

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0585635	(X3) Date Survey Completed 08/22/2024
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
D2121	<p>HEMATOLOGY CFR(s): 493.851(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's proficiency testing (PT) records from the American Proficiency Institute (API) and interviews with the technical supervisor (TS), administrative director (AD), and laboratory quality manager (LQM), it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for the subspecialty of Coagulation on the second event of 2023 (Q2-2023). The findings include: 1. Based on review of the API PT records, an unacceptable score of 20 percent was obtained for the subspecialty of Coagulation for Q2-2023 for Partial Thromboplastin Time (PTT) analyte. 2. The TS, AD, and LQM confirmed by interviews on August 22, 2024, at approximately 11:00 a.m. that the laboratory received the proficiency testing score of 20 percent as described in statement #1. 3. Based on the laboratory's annual testing declaration submitted on the day of the survey on August 22, 2024; the laboratory analyzed and reported approximately 193,120 Hematology samples that included Coagulation tests during the time the laboratory had unsatisfactory proficiency testing results for PTT.</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p>

This STANDARD is not met as evidenced by:
 Based on an interview with the laboratory's technical supervisor (TS) and the surveyor's observation of the reagent materials and solutions used in the laboratory during the facility's tour, it was determined that the laboratory failed to completely label various reagents and solutions to indicate the identity, opening, preparation, and expiration dates when such materials were used in the laboratory. The findings include: 1. Based on the surveyor's observation during the laboratory tour on August 22, 2024, at approximately 12:00 pm.; an incomplete labelling of various reagents and solutions were found. For example: a. The Gram's staining reagents found by the processing area lacked initials of testing personnel, opening or expiration date labels. b. The de-ionized water found inside the Microbiology biological safety hood had no lot number, aliquot date, expiration date or initials of personnel. c. The optical lens cleaner bottles found in multiple sections of the laboratory had no open date or initials of personnel. d. The currently in-use KOH reagent (Lot# 633178, expiry date: 3-29-2025) had no open date or initials of personnel. e. 10% Bleach, Methanol and Ethanol had no initials of personnel, lot number, preparation, and expiry dates in various sections of the laboratory. f. The back-up stains for the Hematek stainer had no identity label in the glass containers, lot number, open and expiration dates. g. The saline squirt bottle found beside Grifols analyzer for Immunohematology had no aliquot date, lot number, and initials. 2. The TS affirmed by interview on August 22, 2024, at approximately 12:00 p.m. that the reagents and solutions found during the tour were not labeled correctly with the identity, opening, preparation, and expiration dates as mentioned in statement #1. 3. Based on the laboratory's annual testing declaration submitted at the time of the survey, the laboratory analyzed and reported approximately 70,876 Microbiology, 193,120 Hematology, and 5,501 Immunohematology test samples during the time various reagents and solutions had incomplete labelling.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
 CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:
 Based on the surveyor's observation during the laboratory tour, examination of laboratory reagents, and interviews with the laboratory's technical supervisor (TS); it was determined that the laboratory failed in using reagents when they have exceeded their expiration date. The findings include: 1. Based on the surveyor's observations during the laboratory tour, the Epredia immersion oil tube with lot number 120533 used for manual differential count had expired since 4/2024. Five more tubes of the same brand, lot number and expiry date were found in the drawer at Hematology bench. 2. The TS affirmed on August 22, 2024 at approximately 12:30 p.m. that the laboratory was using the reagent listed on #1 beyond its expiration date. 3. Based on the laboratory's submitted testing declaration test volume, the laboratory tested and reported approximately 192,646 Hematology tests samples that included the manual differential count tests where expired reagent are used.

D6082

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(1)

The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing.

This STANDARD is not met as evidenced by:

Based on the interviews with the technical supervisor, administrative director, and laboratory quality manager, observations during the laboratory tour, review of the laboratory's policies and procedures, preventive maintenance, proficiency testing (PT) records and review of fourteen randomly selected patient records on August 22, 2024, the laboratory director is herein cited for failure to ensure that several aspects of the analytic, and postanalytic phases of the laboratory testing were monitored. 1. Less than 80 percent in Coagulation PT results. See D2121 2. Incomplete labelling of various reagents and solutions. See D5415 3. Use of expired reagent. See D5417