

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0585635	(X3) Date Survey Completed 10/05/2021
Name of Provider or Supplier Adventist Health Tulare	Street Address, City, State 869 North Cherry St, Tulare, CA	
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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (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. This CONDITION is not met as evidenced by: Based on the severity of the deficiencies cited herein, the Condition: Laboratories Performing High Complexity Testing: Laboratory director was not met. The laboratory director, high complexity testing, failed to ensure that PT samples were tested as required under Subpart H of this part. (See D2162)
D2162	ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(f) Failure to achieve satisfactory performance for the same analyte in two consecutive

	testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: 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, Compatibility Testing, 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 100% of acceptable responses in two out of three consecutive PT events for the analyte, Compatibility Testing, as follows: 2020 2021 Q3 Q2 Compatibility Testing 80% 80% Q2 = Second Testing Event Q3 = Third 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 analyte, Compatibility Testing.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 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. This CONDITION is not met as evidenced by: Based on the severity of the deficiencies cited herein, the Condition: Laboratories Performing High Complexity Testing: Laboratory director was not met. The laboratory director, high complexity testing, failed to ensure that PT samples were tested as required under Subpart H of this part. (See D6089)
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on a desk review of CMS PT records, it was determined the laboratory director, high complexity testing, failed to ensure that PT samples were tested as required under subpart H. of this part. The findings included: For the analyte, Compatibility Testing, Total, 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 D2162)