Department of Health & Human Services
Centers for Medicare & Medicaid Services

Form Approved
OMB No. 0938-0391

Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 16D2171092	**(X3) Date Survey Completed** 07/19/2021
Name of Provider or Supplier Central Iowa Dermatology	**Street Address, City, State** 5705 Nw 100th Street, Suite 100, Johnston, 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
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (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. This STANDARD is not met as evidenced by: Based on review of patient testing records, lack of quality control records, review of the laboratory's Hematoxylin and Eosin Stain procedure, and confirmed by the laboratory's histotechnologist at approximately 10:00 am on 07/19/2021, the laboratory failed to document Hematoxylin and Eosin stain quality each day of use for three out of three days of patient testing reviewed in January-February 2021. The findings include: 1. Patient A had Mohs surgery performed on 01/27/2021. 2. Patient B and C had Mohs surgery performed on 02/10/2021. 3. Patient D had Mohs surgery performed on 02/24/2021. 4. At the time of the survey, the laboratory did not have documentation of Hematoxylin and Eosin stain quality for the dates listed above.
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: Based on review of the laboratory's KOH Examination policy, patient test logs, patient electronic health records (EHR), and confirmed by the laboratory's histotechnologist at approximately 10:30 am on 07/19/2021, the laboratory failed to have a system in place to ensure the accurate and reliable transcription of manual test results into the laboratory's EHR for one out of three patients (patient identifier E) having potassium hydroxide (KOH) examination testing performed in February and April 2021. The findings include: 1. The laboratory's KOH Examination policy stated that all KOH testing will be logged in the KOH log book and then logged or dictated in the EHR patient chart. 2. Review of the KOH log indicated that patient E had a KOH examination performed on 04/27/2021. 3. Patient E's EHR chart did not include a record of the KOH examination performed on 04/27/2021. 4. At the time of the survey, the laboratory's histotechnologist confirmed that the laboratory did not have a system in place to ensure the accurate and reliable transcription of KOH testing into the EHR.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Assurance (QA) policy, lack of QA audit records, and confirmed by the laboratory's histotechnologist at approximately 11:00 am on 07/19/2021, the laboratory director failed to ensure that the laboratory performed monthly quality assessment activities as established in its quality assessment program for 17 out of 17 months from February 2020- June 2021. The findings include: 1. The laboratory's Quality Assurance policy stated that monthly, the nurse or tech will check off the Monthly Quality Assurance Checklist and that the laboratory director will also review and sign off the checklist. 2. At the time of the survey, the laboratory's histotechnologist confirmed that the laboratory did not have Monthly Quality Assurance Checklists for February 2020- June 2021.