

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0370319	(X3) Date Survey Completed 08/23/2022
Name of Provider or Supplier Grosse Pointe Dermatology	Street Address, City, State 16815 E Jefferson Suite 260, Grosse Pointe, 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
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the laboratory liaison (LL), the laboratory failed to evaluate hematoxylin and eosin (H&E) staining materials for intended reactivity each day of use for 6 (LB21-0976, LB22-0111, LB22-0234, LB22-0378, LB22-0440, and LB22-0491) of 10 patient reports reviewed. Findings include: 1. A review of patient test reports revealed for 6 of 10 patient dermatopathology reports the reports lacked documentation of the hematoxylin and eosin stain quality for the slides reviewed as follows: a. LB21-0976 performed on 12/21/2021 b. LB22-0111 performed on 2/17/2022 c. LB22 - 0234 (A) and (B) performed on 4/11/2022 d. LB22-0378 (A) and (B) performed on 6/13/2022 e. LB22-0440 performed on 7/08 /2022 f. LB22-0491 (A) and (B) performed on 8/01/2022 2. An interview on 8/23 /2022 at 10:30 am, the LL confirmed the H&E staining quality was not performed and documented since the new computer system went into place.</p>
D5801	<p>TEST REPORT CFR(s): 493.1291(a)</p> <p>The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported</p>

from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the laboratory liaison (LL), the laboratory failed to establish a system to ensure the transcribed anatomic site was accurately transcribed for 1 (LB21-622) of 10 patient dermatopathology reports reviewed. Findings include: 1. A record review revealed for 1 of 10 dermatopathology reports reviewed, the anatomical site on the "Dermatopathology Report" was transcribed onto the worksheet inaccurately as follows: a. LB21-622 i. Pathology requisition and Visit note - left inferior central malar cheek ii. "Dermatopathology report" - left malar cheek 2. An interview on 8/23/2022 at 10:24 am, the LL confirmed the transcribed anatomical site was not accurately written on the "Dermatopathology Report" worksheet.