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| <b>Statement of Deficiencies</b>                                                                                           | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>05D2154950      | <b>(X3) Date Survey Completed</b><br><br>08/05/2021 |
| <b>Name of Provider or Supplier</b><br><br>Altera Laboratory Services Llc                                                  | <b>Street Address, City, State</b><br><br>2670 N Main St Ste 100, Santa Ana, CA |                                                     |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |                                                                                 |                                                     |

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| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>D2016</b>              | <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 CMS proficiency testing (PT) records (i.e. CMS CASPER Reports 0155D entitled, "Individual Laboratory Profile" and CMS CASPER Report 0153D entitled, "Unsuccessful (2 of 3) Report"), it was determined that the laboratory failed to successfully participate in a PT program approved by CMS for each analyte or test in which the laboratory is certified under CLIA. The findings included: The laboratory failed to achieve satisfactory performance for the same analyte or test in two out of three consecutive testing events in the specialty of Hematology constituting unsuccessful PT performance. (See D2130)</p> |
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| <p><b>D2130</b></p> | <p>HEMATOLOGY<br/>CFR(s): 493.851(f)</p> <p>Failure to achieve satisfactory performance for the same analyte in two consecutive 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 CMS PT records (CMS CASPER Report 0155D and 0153D, it was determined that the laboratory failed to achieve satisfactory performance for the same analyte or test in two out of three consecutive PT events for the analyte, Glucose and BUN, resulting in an "initial" (first) unsuccessful performances. The findings include: a. The laboratory failed to maintain successful performance with the PT program by failing to obtain a score of 80% of acceptable responses in two out of three consecutive PT events for the analytes, WBC Diff, Red Blood Cell (RBC), and Hematocrit (HCT), as follows: 2021 Q1 2021 Q2 WBC Diff 13% 0% RBC 60% 0% HCT 60% 0% Q1 = First Testing Event Q2 = Second Testing Event b. Failure to achieve satisfactory performance for the same analyte or test in two out of three consecutive PT resulted in an initial unsuccessful performance for the analytes, WBC Diff, RBC, and HCT.</p> |
| <p><b>D6000</b></p> | <p>MODERATE COMPLEXITY LABORATORY DIRECTOR<br/>CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by:<br/>Based on the severity of the deficiencies cited herein, the Condition: Laboratories Performing Moderate Complexity Testing: Laboratory director was not met. The laboratory director, moderate complexity testing, failed to ensure that PT samples were tested as required under Subpart H of this part. (See D6016)</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <p><b>D6016</b></p> | <p>LABORATORY DIRECTOR RESPONSIBILITIES<br/>CFR(s): 493.1407(e)(4)(i)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;</p> <p>This STANDARD is not met as evidenced by:<br/>Based on a desk review of CMS PT records, it was determined the laboratory director, moderate complexity testing, failed to ensure that PT samples were tested as required under subpart H. of this part. The findings included: For the analytes, WBC Diff, RBC, and HCT, the laboratory repeatedly failed to achieve satisfactory performance for the same analyte or test in two out of three consecutive testing events, resulting in unsuccessful PT performance. (See D2016 and D2130)</p>                                                                                                                |