

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0994686	(X3) Date Survey Completed 05/31/2023
Name of Provider or Supplier Tulane University Health Sciences Center	Street Address, City, State 1430 Tulane Avenue, 86-79, Room 6524, New Orleans, LA	
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 Certification survey was performed on May 31, 2023 at Tulane University Health Sciences Center, CLIA ID # 19D0994686. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5785	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's temperature logs and interview with personnel, the laboratory failed to document corrective actions performed when the room temperature was not maintained within acceptable limits per laboratory policy for seventy three (73) of 146 days reviewed. Findings: 1. Review of the laboratory's "Room 6515 Temp/Humidity/Eyewash" logs revealed the acceptable temperature range as 20-25 degrees Celsius and "For any measurements out of range record corrective actions." 2. Further review of the laboratory's "Room 6515 Temp/Humidity/Eyewash" logs revealed the room temperature was documented as outside of acceptable limits without corrective actions for the following seventy three (73) days: October 3, 2022 documented temperature of 19.7 degrees Celsius October 4, 2022 documented temperature of 19.7 degrees Celsius October 18, 2022 documented temperature of 19.9 degrees Celsius October 19, 2022 documented temperature of 19.2 degrees Celsius October 20, 2022 documented temperature of 19.7 degrees Celsius October 31, 2022 documented temperature of 19.9 degrees Celsius November 1, 2022 documented temperature of 19.9 degrees Celsius November 14, 2022 documented temperature of 19.7 degrees Celsius November 16, 2022 documented</p>

temperature of 19.7 degrees Celsius November 17, 2022 documented temperature of 19.9 degrees Celsius November 18, 2022 documented temperature of 19.7 degrees Celsius November 21, 2022 documented temperature of 17.9 degrees Celsius November 22, 2022 documented temperature of 18.0 degrees Celsius November 23, 2022 documented temperature of 18.7 degrees Celsius December 5, 2022 documented temperature of 19.7 degrees Celsius December 15, 2022 documented temperature of 19.7 degrees Celsius December 16, 2022 documented temperature of 19.5 degrees Celsius December 19, 2022 documented temperature of 19.8 degrees Celsius December 23, 2022 documented temperature of 17.7 degrees Celsius December 27, 2022 documented temperature of 19.4 degrees Celsius December 28, 2022 documented temperature of 18.7 degrees Celsius January 4, 2023 documented temperature of 19.6 degrees Celsius January 5, 2023 documented temperature of 19.4 degrees Celsius January 6, 2023 documented temperature of 19.1 degrees Celsius January 9, 2023 documented temperature of 17.6 degrees Celsius January 10, 2023 documented temperature of 18.9 degrees Celsius January 11, 2023 documented temperature of 19.0 degrees Celsius January 12, 2023 documented temperature of 19.1 degrees Celsius January 13, 2023 documented temperature of 19.2 degrees Celsius January 16, 2023 documented temperature of 18.6 degrees Celsius January 17, 2023 documented temperature of 19.1 degrees Celsius January 19, 2023 documented temperature of 19.8 degrees Celsius January 20, 2023 documented temperature of 19.3 degrees Celsius January 23, 2023 documented temperature of 18.7 degrees Celsius January 24, 2023 documented temperature of 19.2 degrees Celsius January 25, 2023 documented temperature of 19.5 degrees Celsius January 26, 2023 documented temperature of 19.1 degrees Celsius January 27, 2023 documented temperature of 19.0 degrees Celsius January 31, 2023 documented temperature of 19.8 degrees Celsius February 2, 2023 documented temperature of 19.8 degrees Celsius February 3, 2023 documented temperature of 19.3 degrees Celsius February 6, 2023 documented temperature of 19.2 degrees Celsius February 7, 2023 documented temperature of 19.8 degrees Celsius February 10, 2023 documented temperature of 19.8 degrees Celsius February 13, 2023 documented temperature of 18.5 degrees Celsius February 14, 2023 documented temperature of 19.3 degrees Celsius February 15, 2023 documented temperature of 19.5 degrees Celsius February 17, 2023 documented temperature of 19.7 degrees Celsius February 20, 2023 documented temperature of 19.2 degrees Celsius February 22, 2023 documented temperature of 19.8 degrees Celsius February 27, 2023 documented temperature of 19.7 degrees Celsius March 7, 2023 documented temperature of 19.8 degrees Celsius March 13, 2023 documented temperature of 19.7 degrees Celsius March 14, 2023 documented temperature of 19.7 degrees Celsius March 15, 2023 documented temperature of 19.7 degrees Celsius March 16, 2023 documented temperature of 19.8 degrees Celsius March 20, 2023 documented temperature of 18.4 degrees Celsius March 21, 2023 documented temperature of 18.7 degrees Celsius March 22, 2023 documented temperature of 18.8 degrees Celsius March 29, 2023 documented temperature of 19.3 degrees Celsius March 30, 2023 documented temperature of 19.0 degrees Celsius April 7, 2023 documented temperature of 19.5 degrees Celsius April 10, 2023 documented temperature of 19.8 degrees Celsius April 11, 2023 documented temperature of 19.6 degrees Celsius April 12, 2023 documented temperature of 19.8 degrees Celsius April 13, 2023 documented temperature of 19.5 degrees Celsius April 14, 2023 documented temperature of 19.6 degrees Celsius April 17, 2023 documented temperature of 18.1 degrees Celsius April 18, 2023 documented temperature of 19.5 degrees Celsius April 19, 2023 documented temperature of 19.2 degrees Celsius April 24, 2023 documented temperature of 18.9 degrees Celsius April 25, 2023 documented temperature of 18.7 degrees Celsius April 26, 2023 documented temperature of 19.6 degrees Celsius 3. In interview on May 31, 2023 at 3:15 pm, the General Supervisor confirmed the

	<p>laboratory did not have documentation of performance of corrective actions for unacceptable temperatures for the identified days.</p>
D6096	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7)</p> <p>The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D5785.</p>
D6103	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13)</p> <p>The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Refer to D6126.</p>
D6126	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(vi)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, competency assessment records, and interview with personnel, the Technical Supervisor failed to document the competency assessment of problem solving skills for one (1) of two (2) Testing Personnel in 2022. Findings: 1. Review of the laboratory's "Verification of Personnel Competency and Assessment of Problem Solving Skills" policy revealed the following: " All employees are assessed of their abilities to solve problems that could arise. An on-going assessment of problem-solving skills. This can be achieved by: Asking the employee to write up a situation where they had to solve a problem that was encountered in the laboratory and asking the employee how he or she would handle the situation. Should the need arise the employee will use the Corrective Action Form to document the identified disparity and how it was resolved. The Supervisor may create quizzes for to {sic} assess problem solving skills. The supervisor will go over the quizzes and discuss the responses. The Supervisor will</p>

document all of the assessments using the Annual Performance/Competency Checklist, New Employee Evaluation Checklist and Corrective Action Forms." 2. Review of the 2022 competency assessment records for the General Supervisor, who also serves as Testing Personnel, revealed the competency assessment forms for his testing personnel duties did not include problem solving skills as a task that is assessed annually. 3. In interview on May 31, 2023 at 3:15 pm, the General Supervisor stated corrective actions are documented in the corrective action log. The General Supervisor confirmed corrective actions or problem solving actions performed by him in 2022 were not included and documented by the Technical Supervisor as part of his annual competency assessment.