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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 45D0999132 | (X3) Date Survey Completed 02/03/2021 |
| Name of Provider or Supplier Laboratory Corporation Of America | Street Address, City, State 2727 West Holcombe Blvd, Houston, TX | |
| 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 | Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. |
| D5783 | <p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the corrective action logs and patient test records from August and September 2020, and confirmed in interview, the laboratory failed to evaluate and document all patient test results obtained in the unacceptable test run and since the last acceptable test run when quality control failed for the Roche Integra 400 chemistry analyzer for 4 of 20 days reviewed. Findings were: 1. Random review of the laboratory Instrument QC Problem Action Log for the Integra 400 from August and September 2020 revealed the following 4 of 20 days with quality control failures with corrective action that included recalibration. 8/07/20 - AST L2 [down arrow] BUN L1 [down arrow] HDL L1 and L2 [down arrow] rerun QC Bun ok; recal AST and HDL 8/31/20 - CO2 L1 and L2 [down arrow] will recal and run QC 9/09/20 - Crea L1 [up arrow] CK L2 [down arrow] will recal and run QC 9/24/20 - AST L2</p> |

[down arrow] CA L1 [up arrow] MG L2 [down arrow] recal and new QC 2. Random review of the patient test logs from 8/6/20 revealed the laboratory performed 6 AST testing. Specimen 021964500110 021964500330 021964500050 021964500790 021964500800 021964500910 3. Random review of the patient test logs from 8/28/20 revealed the laboratory performed 8 CO2 testing. Specimen 024164500590 024164500740 024164500370 024164500170 024164500630 024164500190 024164500520 024164500060 4. Random review of the patient test logs from 9/8/20 revealed the laboratory performed 8 Crea testing. Specimen 025264500450 025264501050 025264500370 025264500270 025264500960 025264500350 025264500700 025264500010 5. Random review of the patient test logs from 9/23/20 revealed the laboratory performed 4 AST testing. AST 026764500190 026764500180 026764500160 026764500020 6. Review of the laboratory records for the above dates revealed no documentation of the patient evaluation since the last acceptable quality control run (the previous day) to include the above patients. 7. An interview with the quality manager and technical consultant #1 on 2/02/21 at 15300 hours in the conference confirmed the above findings. key: AST - aspartate aminotransferase HDL - high-density lipoproteins CO2 - carbon dioxide CREA - creatinine L1 and L2 - Biorad level 1 lot 31891 and Biorad Level 2 lot 31892