

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0858935	(X3) Date Survey Completed 12/18/2025
Name of Provider or Supplier Base Of The Bays Dermatology, Pc	Street Address, City, State 3950 Shore Road, Williamsburg, 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 the laboratory director, the laboratory failed to follow competency assessment policies to ensure testing personnel were competent to perform Potassium Hydroxide (KOH) preparations for one (2024) of two years reviewed. Findings include: 1. A review of the laboratory's Form CMS-209 revealed the laboratory director serves all regulatory roles for the laboratory and is the only testing personnel. 2. A review of the laboratory's "Potassium Hydroxide (KOH) Examination" policy revealed a section titled "Quality Control" stating, "The laboratory director will maintain proficiency by completing testing by the Michigan Dermatological Society twice yearly." 3. A review of the testing personnel's Michigan Dermatological Society Provider-Performed Microscopy assessments revealed a lack of assessments performed in 2024. 4. An interview on 12/18/25 at 2:45 pm with the laboratory director confirmed Michigan Dermatological Society Provider-Performed Microscopy assessments were not performed in 2024.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by:</p>

. Based on record review and interview with the laboratory director, the laboratory failed to verify the accuracy of its Potassium Hydroxide (KOH) preparation testing at least twice annually for one (2024) of two years reviewed. Findings include: 1. A review of the laboratory's "Potassium Hydroxide (KOH) Examination" policy revealed a section titled "Quality Control" stating, "The laboratory director will maintain proficiency by completing testing by the Michigan Dermatological Society twice yearly." 2. A review of the testing personnel's Michigan Dermatological Society Provider-Performed Microscopy assessments revealed a lack of assessments performed in 2024. 3. An interview on 12/18/25 at 2:45 pm with the laboratory director confirmed Michigan Dermatological Society Provider-Performed Microscopy assessments were not performed in 2024.

D5433

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(b)(1)

(b)(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section.

This STANDARD is not met as evidenced by:
. Based on observation, record review, and interview with the laboratory director, the laboratory failed to perform microscope maintenance in accordance with the laboratory's established maintenance protocol for two (December 2023 to December 2025) of two years reviewed. Findings include: 1. The surveyor observed the laboratory's microscope on 12/18/25 at 1:10 pm. The microscope had a sticker from "Toby's Inst. Shop INC" with the date serviced of 10/27/21. 2. A review of the laboratory's "Equipment Quality Control- Microscope" policy revealed a section stating, "Microscope stage and ocular eye pieces are to be cleaned every six months. Annually by Toby's." 3. A review of the laboratory's "Maintenance Record- Microscope" revealed the last date the microscope was cleaned by the laboratory was 10/16/24. 4. A review of the laboratory's invoice from Toby's Instrument Shop Inc confirmed the last annual service was performed on 10/27/21. 5. An interview on 12 /18/25 at 2:36 pm with the laboratory director confirmed the above findings.