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| <b>Statement of Deficiencies</b>                                                                                           | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>01D0304601                   | <b>(X3) Date Survey Completed</b><br><br>06/10/2026 |
| <b>Name of Provider or Supplier</b><br><br>Clay County Hospital Laboratory                                                 | <b>Street Address, City, State</b><br><br>83825 Highway 9, 1st Floor South Hall, Ashland, AL |                                                     |
| 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              | D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing]<br>D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 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/>D2016 Based on a review of the PT evaluation reports from the API (American Proficiency Institute) and an interview with the Laboratory Manager, the laboratory failed to successfully participate (achieve scores of 80% or greater) in proficiency testing for Mono and PMN (polymorphonuclear neutrophils) CSF (cerebrospinal</p> |

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|              | <p>fluid), non-regulated analytes in the specialty of Hematology. The laboratory failed two consecutive PT events, Event #1 in 2025 and Event #3 in 2025, resulting in initial unsuccessful proficiency testing performance. Refer to D2130.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>D2130</b> | <p><b>HEMATOLOGY</b><br/>CFR(s): 493.851(f)</p> <p>(f) 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 a review of the Proficiency Testing (PT) evaluation reports from API (American Proficiency Institute) and an interview with the Laboratory Manager, the laboratory failed to successfully participate (achieve scores of 80% or greater) in PT for Mono and PMN (polymorphonuclear neutrophils) CSF (cerebrospinal fluid), non-regulated analytes in the specialty of Hematology. The laboratory failed two consecutive PT events, Event #1 in 2025 and Event #3 in 2025, resulting in initial unsuccessful proficiency testing performance. The findings included: 1. Based on review of the PT evaluation reports, the laboratory received the following failing scores, resulting in unsatisfactory performances for two consecutive events, as follows: A. 2025-Event #1: Mono CSF: 50%; PMN CSF: 50% B. 2025-Event #3: Mono CSF: 50%; PMN CSF: 50% 2. During the exit interview on 6/10/26 at 12:30 pm, the Lab Manager confirmed the above findings.</p> |
| <b>D6000</b> | <p><b>MODERATE COMPLEXITY LABORATORY DIRECTOR</b><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 a review of the PT (Proficiency Testing) evaluation reports from the API (American Proficiency Institute) the laboratory director failed to ensure successful participation in an HHS approved proficiency testing program. Refer to D6016.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>D6016</b> | <p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b><br/>CFR(s): 493.1407(e)(4)(i)</p> <p>(e)(4)(i) 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 review of the Proficiency Testing (PT) evaluation reports from the API (American Proficiency Institute) the laboratory director failed to ensure the laboratory had successful participation in an HHS approved PT program for Mono and PMN (polymorphonuclear neutrophils) CSF (cerebrospinal fluid), for two consecutive API PT events, resulting in initial unsuccessful participation for the analyte. Refer to D2130.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |