

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2057348	(X3) Date Survey Completed 01/08/2025
Name of Provider or Supplier Cockerell Dermatopathology, Pa	Street Address, City, State 2110 Research Row, Dallas, TX	
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	The facility was found to be out of compliance with CLIA regulations 42 CFR Part 493. CONDITION LEVEL DEFICIENCIES were found to be out of compliance: 493.1487 Testing Personnel, high complexity
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory Daily Microtome/Water Bath Maintenance Logs and confirmed in interview, the laboratory failed to document corrective action when one of seven water bath temperature ranges were not within the laboratory's specifications for 149 of 221 days in 2024 and four of four days in 2025. Findings included: 1. Review of the laboratory's "Daily Microtome/Water Bath Maintenance Log" for Water Bath #3 (Serial # A170536) from January 2024 through January 2025 revealed the laboratory had an established acceptable temperature range the water bath of 43C to 48C. Further review of the laboratory's Daily Microtome/Water Bath Maintenance Logs revealed 149 of 221 days in 2024 and four of four days in 2025 when the water bath temperature was out of the laboratory's acceptable range of 43C to 48C and no corrective action was documented. The following was a random sampling of those readings: 01/02/2024: 39C 01/03/2024: 39C 01/08/2024: 39C 02/13/2024: 39C 02/14</p>

/2024: 40C 02/15/2024: 39C 03/04/2024: 40C 03/05/2024: 40C 03/06/2024: 40C 04/08/2024: 42C 04/09/2024: 42C 04/10/2024: 40C 07/15/2024: 50C 07/16/2024: 50C 07/17/2024: 50C 08/19/2024: 50C 08/20/2024: 50C 08/21/2024: 50C 09/23/2024: 50C 09/24/2024: 50C 09/25/2024: 50C 10/07/2024: 50C 10/08/2024: 50C 10/09/2024: 50C 11/20/2024: 50C 11/21/2024: 50C 11/22/2024: 50C 12/09/2024: 50C 12/10/2024: 50C 12/11/2024: 50C 01/02/2025: 50C 01/03/2025: 50C 01/06/2025: 50C 01/07/2025: 50C 2. During an interview on 01/08/2025 at 1:14 p.m., the laboratory representatives after a review of records, confirmed the laboratory failed to document corrective action when water bath #3 temperature ranges were not within the laboratory's specifications for 149 of 221 days in 2024 and four of four days in 2025. Word Key: C- Celsius

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 policy, CMS (Centers for Medicare and Medicaid Services) 209 form, personnel records, and interview with staff, the laboratory failed to ensure 1 of 13 testing persons (TP-13) met the requirements to perform high complexity testing. 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 review of laboratory policy, CMS (Centers for Medicare and Medicaid Services) 209 form, personnel records, and interview with staff, the laboratory failed to ensure 1 of 13 testing persons (TP-13) met the requirements to perform high complexity testing. Findings included: 1. Review of laboratory policy titled "POLICY FOR CLIA PERSONNEL QUALIFICATIONS" (approval date 10/30/17) revealed: "POLICY FOR CLIA PERSONNEL QUALIFICATIONS ... II. DEFINITIONS ... F. Testing Personnel: Individual qualified to perform and report test results for moderate and/or high complexity testing. (42 CFR 493.1423 and 493.1489) ... III. PROCEDURE A. The laboratory must maintain documentation to confirm that each employee's qualifications meet CLIA regulatory requirements. B. Qualifications must be evaluated at the highest level of academic achievement related to the practice of laboratory medicine. C. Refer to Addenda A for specific CLIA personnel requirements based on testing complexity and laboratory positions. D. All of the above minimum personnel qualifications must be reviewed and reapproved whenever a change in position or job classification occurs. ADDENDA A SUMMARY OF CLIA REGULATIONS FOR PERSONNEL ... Testing Personnel (High Complexity) 42 CFR 493.1489 EDUCATION Licensed MD, DO, DPM or Doctoral*, Masters**, Bachelors** Associate Degree*** TRAINING/EXPERIENCE N/A BOARD CERTIFICATION OR ELIGIBILITY N/A EDUCATION 60 Semester Hours with specified distribution requirements TRAINING/EXPERIENCE ABHES, CAHEA or other HHS approved program or 3 months training in high complexity testing in applicable specialty/subspecialty BOARD CERTIFICATION OR ELIGIBILITY N/A EDUCATION On or before 02/28/1992, previously qualified under 42 CFR 493.1491 TRAINING/EXPERIENCE N/A BOARD CERTIFICATION OR ELIGIBILITY N/A EDUCATION H.S. graduate or equivalent on or before 4/24/1995 TRAINING /EXPERIENCE ABHES/CAHEA or other HHS approved program or 50 week Military Training with position as Medical Laboratory Specialist BOARD CERTIFICATION OR ELIGIBILITY N/A EDUCATION Until 9/1/1997, be a high school graduate or equivalent TRAINING/EXPERIENCE Documentation of Skills BOARD CERTIFICATION OR ELIGIBILITY N/A LEGEND: * Doctoral degree in a chemical, physical, biological or clinical laboratory science. ** Masters or Bachelors [sic] degree in a chemical, physical, biological or clinical laboratory science, medical laboratory technology or cytotechnology. *** Associate Degree in a chemical, physical, biological science or medical laboratory technology. **** Experience in High Complexity Testing within each Specialty or Subspecialty with the exception of those with special requirements. ***** Individuals who successfully passed the HHS proficiency examination given between 03/01/1986 and 12/31/1987, qualify if requirements of 42 CFR 493.1462, were met on or before 01/01/1994" 2. Review of the CMS-209 form listed TP-13 as performing high complexity testing. 3. Review of personnel records for TP-13 included three college transcripts. The educational documents did not meet the qualifications for serving as a high

complexity testing person. The laboratory was asked to provide additional educational documents on 01/08/2025 at 10:35 a.m., and none were provided. 4. During an interview on 01/08/2025 at 10:40 a.m., the Laboratory Manager stated there were no additional educational documents to qualify TP-13 to perform high complexity testing. This confirmed the laboratory failed to ensure 1 of 13 testing persons met the requirements to perform high complexity testing.