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| <b>Statement of Deficiencies</b>                                                                                           | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>18D1092600 | <b>(X3) Date Survey Completed</b><br><br>08/11/2021 |
| <b>Name of Provider or Supplier</b><br><br>Advanced Biomedical DbA United Diagnostic Lab                                   | <b>Street Address, City, State</b><br><br>2754 Veach Road, Owensboro, KY   |                                                     |
| 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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| D2016              | <p>SUCCESSFUL PARTICIPATION<br/>CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by:<br/>Based on desk review of chemistry and Hematology proficiency testing results from the American Association of Bioanalysts (AAB) proficiency testing agency on 08/11 /2021, the laboratory failed to successfully participate in two (2) consecutive testing events for Cholesterol HDL, Cell ID or WBC Differential and Hematocrit (HCT).<br/>See: D2131, and D2096</p> |
| D2096              | <p>ROUTINE CHEMISTRY<br/>CFR(s): 493.841(f)</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |

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|              | <p>Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on desk review of Chemistry proficiency testing results from the American Association of Bioanalysts (AAB) testing agency on 08/11/2021, the laboratory failed to successfully achieve satisfactory performance for the Cholesterol HDL analyte in two (2) consecutive testing events. Findings include: 1. The laboratory failed to achieve a satisfactory score for the Cholesterol HDL analyte in the first (1st) testing event of 2021 with a score of twenty percent (20%). 2. The laboratory failed to achieve a satisfactory score for the Cholesterol HDL analyte in the second (2nd) testing event of 2021 with a score of zero percent (0%).</p>                                                                                                                                                                                                                                                                                                                                     |
| <b>D2131</b> | <p><b>HEMATOLOGY</b><br/>CFR(s): 493.851(g)</p> <p>Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on the desk review of proficiency testing results from the American Association of Bioanalysts (AAB) on 8/11/2021, the laboratory failed to achieve satisfactory overall Hematology testing event scores in two (2) consecutive testing events. Findings include: 1. The laboratory failed to achieve a satisfactory score for the Cell ID or WBC Differential in the first (1st) testing event of 2021 with a score of zero percent (0%). 2. The laboratory failed to achieve a satisfactory score for the Cell ID or WBC Differential in the second (2nd) event of 2021 with a score of zero percent (0 %). 3. The Laboratory failed to achieve a satisfactory score for the Hematocrit (HCT) in the first (1st) testing event of 2021 with a score of sixty percent (60%). 4. The laboratory failed to achieve a satisfactory score for the Hematocrit (HCT) in the second (2nd) event of 2021 with a score of zero percent (0%).</p> |