

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0975234	(X3) Date Survey Completed 08/10/2026
Name of Provider or Supplier Tri-Cities Skin & Cancer	Street Address, City, State 1009 N State Of Franklin Access Rd, Johnson City, TN	
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	During a recertification survey performed on August 10, 2026, the laboratory was found out of compliance with the following conditions: D6168 42 C.F.R. 493.1487 Condition: Laboratories performing high complexity testing; Testing Personnel
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) (e)(12) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results; This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report (CLIA) (Form CMS-209), lack of records, and interview with testing personnel three (TP3), the laboratory director failed to ensure testing personnel four (TP4) had been evaluated and demonstrated accuracy before performing grossing of patient tissue removed during histopathology procedures, with approximately 800 cases done since TP4 began testing on 05.18.2026 until the date of the survey on 08.10.2026. The findings include: 1. Review of the Form CMS-209 revealed that TP4 was listed as a high complexity testing person. 2. No record of documented evaluation of competency or accuracy of test performance for grossing of patient tissue samples removed during histopathology procedures for TP4 by the laboratory director. 3. Interview on 08.10.2026 at 12:15 p.m. with TP3 confirmed the above survey findings. A subsequent interview via electronic communication on 08.18.2026 at 1:34 p.m. confirmed that TP4 performed approximately 800 grossing procedures from 05.18.2026 to the survey date, 08.10.2026.
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 a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report (CLIA) (Form CMS-209), review of education documents, and staff interview, testing personnel five (TP5) did not qualify as a high-complexity testing person (Refer to 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 (b)(2)(i) 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; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or (b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or (b)(3)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii)(A) (A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or (b)(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or (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. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, review of testing personnel education

documents, and staff interview, testing personnel number five (TP5) listed on the Centers for Medicare and Medicaid Services Laboratory Personnel Report (CLIA) (Form CMS-209) failed to meet the high complexity regulatory education requirements for performing grossing of tissue removed during histopathology procedures, with approximately 1500 grossing procedures performed from 03.09.2026 through the survey date of 08.10.2026. The findings include: 1. Observation of the laboratory on 08.10.2026, at 9:30 a.m., revealed one grossing station in use for histopathology testing procedures. 2. Review of education documents revealed that TP5 did not meet the minimum education requirements for performing high complexity testing for grossing of tissue removed during histopathology procedures. 3. Interview on 08.10.2026 at 12:15 p.m. with TP3 confirmed the above survey findings. A subsequent interview via electronic communication with TP3 on 08.18.2026 at 1:34 p.m. confirmed that TP5 performed approximately 1500 grossing procedures from 03.09.2026 to the survey date, 08.10.2026.