

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0999891	(X3) Date Survey Completed 01/17/2023
Name of Provider or Supplier Epiphany Dermatology Of Iowa, Plc	Street Address, City, State 2605 Washington Street, Pella, IA	
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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Mart-1 IHC Stain Log, refrigerator temperature records, NovodiAx Mart-1 stain package insert, and confirmed by the laboratory representative at approximately 10:00 am on 01/17/2023, the laboratory failed to document the refrigerator temperature for two out of three days of Mart-1 immunohistochemical (IHC) staining from 01/01/2022- 12/31/2022. The findings include: 1. According to the Mart-1 IHC Stain Log, the laboratory performed Mart-1 IHC staining procedures on the following dates in 2022: *01/07/2022 (Patient A) *04/01/2022 (Patients B & C) *07/08/2022 (Patient D) 2. The NovodiAx Mart-1 stain package insert states that the stain is to be stored between two and eight degrees Celsius. 3. Review of the laboratory's Refrigerator Temperature Log indicated the laboratory did not document the refrigerator temperature on 01/07/2022 or 04/01/2022. 4. At the time of the survey, the laboratory did not have additional refrigerator temperature records from 01/07/2022 or 04/01/2022.</p>
D5601	<p>HISTOPATHOLOGY CFR(s): 493.1273(a)(f)</p> <p>(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must</p>

be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on review of the Laboratory Test List & Annual Volume form, Mart-1 IHC Stain Log, patient test reports, and confirmed by the laboratory representative at approximately 10:00 am on 01/17/2023, the laboratory failed to document positive and negative control slide reactivity each time of use for special stains performed on four out of four patients from 01/01/2022- 12/31/2022. The findings include: 1. According to the Laboratory Test List & Annual Volume form, the laboratory performs Mart-1 immunohistochemical (IHC) staining procedures. 2. The laboratory performed Mart-1 IHC staining procedures on the following dates: *01/07/2022 (Patient A) *04/01/2022 (Patients B & C) *07/08/2022 (Patient D) 3. Review of the Mart-1 IHC Stain Log revealed the laboratory did not document positive or negative reactivity on any of the dates listed above. 4. At the time of the survey, the laboratory did not have additional IHC staining QC records available.

D5801

TEST REPORT

CFR(s): 493.1291(a)

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 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:

A. Based on review of the Mohs Surgery Log, patient specimen slides, Mohs maps, and test reports, and confirmed by the laboratory representative at approximately 9:50 am on 01/17/2023, the laboratory failed to have a system in place to ensure the accuracy and reliability of Mohs case numbers manually transcribed into patient electronic health records (EHR) for one out of four patients (Patient identifier E) reviewed from 07/01/2022- 08/31/2022. At the time of the survey, the laboratory representative confirmed that the case numbers on the Mohs Surgery Log, patient specimen slides, and Mohs map for patient identifier E did not match the case number in the corresponding patient test report. B. Based on review of the Mohs Surgery Log, patient specimen slides, Mohs maps, and test reports, and confirmed by the laboratory representative at approximately 9:50 am on 01/17/2023, the laboratory failed to have a system in place to ensure the accuracy and reliability of the number of Mohs surgery stages manually transcribed into patient electronic health records (EHR) for one out of four patients (Patient identifier F) reviewed from 07/01/2022- 08/31/2022. The findings include: 1. Patient identifier F had Mohs surgery performed on 07/09/2022. 2. Review of the Mohs Surgery Log, patient specimen slides, and Mohs map for patient identifier F all showed the surgeon performed Mohs surgery in three stages. 3. The test report for patient identifier E listed 2 stages for Mohs surgery performed on

07/09/2022. 4. At the time of the survey, the laboratory representative confirmed that the test report for Mohs surgery performed on 07/09/2022 for patient identifier E should have included three stages.