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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 29D0958025 | (X3) Date Survey Completed 01/16/2019 |
| Name of Provider or Supplier Comprehensive Cancer Centers Of Nevada-Siena | Street Address, City, State 10001 S Eastern Ave Ste 108, Henderson, NV | |
| 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 |
|---------------------------|--|
| D0000 | This Statement of Deficiencies was created as a result of an on-site CLIA recertification survey conducted at your facility on January 16, 2019. The findings and conclusions of any investigation by the Division of Public and Behavioral Health shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws. |
| D5793 | <p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c)</p> <p>(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the quality assessment documents for 2017 and 2018, a review of the director approved policy and procedure manual regarding quality assessment and an interview with the laboratory area manager, the laboratory failed to review and document monthly, the quality assessment activities for analytic systems. Findings include: The laboratory failed to assess and document quality for the analytic phase of laboratory testing in hematology for September, October, November and December of 2018. This was confirmed by the laboratory area manager on January 16, 2019 at approximately 4:00 PM. The laboratory performs approximately 99,450 patient hematology tests annually.</p> |
| D6013 | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii)</p> |

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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

This STANDARD is not met as evidenced by:

Based on a review of the director approved policy and procedure manual and an interview with the laboratory area manager, the director failed to ensure that there was an established policy and procedure to determine the accuracy, precision and linearity of laboratory instrumentation. Findings include: 1. The laboratory director failed to have an established policy and procedure to verify and determine the accuracy, precision and linearity of laboratory instrumentation. 2. The laboratory director had not established a procedure to indicate the number of specimens to be run, the time frame in which the specimens were to be run and the criteria for acceptable test results to determine accuracy, precision and linearity. This was confirmed by the laboratory area manager on January 16, 2019 at approximately 4:00 PM. The laboratory performs approximately 99,450 patient hematology tests annually.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on a review of the testing personnel training and competency documents and an interview with the laboratory area manager, the laboratory director failed to ensure that, prior to performing patient laboratory testing, all personnel have the appropriate training and have shown competency to provide accurate and reliable patient test results. Findings include: The laboratory director failed to ensure that one of five laboratory testing personnel had documentation of training and competency before performing patient Complete Blood Count (CBC) testing on the hematology analyzer. This was confirmed by the laboratory area manager on January 16, 2019 at approximately 2:30 PM. The laboratory performs approximately 99,450 patient hematology tests annually.