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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 46D2094384 | (X3) Date Survey Completed 02/04/2022 |
| Name of Provider or Supplier Ogden Clinic Davis Family Practice | Street Address, City, State 3225 West Gordon Avenue, Layton, UT | |
| 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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| D2007 | <p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory director, the laboratory failed to run proficiency testing (PT) samples using the laboratory's routine methods by not having all testing personnel (TP) perform PT. Findings include: 1. Review of CMS-209 Laboratory Personnel Form showed the laboratory had ten TP. 2. PT record review revealed that TP #7 performed PT for three out of three API Hematology events in 2020 and two out of three events in 2021. 3. The laboratory performs approximately 29,000 hematology tests a year. 4. In an interview on 02/04/2022 at 10:30 AM, the laboratory director confirmed that not all laboratory personnel were performing PT.</p> |
| D5401 | <p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory director, the laboratory failed to follow the procedure for running quality controls for the McKesson Consult</p> |

hCG Combo test. Findings include: 1. The individualized quality control plan procedure for the McKesson Consult hCG Combo test stated that controls should be run monthly, every new lot, and new shipment. 2. Record review of quality controls logs revealed the laboratory failed to run controls for serum hCG five out of twelve months in 2020 and two out of twelve months in 2021. 3. The laboratory performed approximately 35 serum human chorionic gonadotropin (hCG) tests a year. 4. In an interview on 02/04/2022 at 10:15 AM, the laboratory director confirmed the laboratory failed to follow the procedure for running serum hCG controls.

D5807

TEST REPORT
CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:
Based on a review of patient test reports, laboratory procedure manual, and an interview with the laboratory director, the laboratory failed to include the correct normal ranges for complete blood counts on five out of twenty male test reports and six out of twenty female test reports. Findings include: 1. Review of the patient reports revealed six of the twenty parameters for female ranges and five of the twenty parameters for the male ranges did not correctly match those reference ranges for the CBC test in the procedure manual. 2. The procedure manual showed: Parameter Reference Range Mean Corpuscular Volume 80.8-96.9 (female) Percent Neutrophils 35-65 % (male and female) Percent Lymphocytes 25 - 45 (male and female) Percent Monocytes 0 - 8 (male and female) Neutrophils Absolute 1.8 - 8.0 (male and female) Lymphocytes Absolute 1.2 - 5.8 (male and female) 3. The patient report showed: Parameter Reference Range Mean Corpuscular Volume 81.0-97.0 (fL) (female) Percent Neutrophils 44.0-76.0 (male and female) Percent Lymphocytes 23.0-44.0 (male and female) Percent Monocytes 0.0-9.0 (%) (male and female) Neutrophils Absolute 1.80-6.80 (10³/uL) (male and female) Lymphocytes Absolute 1.20-3.40 (10³/uL) (male and female) 4. In an interview on 02/04/2022 at 11:15 AM, the laboratory director confirmed the lab failed to provide pertinent normal ranges on the test report.