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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 05D2182444 | (X3) Date Survey Completed 08/20/2021 |
| Name of Provider or Supplier Golden Coast Dermatology, Skin Cancer | Street Address, City, State 26732 Crown Valley Pkwy Ste 571, Mission Viejo, CA | |
| 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 |
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| D5407 | <p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures (P&P), the laboratory reports, quality assurance documents, and interview with the laboratory personnel and the laboratory director, it was determined that the current laboratory director failed to approve, review, sign and date the laboratory's procedures. The findings included: a. Based on 8/20/21 interview with the laboratory personnel and the laboratory director, the laboratory's operation activities were found inconsistent with its written policies and procedures. b. The current laboratory owner took control of the laboratory operations on March 1, 2021, and the current laboratory director/owner took directorship effective on May 1, 2021. c. There was no evidence that the current laboratory director approved, signed, and dated the laboratory's policies and procedures or manuals, at the time of the inspection (8/20/21).</p> |
| D5791 | <p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by:</p> |

Based on review of the laboratory's Mohs Surgery Map (MSM) reports along with the tissue slides, written policies and procedures (P&P), and interview with the laboratory personnel, it was determined that the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems. The findings included: a. The laboratory performed Mohs surgery and processed histopathology tissue slides for examination onsite. b. At the time of survey, (8/20/21 @ 12:25 PM), review of 6 patient's Mohs Surgery Map (MPS) reports along with the slides, one of the 6 cases identified as GC21-24, was found inconsistent information between the slide labeling and the MPS report date. c. The date indicated 5/5/21 on the MPS report, while the date of 5/27/21 was marked on the slide labeling. d. Further review of the laboratory's "QUALITY ASSURANCE", it stated that "Monthly the nurse or tech will check off the Monthly Quality Assurance Checklist. ..." to perform QA monthly with a checklist. e. There were no QA checklist records available for Monthly Quality Assurance Checklist shown after May 1, 2021, which was the effective date of the current laboratory and the laboratory director took the responsibility for the laboratory operations. f. The laboratory failed to follow the written P&P to perform monthly QA checklist as stated.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policies and procedures (P&P), the laboratory Mohs Surgery Map reports with tissue slides, quality assurance documents, interview with the laboratory personnel and the laboratory director, it was determined that the current laboratory director failed to ensure that the quality assessment programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. The findings included. a. Based on review of the laboratory's records, interview (8/20/21) with the laboratory personnel and the laboratory director, the laboratory failed to follow its written P&P (see D-5791) b. The current laboratory owner took control of the laboratory operations on March 1, 2021, and the current laboratory director/owner took directorship effective on May 1, 2021, the current laboratory director failed to approve, review, sign, and date of the laboratory's policies and procedures (see D-5407).