

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0710168	(X3) Date Survey Completed 06/22/2020
Name of Provider or Supplier Trinity Medical Clinical Laboratory	Street Address, City, State 6569 Hwy 84, Ferriday, LA	
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
D0000	A PT Desk Review was performed on June 22, 2020. Riverland Medical Center, CLIA ID # 19D0710168, was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.803 CONDITION: Successful Participation 42 CFR 493.1441 CONDITION: Laboratories performing high complexity testing, Laboratory Director
D2016	<p>SUCCESSFUL PARTICIPATION 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: Based on review of proficiency testing (PT) results from the CASPER 155D report, the laboratory failed to successfully participate in proficiency testing for Hematology. Refer to D2130.</p>

<p>D2130</p>	<p>HEMATOLOGY 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: Based on review of proficiency testing results from the CMS-155D, the laboratory failed to achieve a score of at least 80% for Hematology analytes in two consecutive events, resulting in initial unsuccessful performance. Findings: 1. Review of proficiency testing records and the CMS 155D Report revealed the laboratory received a score of 60% for the following analytes resulting in initial unsuccessful performance: a. 2019 Event 2: Score of 60% for Cell ID or WBC Diff b. 2019 Event 3: Score of 60% for Cell ID or WBC Diff</p>
<p>D6076</p>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to provide overall management and direction. Refer to D6089.</p>
<p>D6089</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i)</p> <p>The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the laboratory director failed to ensure that proficiency testing samples are satisfactory as required. Findings: 1. The laboratory failed to obtain a satisfactory overall score for Proficiency Testing events for Cell ID or WBC Diff. Refer to D2130.</p>