

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 41D2285652	(X3) Date Survey Completed 01/13/2026
Name of Provider or Supplier Coastal Derm & Cosmetic Center (Cranston)	Street Address, City, State 750 Reservoir Ave, Cranston, RI	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES 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 record review and interview with the laboratory director (LD), the laboratory failed to establish written procedures for performing personnel competency assessment for Potassium Hydroxide (KOH) and Scabies testing. Findings include: 1. Record review on 01/13/2026 of the laboratory's procedure manual signed by the laboratory director on 07/17/2025 revealed there was no procedure for competency assessment of testing personnel who perform KOH and Scabies testing. 2. Interview on 01/13/2026 with the LD at 12:30 PM revealed, "We do not have a procedure for KOH and Scabies competency assessment." 3. Record review on 01/13/2026 of the laboratory's competency records revealed a lack of documentation for competency assessment of Scabies for 4 of 4 testing personnel for 2024 and 2025. 4. The laboratory performs 100 tests in the specialty of Microbiology annually.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on record review and interview with the laboratory director (LD), the laboratory failed to follow their approved "Cryostat Temperature and Daily Maintenance" procedure for 2 of 2 cryostats in 2024 and 2025. Findings include: 1. Record review on 01/13/2026 of the laboratory's "Cryostat Temperature and Daily Maintenance" procedure revealed, "Oiling is done per manufacturer's recommendation. See equipment manual" 2. Record review on 01/13/2026 of the Leica CM1850 and Leica CM1860 Cryostat Instruction Manuals revealed lubrication of the plastic couplings and specimen cylinders with a drop of cryo oil are required to be done weekly. 3. Record review on 01/13/2026 of the laboratory's "Cryostat Maintenance and Temperature Record (Cryostat QC)" log revealed the laboratory performed the required maintenance referenced in 2 above only one time between August 2024 and December 2025 for 2 of 2 cryostats. 4. Interview with the LD on 01/13/2026 at 12:30 PM confirmed the maintenance procedures were not followed. The LD stated, "They oil the cryostats as needed. They do not do it weekly." 5. The laboratory performs 250 tests annually in the specialty of Pathology.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(11)

(e)(11) 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 lack of documentation, record review and staff interview, the laboratory director failed to ensure training was documented for new testing personnel (TP) in 2025 for potassium hydroxide (KOH) and Scabies testing. Findings include: 1. Record review on 01/13/2026 of the laboratory's 2024 CMS-209 form compared with the 2026 CMS-209 form revealed 1 new TP. 2. Record review on 01/13/2026 of the laboratory's TP records revealed a lack of training documentation for the performance of KOH and Scabies testing for the new TP noted in 1 above. 3. Staff interview on 01/13/2026 at 12 PM with the laboratory director revealed the new TP was hired 06/03/2025 and confirmed training for them was not documented. The LD stated, "They were trained, but we did not document it." 4. The laboratory performs 100 Microbiology tests annually.