

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  16D2271107	<b>(X3) Date Survey Completed</b>  08/16/2024
<b>Name of Provider or Supplier</b>  Goldfinch Laboratory	<b>Street Address, City, State</b>  4637 121st St, Urbandale, IA	
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>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> 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: Based on review of the Quality Control procedure and confirmed by laboratory personnel identifier # 2 (refer to the Laboratory Personnel Report) at 10:31 am on 8/16 /2024, the laboratory failed to follow written policies and procedures for documenting competency for four out of eight laboratory personnel in 2023. The findings include: 1. The Quality Control procedure stated, "Yearly reviews will be performed to assess the employee's performance and noted what needs to be worked on for pre-analytic and post-analytic parts of the job duties." 2. Laboratory personnel identifier #1 fulfilled the responsibility of laboratory director, general supervisor and read histopathology slides. 3. Laboratory personnel identifier #3 fulfilled the responsibility of technical supervisor and read histopathology slides. 4. Laboratory personnel identifiers #4 and #5 fulfilled the responsibility of clinical consultant and read histopathology slides. 5. At the time of the survey, the laboratory did not have documented competency assessments for the above laboratory personnel.</p>
<b>D5217</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of the Laboratory Test List and Annual Volume form and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at 11:17 am on 8/16/2024, the laboratory failed to verify the accuracy for reading biopsy slides twice annually for three out of three time periods from 1/1/2023 - 8/16/2024 . The findings include: 1. The laboratory prepared and read biopsy slides using hemotoxylin and eosin, immunohistochemical, in situ hybridization, and special stains. 2. At the time of the survey, the laboratory had not verified the accuracy twice annually for the above testing.

**D6168**

TESTING PERSONNEL  
CFR(s): 493.1487

The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.

This CONDITION is not met as evidenced by:  
Based on review of laboratory personnel records and confirmed by laboratory personnel identifier #2 at 10:31 am on 08/16/2024, the laboratory failed to meet the testing personnel requirements by providing documentation to qualify the testing personnel who perform high complexity testing as specified in standard D6171.

**D6171**

TESTING PERSONNEL QUALIFICATIONS  
CFR(s): 493.1489(b)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory

Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Based on review of laboratory personnel records and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at 10:31 am on 08/16/24, the laboratory failed to ensure one out of eight testing personnel met the educational requirements to perform high complexity testing. The findings include: 1. Laboratory personnel identifier #2 performed grossing of tissues, which is consider high complexity testing. 2. Laboratory personnel identifier #2 did not meet the minimum semester hours required to perform high complexity testing.