat cultures). Findings include: 1.) A review of laboratory documents revealed that there was no enrollment in a CMS approved proficiency testing program for the years of 2017 and 2018 for the speciality of Microbiology (Throat cultures). 2.) An interview with the Clinic's laboratory coordinator (TP # 1, CMS 209) and the laboratory director at approximately 11:30 am, on September 05, 2018 in the review room confirmed that the laboratory was not enrolled in a CMS approved PT program</p>

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on maintenance document review, observation, and interview with the laboratory coordinator (TP # 1 CMS 209), the laboratory failed to perform and document maintenance as defined by the manufacturer. Findings include: 1. Upon initial tour of the laboratory, it was observed the Horizon centrifuge was last calibrated 11/10/2016. Next due date was suppose to be 11/10/2017. 2. An interview with TP #1 (CMS 209) at approximately 11:40 a.m. on September 05, 2018 in the breakroom confirmed that Horizon centrifuge calibrations was not performed nor documented on 11/10/2017.