

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2119620	(X3) Date Survey Completed 08/13/2024
Name of Provider or Supplier Tru North Dermatology	Street Address, City, State 315 Oak Grove St, Manistee, MI	
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 Mohs Technician, the laboratory failed to establish competency assessment policies to assess staff competency. Findings include: 1. A record review of the laboratory's policies and procedures revealed that laboratory did not have a competency assessment policy. 2. An interview with Mohs Technician on 08/13/2024 at 4:30 pm confirmed that the laboratory did not establish a competency assessment policy.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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 observation, record review, and interview with the Mohs technician, the laboratory failed to ensure that 1 of 1 bottles of Potassium Hydroxide (KOH) 10% reagent was not used beyond the expiration date. Findings include: 1. The surveyor observed 1 bottle of Potassium Hydroxide (KOH) 10% reagent on 08/13/2024 at 1:15 pm with an expiration date of 3/31/2024. 2. Record review of patient testing reports revealed 1 patient (patient #1) had KOH prep performed on 6/3/2024. 3. An interview</p>

with Mohs Technician on 8/13/24 at 4:30 pm confirmed the KOH prep testing for patient #1 was performed with the expired KOH reagent currently available for use in the laboratory.