| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 46D0958332 | 10/15/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Utah Cancer Specialists | 5131 South Cottonwood Street L2, Murray, 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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| **D5775** | COMPARISON OF TEST RESULTS<br>CFR(s): 493.1281(a)(c)<br><br>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of documentation, proficiency reports review, quality control reagents observation, and interview with the technical consultant, the laboratory failed to document their system defined and evaluated the relationship between test results from the primary complete blood cell counter (the DXH 800) and the back up instrument (the AcT Diff II) at least twice a year. The laboratory performed approximately 37000 tests per year. The number of tests performed on the back up instrument was not determined. Findings include: 1. The laboratory failed to document they defined the correlation relationship between the DXH800 cell counter and the AcT Diff II back up cell counter. 2. Proficiency testing and quality controls observed on 10/15/2019 at approximately 12:50 P.M. for the two instruments were not the same proficiency testing module and daily cell counting controls observed were not the same lot numbers used for each instrument to facilitate comparison of test results using the information each assay tool provided. 3. In an interview with the technical consultant on 10/17/2019 at approximately 12:55 P.M. the technical consultant confirmed the laboratory did not use the same controls, the same proficiency samples, or compare patient test results between instruments to compare the relationship between instruments in order to provide information to the users of complete blood count reports of differences or bias between testing methods. |
| **D6021** | LABORATORY DIRECTOR RESPONSIBILITIES |

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| | 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 records review, lack of documentation, and interview with the laboratory staff, the laboratory failed to maintain the quality assessment (QA) program for 3 of 24 months of hematology quality assessment monthly review records reviewed. Findings include: 1. Monthly Quality Assessment reports review failed to include documentation the laboratory performed a monthly site visit to review pre-analytic, analytic, and post analytic portions of Hematology complete blood count (CB) and prothrombin time (PT) testing for November 2018, March and May 2019. 2. In an interview conducted on 10/15/2019 at approximately 11:50 P.M. the technical consultant and staff member stated the site visit documentation was not retained for the stated QA activity. |