

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0997580	(X3) Date Survey Completed 01/07/2020
Name of Provider or Supplier Georgetown Pediatrics	Street Address, City, State 416 Pirkle Ferry Road Suite 300 J, Cumming, 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 January 7, 2019. 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:
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on observation and staff interview, the laboratory failed to ensure protection from physical, chemical, and electrical hazards as required 1. Observation during the laboratory tour revealed fire extinguisher (Serial #027289) and fire extinguisher (Serial #994587) had not been inspected since January 8, 2018. 2. An interview with Staff #2 (CMS 209) in the hallway near the laboratory confirmed the lack of aforementioned fire extinguisher inspection since January 8, 2018.</p>
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</p>

reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
Based on temperature log review and staff interview, the laboratory failed to perform required corrective action for out of range temperatures for microbiology specimen incubation.. Findings include: 1. Microbiology Lab Line incubator temperature log review revealed out of range temperatures with no corrective action for the following dates: 2018 - June (17 of 21 days); July (17 of 21 days), December (9 of 17 days); 2019 - January (7 of 18 days), April (9 of 22 days).. 2. An interview with Staff #2 (CMS 209) in a medical office on 1/07/2020 at approximately 11:45 a.m. confirmed the lack of corrective action for the aforementioned out of range incubator temperatures for 2018 and 2019. .

D6029

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
Based on testing personnel (TP) document review and staff interview, the laboratory director/technical consultant (LD/TC) failed to ensure all TO have the required appropriate training prior to testing patients' samples for the type and complexity of the services offered. Findings include: 1. TP competency document review revealed the LD/TC failed to ensure an initial competency was performed for Staff #7 (CMS 209) and Staff #8 (CMS 209) in 2018. 2. An interview with Staff #2 (CMS 209) in a medical office on 1/7/2020 at approximately 11:00 a.m. confirmed the lack of aforementioned TP initial competency performance.

D6036

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413

The technical consultant is responsible for the technical and scientific oversight of the laboratory.

This STANDARD is not met as evidenced by:
Based on review of temperature logs and staff interview, the technical consultant /laboratory director (TC/LD) failed to provide required technical oversight over the laboratory. Findings include: 1. Lab Line incubator 2019 temperature log review revealed the TC/LD failed to perform a review of January through December temperature logs. 2. Lab Line incubator 2019 temperature log review revealed incubator temperatures were out of range for the following months with no corrective action: January (7 of 18 days) and April (9 of 22 days). 3. An interview with Staff #2

(CMS 209) in a medical office on 1/7/2020 at approximately 11:00 a.m. confirmed the lack of TC/LD review of 2019 incubator temperatures.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on testing personnel (TP) document review and staff interview, the technical consultant/laboratory director (TC/LD) failed to evaluate and document TP performance for moderate complexity testing at least annually after the first year. Findings include: 1. TP competency document review the TC/LD did not perform an annual competency for Staff #8 (CMS 209) in 2018 or 2019. 2. An interview with Staff #2 (CMS 209) in a medical office on 1/07/2020 at approximately 11:45 a.m. confirmed the lack of annual competencies in 2018 and 2019 for Staff # 8 (CMS 209).