

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D0954953	<b>(X3) Date Survey Completed</b> 01/29/2020
<b>Name of Provider or Supplier</b> C G Laboratories Inc	<b>Street Address, City, State</b> 1410 Southtown Drive, Granbury, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The QA/Audit Manager and Laboratory Director were at the entrance conference conducted 01/29/2020. The survey process was discussed. An opportunity for questions and comments was given. Exit conference was held with the QA/Audit Manager and Laboratory Director on 01/29/2020. The laboratory was found to be in substantial compliance for the specialties/subspecialties for which it was surveyed. The standard level deficiencies cited were discussed. The process for submitting the corrections was explained.
<b>D3009</b>	<p><b>FACILITIES</b> CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by: Based on review of test request form, bioburden testing report, and in interview with staff, the laboratory failed to obtain and possess California State licensure when specimens were received and tested from State of California (CA), as required. Findings included: 1. Review of the test request form included "Reporting Information: ... City: Fullerton; State: CA" and the specimens from this client were received by the laboratory on 12/26/2019. 2 Review of the Bioburden Testing Report included "Customer: ...Fullerton, CA..." and results for Sample ID Non-Sterile IOSG025 (01/28/2020). 3. During an interview on 01/29/2020 at 1:12 pm, the QA /Audit Manager was asked whether the laboratory obtained and possessed a California State license based on receiving and testing specimens from the State of California, she stated no. She reviewed the above findings and stated the client was fairly new.</p>
<b>D5317</b>	<p><b>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL</b> CFR(s): 493.1242(d)</p>

If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies, test request forms, and in interview with staff, the laboratory failed to implement written instructions for clients, who ship tissue and bone specimens to the laboratory for bioburden and sterility testing. Findings included: 1. During an interview on 01/29/2020 at 1:15 pm, the QA/Audit Manager was asked for the client services manual provided to clients to ensure proper storage, shipment, and stability of specimens, she stated the laboratory did not have one for clients. She stated the clients determine specimen handling. During an interview on 01/29/2020 at 12:08 pm, Testing Person - 2 (TP-2) was asked about the disposition of specimens when received into the laboratory, she stated specimens come in a box in room temperature conditions, with ice packs, or dry ice. She stated the customers determine how samples were shipped and stored and there was not a client services manual. She stated the laboratory stores the specimens in conditions in which they were shipped (room temperature, refrigerated, or frozen). She stated the disposition of the specimens are documented in their "LIMS" system ("room temperature, refrigerated, or frozen"). 2. Review of laboratory policies stated, "Receiving Laboratory Test Samples: 6.11. Samples containers should be...stored on the designated shelf in the Lab Department. Refrigerated samples will be stored on the designated shelf in the Lab refrigerator until testing commences" and in policy "Tissue and Bone Standard Operating Procedure: 7.1.4. The samples are stored in accordance with Customer's instructions as per 82070-548, CGL Tissue Test Request Form...7.1.7. Samples are stored properly until testing is ready to begin. " The stability of specimens in all storage conditions was not established and defined. 3. The laboratory did not ensure written instructions were available and provided to their clients to include the following (that are applicable), as required by 493.1242: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. The laboratory did not establish and define a "refrigerated" and "room temperature" range for specimen storage; and did not define stability for specimens stored in all conditions. (a)(5) Conditions for specimen transportation. The laboratory did not establish and define a "refrigerated" and "room temperature" range for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. 4. During an interview on 01/29/2020 at 3:00 pm, the QA/Audit Manager was asked what was the stability of specimens stored at room temperature, refrigerated and frozen conditions, she stated that is up to the customers, they determine the shelf-life of specimens. The laboratory did not have a defined stability for specimens stored in all conditions. 5. Random review of tissue test request forms and reports from 2018 and 2019 included the following bone and tissue samples: Sample #THB0698887, THB0698892, THB0698901, THB0698904 were packed on 01/10/2018 and received into the laboratory 01/11/2018 with "Storage Conditions at CGL: Frozen (-20 to -35C)." Bioburden testing was performed from 01/18/2018 through 01/22/2018. Sample # "RTX191006-003 TO RTX191006-024" were packed 03/11/2019 and received into the laboratory 03/12/2019 with "Storage Conditions at CGL: Room Temperature." Product Sterility Testing was performed from 03/20/2019 through 04/03/2019. Sample #Non-sterile IOSG025 was packed 06/05/2018 and received into the laboratory 06/05/2018 with "Storage Conditions at CGL: Room Temperature." Bioburden testing was performed from 06/21/2018 through 06/25/2018. Sample

#THB0903362, THB0903363, THB0898963, THB0898964, THB0898973, THB0898974, THB0903552, THB0903553, THB0903553, THB0903307, THB0903308, THB0903533, THB0903536, THB0896451, THB0896452, THB0903282, THB0903283 were packed 11/22/2019 and received into the laboratory 11/25/2019 with "Storage Conditions at CGL: Room Temperature." Bioburden testing was performed from 12/12/2019 through 12/16/2019. Sample #THB0906901, THB0906898, THB0906899, THB0906900 were packed 12/05/2019 and received into the laboratory 12/06/2019 with "Storage Conditions at CGL: Room Temperature." Bioburden testing was performed from 12/12/2019 through 12/16/2019. Room temperature and refrigerated did not include an established and defined acceptable range for shipping and storage. Stability for specimens in the above conditions was not established and defined to ensure maintenance of specimen integrity and accurate/reliable test results. 6. During a tour of the "Incubator Room" on 01/29/2020 at 1:30 pm, the following (sampling) specimens were observed to be stored in a freezer and at room temperature awaiting testing: Sample identifications - Cancellous: THB0921211, THB0921962; Cortical: THB0898427, THB0898428; Cortical/Cancellous: THB0921990, THB0921991; ST: THB0914337, THB0921338, Amnion Dual: THB0917176, THB0917177, THB0917178, THB0917179, THB0921214, THB0921215, THB0921216, THB0921217, THB0917192, THB0917193, THB0917194, THB0917195, BTB: THB0898439, THB0898440 - tissue test request form included packed date of 01/21/2020 and received into the laboratory 01/23/2020 with "Storage Conditions at CGL: Frozen (-20 to -35C)." The freezer in which these samples were stored was monitored, documented, and the range was consistent with the frozen range of -20 to -35C. The stability of the specimens in frozen conditions prior to testing was not defined. Sample identifications - THB0928589, THB0928590, THB0928579, THB0928578, THB0930007, THB0930008, THB0929961, THB0929962, THB0928596, THB0928597, THB0928580, THB0928581, THB0930009, THB0930010, THB0929970, THB0929971 - tissue test request form included packed date of 01/24/2020 and received into the laboratory 01/27/2020 with "Storage Conditions at CGL: Room Temperature." The room in which these samples were stored was not monitored and documented for temperature. The laboratory had not established and defined a "room temperature" range for acceptability. The laboratory had not defined all storage conditions and stability of samples tested in the laboratory to provide to their clients. 7. During an interview on 01/29/2020 at 3:15 pm, the QA/Audit Manager and the laboratory director confirmed the above findings.