

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D0496518	<b>(X3) Date Survey Completed</b>  11/03/2022
<b>Name of Provider or Supplier</b>  Baytown Dermatopathology Laboratory	<b>Street Address, City, State</b>  3730 Emmett Hutto Blvd, Baytown, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	<p>Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the CMS Southern Operations Branch-Dallas for referral to the Office of Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.</p>
<b>D5217</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> 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: Based on review of the laboratory's submitted test menu, review of laboratory's test accuracy verification records for 2021 and 2022, and staff interview, it was determined the laboratory failed to verify at least twice annually the accuracy of Skin Scraping in Mineral Oil microscopy (used in identification of parasites for diagnosis of scabies), one of four tests performed by the facility. Findings included: 1. Review of the laboratory's submitted test menu revealed the laboratory performed Skin Scraping in Mineral Oil microscopy used in identification of parasites for diagnosis of scabies, one of four tests performed by the facility. 2. Review of laboratory's test accuracy verification records for 2021 and 2022 revealed there was no documentation of test accuracy verification for the Skin Scraping in Mineral Oil microscopy. 3. In an</p>

interview on 11/03/2022 at 0950 hours in the breakroom, the facility's Office Manager confirmed the findings.

**D5221**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**  
CFR(s): 493.1236(d)

All proficiency testing evaluation and verification activities must be documented.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's submitted test menu, review of laboratory's twice annual test accuracy verification records for 2021 and 2022, and staff interview, it was determined the laboratory failed to document evaluation of its twice annual test accuracy verification for three of four tests performed by the laboratory. Findings included: 1. Review of the laboratory's submitted test menu revealed the laboratory performed the following procedures: Wet Mount with KOH Skin Scraping in Mineral Oil Culture Histopathology slide interpretation 2. Review of laboratory's twice annual accuracy verification records for 2021 and 2022 revealed test accuracy verification was performed as follows: a. KOH 2021: 01/05/2021 07/08-07/12/2021 2022: 01/03 /2022 07/06-07/08/2022 b. Culture 2021: 01/05/2021 07/07-07/13/2021 2022: 01/03-01/04/2022 07/13-07/18/2022 c. Histopathology slide interpretation 2021: Each month, or at least every 100 cases. 2022: Each month, or at least every 100 cases. d. Skin Scraping in Mineral Oil did not have twice annual test accuracy verification performed. Refer to D5217. 3. Review of the above accuracy verification records revealed the laboratory did not document evaluation of the twice annual test accuracy verification studies (who performed the evaluation, or whether the obtained results were acceptable). 4. In an interview on 11/03/2022 at 0950 hours in the breakroom, the facility's Office Manager, after review of the data, confirmed the findings.

**D5429**

**MAINTENANCE AND FUNCTION CHECKS**  
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's microscopes manufacturer instructions for use, review of laboratory's equipment maintenance records, review of laboratory's submitted Form 116 and staff interview it was determined the laboratory failed to document manufacturer required maintenance for 2 of 2 microscopes in use. Findings included: 1. Review of the laboratory's microscopes' manufacturer instructions for use revealed: a. Olympus BX40 System Microscope Instructions, Quality Assurance Manual, section "Important": "2. Care and Frame 1. Clean lenses by wiping lightly with gauze. To remove fingerprints or other oils, dampen the gauze with a very small quantity of a 7 parts ether / 3 parts alcohol solution, or with Xylol." b. Olympus Model BHS System Microscope, Instructions (document AX5142), section "Important": "Maintenance 1. Lenses must always be kept clean. Carefully wipe off oil or fingerprints deposited on the lens surfaces with gauze moistened with a small amount of xylene, alcohol or ether." 2. Review of laboratory's equipment maintenance records revealed the laboratory performed microscope Preventive Maintenance once a year. Preventive maintenance was documented with a date for both microscopes at

once, without differentiation of either microscope model, or steps taken during the process. There was no documentation of cleaning the lenses. 3. Review of laboratory's submitted Form 116 revealed the laboratory performed yearly evaluation of 1019 histology cases on the Olympus Model BHS System Microscope, and 1075 microbiology tests on the Olympus BX40 System Microscope. 4. In an interview on 11/03/2022 at 1055 hours in the breakroom, the facility's Office Manager and Laboratory Director both stated that the microscopes' lenses were cleaned, but that it was not documented. This confirmed the findings.