| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 46D1083217 | 10/17/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Ogden Clinic Utah Hematology Oncology Ogden | 5290 South 400 East, Ogden, 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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| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.<br><br>This STANDARD is not met as evidenced by:<br>Based on patient test reports review, lack of documentation, and interview with staff, the laboratory lacked a procedure describing how they document critical value reporting for complete blood count tests for 3 of 12 reports reviewed. Findings include: 1. Patient test reports reviewed for patient 29706 on 10/23/2017, 30854 on 02 /11/2019, and 26650 on 08/07/2019 included critical complete blood count values of platelet count of 8, white blood cell count of 1.5, and platelet count of 37 respectively. 2. The laboratory lacked documentation the values were reported to the provider to ensure the provider was aware of the values. 3. In an interview conducted on 10/17 |

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| | /2019 at approximately 2:45 P.M. staff stated the laboratory policy varied for critical value reporting depending on the patient's diagnosis and previous test results. Staff stated they did not follow a written procedure to document critical values are reported to providers by the process the director approved to ensure patients were evaluated in a timely manner to address the test results. |
| **D6021** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on quality assessment plan review, lack of documentation, and interview with staff, the laboratory director failed to ensure the quality assessment (QA) program was maintained following the transition to an electronic medical record (EMR) system and interfaced complete blood count (CBC) instruments. The laboratory performed approximately 20 to 30 CBC tests per day. Findings include: 1. The laboratory failed to document quarterly pre and post analytic QA activities after 2018. 2. The laboratory failed to document a change in the QA plan to monitor pre and post-analytic portions of testing . 3. In an interview with staff on 10/17/2019 at approximately 2:45 P.M. staff stated the laboratory discontinued quarterly QA documentation and did not update the QA plan after the new EMR was installed since the system ensured the QA activities were documented. The laboratory failed to document they checked the EMR for pre and post analytic quality assessment. |