

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0646021	(X3) Date Survey Completed 07/18/2022
Name of Provider or Supplier Oral & Maxillofacial Path Diag & Consultative Serv	Street Address, City, State 1430 John Wesley Gilbert Drive, Gc2164, Augusta, 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 July 18, 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:
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: A review of the procedure manual, training and competency assessment documents including staff interview (TP#3 CMS 209), the laboratory director failed to perform Competency Assessments for his staff in the specialty of Histopathology in 2020 to 2022. Findings include: 1.) Testing Personnel (TP) records review revealed competency assessments were not performed on (TPs # 2 and 3 CMS 209) in 2020, 2021 and 2022. 2.) An interview with the laboratory lead (TP#3 CMS 209) at approximately 11:30 AM on 07/18/2022 in the lab room confirmed the findings.</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>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 general laboratory systems requirements specified at 493.1231 through 493.1236.</p>

This STANDARD is not met as evidenced by:
Based on laboratory records review and staff interview, the laboratory failed to establish adequate quality assessment plan (QA) to monitor, assess, and correct problems in the laboratory as they occur. The laboratory did not have a written quality assessment policy that covers Pre-Analytic, Analytic and Post Analytic technical and non-technical functions of the lab. 1. The laboratory failed to have a QA policy to assess specimen identification and integrity, complaint investigations and personnel competency. 2. The laboratory does not have a written QA checklist for 2020, 2021 and 2022 at the time of survey. 3. An interview with lab lead (TP #3 CMS 209) on 07/18/2022 at approximately 12:45 PM in the lab room confirmed that the laboratory did not have a written and established QA policy for the laboratory.

D6022

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

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)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:
Based on Quality Assurance(QA) documents review and staff interview, the Lab Director(LD) failed to ensure that proper QA guidelines were established and followed to identify and fix problems in the laboratory as required by Clinical Laboratory Improvement Amendments (CLIA). Findings include: 1. (QA) documents review revealed the laboratory director did not establish adequate guidelines to identify and correct problems in the laboratory as they occur in 2020 thru date of survey 07/18/2022. 2. An interview with the lab lead (TP#3 CMS209) in the lab room on 07/18/2022, at approximately 12:00 PM, confirmed the LD did not have the aforementioned (QA) policy in 2020 thru the date of survey 07/18/2022.