

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D2197346	(X3) Date Survey Completed 07/23/2025
Name of Provider or Supplier Pathology Services, Pc	Street Address, City, State 497 West 4800 South, Suite 201, Murray, UT	
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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation and interview with the General Supervisor, the laboratory failed to ensure that the tissue marking dyes were not used past the expiration date. Findings Include: 1. Direct observation of Cancer Diagnostics tissue marking dyes revealed the red tissue marking dyes, lot numbers 23093 and 23058, had an expiration date of 2025-4-30 and 2025-2-28, the blue tissue marking dye, lot number 23054, had an expiration date of 2025-02-28, the black tissue marking dye, lot number 23117, had an expiration date of 2025-4-30, the green tissue marking dye, lot number 23124, had an expiration date of 2025-5-31, the yellow tissue marking dye, lot number 23094, had an expiration date of 2025-4-30 at 1:30 PM on 7/23/2025. 2. Interview with the General Supervisor at 1:30 PM on 07/23/2025 confirmed the tissue marking dyes were used for patient testing past the expiration date. 3. The laboratory performs approximately 20,000 Histopathology grossing specimens per year.</p>
D6107	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15)</p> <p>(e)(15) Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.</p>

This STANDARD is not met as evidenced by:
Based on lack of documentation and interview with the General Supervisor, the laboratory director failed to delegate, in writing, the duties and responsibilities of the Technical Supervisor (TS) and the General Supervisor (GS). Findings: 1. Record review revealed the laboratory lacked documentation of delegation of duties and responsibilities for the TS and the GS. 2. Interview with General Supervisor at 2:00 PM on 7/23/2025 that confirmed lack of written delegation of duties and responsibilities for the TS and GS. 3. The laboratory performs approximately 20,000 histopathology grossing tests annually.

D6120

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(7)(8)

(b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
Based on review of competency documentation and interview with the General Supervisor (GS), the laboratory failed to evaluate competency for Histopathology grossing for 2 out of 2 Testing Personnel (TP) . Findings include: 1. A laboratory record review revealed lack of competency documentation for Histopathology grossing for the year 2023 for 2 out of 2 TP. 2. Interview with GS on 7/23/2025 at approximately 12:00 p.m. confirmed that the lab failed to document competency for Histopathology grossing for the year of 2023 for 2out of 2 TP. 3. The laboratory performs approximately 20,000 Histopathology grossing specimens per year.

D6141

GENERAL SUPERVISOR
CFR(s): 493.1459

The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart.

This CONDITION is not met as evidenced by:
Based on record review and interview with the General Supervisor, the laboratory failed to provide documents to show qualifications for the General Supervisor. (See D6143)

D6143

GENERAL SUPERVISOR QUALIFICATIONS
CFR(s): 493.1461

(a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The general supervisor must be qualified as a-- (b)(1) Laboratory director under 493.1443; or (b)(2) Technical supervisor under 493.1449. (c) If the requirements of paragraph (b)(1) or (2) of this section are not met, the individual functioning as the general supervisor

must-- (c)(1)(i) 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, biological, clinical or medical laboratory science, or medical technology from an accredited institution; and (c)(1)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or (c)(2)(i) Qualify as testing personnel under 493.1489(b)(3); and (c)(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or (c)(3) Meet the requirements at 493.1443(b)(3) or 493.1449(c)(4) or (5); or (c)(4) Notwithstanding any other provision of this section, an individual is considered qualified as a general supervisor under this section if they were qualified and serving as a general supervisor in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (d) For blood gas analysis, the individual providing general supervision must-- (d)(1) Be qualified under 493.1461(b)(1) or (2), or 493.1461(c); or (d)(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (d)(2)(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or (d)(3) (i) Have earned an associate degree related to pulmonary function from an accredited institution; and (d)(3)(ii) Have at least two years of training or experience, or both in blood gas analysis. (e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed: (e)(1) In histopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or (f)(1); (e)(2) In dermatopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(f)(2); (e)(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(f)(3); and (e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or (g).

This STANDARD is not met as evidenced by:

Based on lack of documentation and interview with the General Supervisor, the laboratory failed to provide documentation to show qualifications for the General Supervisor. Findings Include: 1. Personnel qualification records review failed to include documentation for experience for the GS to qualify as a high complexity General Supervisor. 2. In an interview with the GS at 1:25 PM on 7/23/2025 revealed that the laboratory did not have the proper documentation to show qualifications for experience for the GS role.