

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1098824	(X3) Date Survey Completed 12/05/2022
Name of Provider or Supplier Collier Boulevard Hma Physician Management Llc	Street Address, City, State 8340 Collier Blvd Ste 406, Naples, FL	
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
D0000	<p>An announced recertification survey was conducted 11/17/22 through 12/5/22 at Collier Boulevard HMA Physicians Management LLC , a clinical laboratory in Naples, Florida. Collier Boulevard HMA Physicians Management LLC is not in compliance with Code of Federal Regulations (CFR) 42, Part 493, Laboratory Requirements due to the survey completed in conjunction. The following is description of the Standard-level deficiency.</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: Based on record review and interview with the histotechnologist, the laboratory failed to verify the accuracy of testing twice a year for 2 out of 2 years (2021-2022) reviewed for the subspecialties of Mycology (Fungi), Virology (Tzanck for herpes) and histopathology (hematoxylin and eosin stain). The findings included: Review of records for verification of the accuracy of Fungi and Tzanck testing twice a year revealed that the Testing Person #A performed one "American Osteopathic College of Dermatology Dermatologic Laboratory Quality Assurance and Proficiency Testing Program" for Tzanck preparations and potassium hydroxide (KOH). Certificate was issued December 31, 2020. Review of records for verification of the accuracy of histopathology testing twice a year revealed that Testing Person #A performed one "American Osteopathic College of Dermatology Dermatologic Laboratory Quality Assurance and Proficiency Testing Program which testing included evaluation of Mohs (micrographic surgery) slides to include evaluation for both positive and negative margins of various types of cutaneous tumors in addition to the recognition of normal anatomical structures". Certificate was issued December 31, 2020 and Testing Person #A completed educational activity titled "2021 American College of</p>

Mohs Surgery Virtual Annual Meeting" . Statement of Credit was issued August 8/15 /21. Review of the procedure "Proficiency Testing for MOHS surgeon revealed that "For tests that are not subject to proficiency testing in the CLIA (Clinical Laboratory Improvement Amendment) regulations, the laboratory must establish the accuracy and reliability of its test procedures at least twice a year through alternate means. This includes the tests performed at Tzanck smears/ KOH preparations." Review of the "MOHS QA(quality assurance)/QC(quality control" procedure signed and dated by laboratory director on 09/03/2020 revealed "2. On an annual basis....will send a random selection of slides to and [sic] outside pathologist for audit. 3. The outside pathologist will send back the slides and results to the MOHS surgeon for any remedial action, if necessary. 4. Alternative, the MOHS surgeon will take proficiency courses offered;". On 11/17/22 at 9:30 a.m., during a telephone interview the histotechnologist confirmed and stated the laboratory had not verified the accuracy of testing for fungi and herpes from 2021 - 2022 because the laboratory had not performed fungi or herpes testing since 2020 and she thought the histopathology verification of accuracy only had to be performed annually.