

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0676736	(X3) Date Survey Completed 05/11/2022
Name of Provider or Supplier Gwinnett Pediatrics	Street Address, City, State 3790 Pleasant Hill Road, Suite 230, Duluth, 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 May 11., 2022. 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:
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on review of daily control logs and staff interview, the lab failed to document corrective actions when relative humidity (RH) exceeded acceptable limits (30% - 80%). Findings include: 1. Review of daily control logs: March 2020 and April 2021 reveals RH readings were out of range without corrective actions documented. 2. Interview with testing personnel #3 (CMS 209 form) on 5/11/22 at approximately 11:30 AM in the back,corner office, confirmed the corrective actions were not documented.</p>
D5791	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p>

(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 review of the laboratory Quality Assessment (QA) policy, monitor documents, temperature & humidity logs, and staff interview, the laboratory failed to follow the QA policy & procedures to correct errors. Finding include: 1. Review of the daily control logs of 2020 and 2021 reveals the relative humidity (RH) was out of range (30% - 80%) without corrective actions noted. RH was out of range 5 of 31 days in March 2020 and 5 of 30 days in April 2021. 2. Review of the QA monitors review for 1st quarter of 2020 and 2nd quarter of 2021 reveals the lab director noted : "The lab temperature and humidity were measured and recorded daily, refrigerator and freezer temperatures were measured in the morning and in the afternoon and fell with acceptable ranges". 3. Interview with staff #3 (CMS 209) in the back, corner office on 5/11/22 at approximately 1130 PM confirms the aforementioned statements.