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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 04D2102180 | (X3) Date Survey Completed 07/25/2024 |
| Name of Provider or Supplier Kota Cancer Clinic ,Pllc | Street Address, City, State 180 Medical Park Place, Hot Springs, AR | |
| 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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| D5481 | <p>CONTROL PROCEDURES CFR(s): 493.1256(f)(g)</p> <p>(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Review of the laboratory's Policy and Procedure for Quality Control (QC)A, quality control results for October 16, 2023 through December 7, 2023, patient result reports for December 5, 2023, and interview with laboratory staff determined that the laboratory reported patient results for hematocrit (Hct) tests on one of thirty-four days of testing reviewed when QC results failed to meet the laboratory's criteria for acceptability. Survey findings follow: A) Review of the Laboratory's Policy for "Quality Control " revealed "QC rules followed for unacceptable QC results were two of three levels of controls outside 2 standard deviation (SD) limits or any single control outside 3 SD limits and "patient results should not be reported if controls exceed acceptable limits". B) Review of the QC report for Hct revealed that on 12/5 /23 at 08:30 a.m. result for level 1 of Sysmex eCheck (XS) hematology control lot # 32619804 was reported as 19.7 with acceptable limits (18.5 to 19.5) and level 2 of Sysmex eCheck (XS) hematology control lot # 32610805 was reported as 37.9 with acceptable limits of (36.0 to 37.8). This represents two of three levels of control exceeding 2 SD. C) Review of patient reports for December 5 , 2023 revealed that Hct assays were performed and reported on twelve patients (identified as 1 through 12 on a separate patient identification list). D) In an interview on 7/25/24 at 11:17 a.m., the laboratory staff members (identified as #2 and #4 form CMS 209) confirmed that patient results were released for Hct assays on 12/5/23 against laboratory policy when QC results on two of three levels of control were outside the laboratory's acceptable range..</p> |