| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 37D0656687 | 02/24/2021 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Diagnostic Laboratory Of Oklahoma | 1145 S Utica Ave, Suite G-162, Tulsa, OK | |

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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| **D0000** | The recertification survey was performed on 02/21, 22, 23/2021 The findings were reviewed with the laboratory director, technical supervisor, general supervisor #1, quality assessment specialist, laboratory operations director, and the laboratory regional manager during an exit conference performed at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited. |
| **D5411** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(a)<br><br>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records, manufacturer's instructions, and interview with the quality assurance specialist and general supervisor #1, the laboratory failed to follow the manufacturer's instructions for implementing reagents for two of two lot numbers. Findings include: (1) On 02/23/2021 at 10:30 am, the general supervisor #1 stated to the surveyor PT/INR (Protime/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing were performed on the Sysmex CA-620 analyzer (note: the INR value was calculated using the normal patient PT geometric mean determined by the laboratory). General supervisor #1 also stated the following lot numbers had been put into use on 10/12/2020: (a) PT reagent - Dade Innovin lot #549772B (b) PTT reagent - Dade Actin FSL lot #562615A (2) The surveyor reviewed the manufacturer's implementation instructions, titled "Hemostasis Laboratory Reagent Lot Roll-Over Studies CA-500/600 Series"; (a) Section I titled "Verification of Reference Range" stated: (i) "A. 20 Normal Individuals" * "10 males; 10 females representing reference population. 20 is the minimum requirement for a statistically valid study." * "Fresh samples preferred but frozen platelet poor plasma may be used if prepared and thawed |

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| | per CLSI Guidelines." * "Note medication history. After review of data, history may be used for excluding abhorrent results." (ii) "B. Assay samples on current and new lot number reagents simultaneously or within 1 hour of each other." (3) The surveyor reviewed the implementation records for the reagent lot change. The following was identified: (a) PT - Although the laboratory had screened 20 normal individuals as stated above, they only assayed 14 of the normal samples using the current and new lot reagent numbers simultaneously; (b) PTT - Although the laboratory had screened 20 normal individuals as stated above, they only assayed 10 of the normal samples using the current and new lot reagent numbers simultaneously. (4) The surveyor reviewed the findings with the quality assurance specialist and general supervisor #1. On 02/23/2021 at 11:30 am, both stated the laboratory had not followed the manufacturer's instructions as indicated above. |
| **D5441** | CONTROL PROCEDURES<br>CFR(s): 493.1256(a)(b)(c)(g)<br><br>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records and interview with the quality assurance specialist, general supervisor #1, and technical supervisor, the laboratory failed to have control procedures that monitored the accuracy and precision of the complete analytic process for 2 of 2 lot numbers of coagulation control materials and 1 of 1 lot number of glucose control material. Findings include: COAGULATION CONTROL MATERIAL (1) On 02/23/2021 at 10:30 am, general supervisor #1 stated the following to the surveyor: (a) PT/INR (Protime/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing were performed on the Sysmex CA-620 analyzer; (b) Two levels of Dade CiTrol quality control (QC) materials (level 1 and level 3) were performed each eight hours of patient testing; (c) Established means and ranges were used for determining acceptability of QC results. (2) The surveyor reviewed coagulation records and identified QC level 3 lot #556532 had been put into use on 10/12/2020. The documentation showed the following means had been established by the laboratory: (a) PT Level 3 - 46.9 (b) PTT Level 3 - 55.5 (3) The surveyor reviewed QC records, which consisted of laboratory worksheets utilized while establishing QC ranges, Levey-Jennings graphs, and cumulative data generated from the analyzer from 11/02/2020 through 11/30/2020. The documentation showed the established means had not been updated in the analyzer and had not put into use. The laboratory was using the following means: (a) PT Level 3 - 45.9 (b) PTT Level 3 - 55.0 (4) The surveyor reviewed the records with the quality assurance specialist, general supervisor #1, and technical supervisor. The general supervisor #1 stated on 02/23/2021 at 11:45 am the following: (a) The laboratory had not updated the established means in the analyzer when the materials had been put into use on 10/12/2020; (b) The laboratory had carried over the means that had been used for the |

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| | previous lot number of QC for PT level 3 and PTT level 3 instead of entering their established means. GLUCOSE QUALITY CONTROL MATERIAL (1) On 02/24 /2021 at 02:00 pm, general supervisor #1 stated the following to the surveyor: (a) Glucose testing was performed on the Abbott Architect analyzer; (b) Three levels of BioRad Unassayed MultiQual quality control (QC) materials (level 1, level 2, and level 3) were performed each day of patient testing; (c) Established mean and ranges were used for determining acceptability of QC results. (2) The surveyor reviewed Glucose records and identified QC level 3 lot #56663 had been put into use on 08/01 /2020. The documentation showed the following mean had been established by the laboratory: (a) Glucose Level 3 - 371 (3) The surveyor reviewed QC records, which consisted of laboratory worksheets utilized while establishing QC ranges, Levey-Jennings graphs, and cumulative data generated from the analyzer from 08/01/2020 through 08/30/2020. The documentation showed the established mean had not been updated in the analyzer and had not put into use. The laboratory was using the following mean: (a) Glucose Level 3 - 361.7 (4) The surveyor reviewed the records with the general supervisor #1. The general supervisor #1 stated on 02/24/2021 at 03: 00 pm the following: (a) The laboratory had not updated the established mean in the analyzer when the material had been put into use on 08/01/2020; (b) The laboratory had carried over the mean that had been used for the previous lot number of QC for Glucose level 3 instead of entering their established mean. |