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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br>04D2184929    | <b>(X3) Date Survey Completed</b><br>07/28/2021 |
| <b>Name of Provider or Supplier</b><br>Highlands Oncology Group Lab Iii  | <b>Street Address, City, State</b><br>3901 Parkway Circle, Springdale, AR |   |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |   |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>  |
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| <b>D5291</b>              | <p><b>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT</b><br/>CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on the lack of written procedures and interview, the Surveyor determined that the laboratory failed to establish and follow written Quality Assessment policies and procedures to monitor, assess and correct problems identified in the laboratory. Findings Follow: A). Upon request and the laboratory failed to provide quality assessment reports or a written Quality Assessment policy and procedure for the laboratory. B) The laboratory staff member, identified as number two on the CMS 209 form, confirmed during an interview with the surveyor at 9:25 AM on July 28, 2021 that the laboratory had not established written Quality Assessment policy and procedures.</p> |
| <b>D5469</b>              | <p><b>CONTROL PROCEDURES</b><br/>CFR(s): 493.1256(d)(10)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the</p>  |

laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Through review of the laboratory's policy for quality control (QC), review of QC summary report for AST analysis for June 2021 and interview it was determined that the laboratory's acceptable range was greater by a factor of four times than that required by the laboratory's policy for quality control. Findings follow: A) Review of the laboratory's policy and procedure for QC revealed that the laboratory employed Westgard Multi-Rules to evaluate QC results as acceptable. Westgard Multi-Rule uses a calculated standard deviation (SD) to evaluate QC results and results exceeding +/- 2SD are not acceptable. B) Review of QC summary report for June 2021 revealed that the actual calculated SD for AST analysis for Biorad Lyphochek chemistry control level one lot# 26471 was 0.75 . C) Review of the QC summary report for June 2021 revealed that the mean value for AST analysis for level one chemistry control lot# 26471 was 33.6 with an acceptable range employed by the laboratory of 21.6 to 45.6 which represents an SD of 3.0, which is four times greater than the actual calculated SD. Utilizing the calculated actual SD, which is required for the utilization of Westgard Multi-Rule analysis, would result in an acceptable range of (32.1 - 35.1). D) In an interview on 7/28/21 at 01:35 PM the laboratory staff member, identified as number two on the CMS 209 form, confirmed that the laboratory used Westgard Multi-Rule analysis to determine acceptable QC performance and the 3.0 was used as one SD in the determination of an acceptable range for level one QC for AST analysis and the range was four times greater than the range required by Westgard Multi-Rule analysis.

**D5781**

**CORRECTIVE ACTIONS**

CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Through review of the Unity peer review monthly evaluation, quality control summary reports, lack of documentation and interview with laboratory staff it was determined that the laboratory failed to document corrective action taken when results of quality control failed to meet the laboratory's criteria for acceptability in one of two months reviewed. Findings follow: A) Review of the Unity peer review evaluation report for the month of October, 2020 covering the laboratory's performance of Biorad Lyphochek assayed chemistry controls level one and two lot #'s 26471 and 24672 respectively revealed that the laboratory's mean performance of level one control for blood glucose differed from the peer comparison group, using the same lot# of control

and the same instrumentation, by -2.06 standard deviation index (SDI) and was flagged with a "warning". B) Review of the laboratory's quality control summary report for October 2020 revealed that level one Biorad Lyphochek assayed control , lot# 26471, with an acceptable range of (71.64 to 79.16) for glucose was reported as 71 at 08:17 AM, 71 at 08:25 AM, 71 at 08:36 AM before an acceptable result of 72 at 08:56 AM on 10/26/20. C) Upon request, the laboratory was unable to provide documentation of corrective action taken in regard to the warning of excessive negative SDI on the Unity peer review evaluation or the multiple unsuccessful performances of quality control on 10/26/20, identified above. D) In an interview on 7/28/21 at 11:50 AM the laboratory staff member, identified as number two on the CMS 209 form, confirmed that documentation of corrective action taken in the instances identified above was not available.