

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D1045493	(X3) Date Survey Completed 08/25/2025
Name of Provider or Supplier Nashville Skin And Cancer Plc	Street Address, City, State 2301 21st Ave S, 2nd Floor, Nashville, 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
D5779	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(a)</p> <p>(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory procedure manual, laboratory temperature records, patient test reports, and staff interviews, the laboratory failed to follow the procedure for corrective action when the laboratory did not document corrective action for temperatures recorded outside of the acceptable range for the Cryostat instruments used to process patient tissue samples used for histopathology testing removed during micrographic oriented histopathology surgery (Mohs) procedures for 12 of 20 months reviewed in 2024 and 2025. The findings include: 1. Observation of the laboratory on 08/25/2025 at 10:30 a.m. revealed the Avantik QS11 and QS12 Cryostat instruments used to process patient tissue samples removed during Mohs procedures for histopathology testing. 2. A review of the laboratory procedure titled "Quality Management Program" in the section titled "Cryostat Quality Control Policy" revealed "The acceptable temperature range is -20 to -35C. Should the temperature be outside of this range, the laboratory technician will notify the Laboratory Director. The corrective action and the result of the corrective action will be documented in the Comments section of the Cryostat Quality Control Log." 3. A review of the laboratory's "Cryostat Quality Control Log" records revealed that the laboratory recorded Cryostat temperatures of -36C and did not document corrective action on the following dates: February 2024: 02/01, 02/13, and 02/20 (three of fifteen dates used) May 2024: 05/17 and 05/21 (two of twenty-one dates used) June 2024: 06/06 and 06/18 (two of twenty dates used) July 2024: 07/15, 07/16, and 07/17 (three of twenty dates used) August 2024: 08/21 and 08/30 (two of twenty-two dates used) September 2024: 09/03, 09/05, 09/17, 09/18, 09/19, 09/20,</p>

and 09/24 (seven of nineteen dates used) January 2025: 01/07 (one of twenty-one dates used) March 2025: 03/06, 03/07, and 03/20 (three of twenty dates used) April 2025: 04/02, 04/10, 04/15, 04/18, and 04/24 (five of twenty dates used) May 2025: 05/01, 05/08, 05/15, 05/19, 05/21, and 05/28 (six of seventeen dates used) June 2025: 06/03, 06/05, and 06/30 (three of nineteen dates used) July 2025: 07/07 and 07/15 (two of eighteen dates used) 4. A review of patient test reports revealed the following patients had Mohs procedures performed, and the laboratory used the Cryostat instruments to process the patient tissue samples: 09/18/2024: Patient H24-724 02/16/2024: Patient H24-70 07/15/2025: Patient B25-1008 5. The survey findings were confirmed by an interview with the laboratory director, office manager, and laboratory personnel on 08/25/2025 at 12:00 p.m. Word Key: - degrees C- Celsius