

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0644257	(X3) Date Survey Completed 02/16/2018
Name of Provider or Supplier Trinity Hospital Lab	Street Address, City, State 60 Easter Ave, Weaverville, 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
D2164	<p>UNEXPECTED ANTIBODY DETECTION CFR(s): 493.861(a)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of the first quarter (Q1-2016) of the American Proficiency Institute (API) proficiency testing records, random patient sampling test results and interview with the technical supervisor, it was determined that the laboratory failed to attain an overall testing event score of at least 80 percent performance. The findings included: a. API reported an unsatisfactory score of 60% for Unexpected Antibody Detection testing for Q1-2016. b. For one (1) out of two (2) random patient sampling test results reviewed covering from period 2/3/2016 to 3/15/2016, the laboratory analyzed and reported Unexpected Antibody tests even with the laboratory's failure in proficiency test. c. The technical supervisor affirmed (2/16/2018, 10AM), that the laboratory received the above unsatisfactory proficiency testing score of 60% for Unexpected Antibody test.</p>
D2173	<p>COMPATIBILITY TESTING CFR(s): 493.863(a)</p> <p>Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of the second quarter (Q2-2017) of the American Proficiency Institute (API) proficiency testing records, random patient sampling test results and interview with the technical supervisor, it was determined that the laboratory failed to</p>

attain an overall testing event score of at least 100 percent performance. The findings included: a. API reported an unsatisfactory score of 80% for Compatibility testing for Q2-2017. b. For one (1) out of two (2) random patient sampling test results reviewed covering from period 2/3/2016 to 3/15/2016, the laboratory analyzed and reported Compatibility tests even with the laboratory's failure in proficiency test. c. The technical supervisor affirmed (2/16/2018, 10AM), that the laboratory received the above unsatisfactory proficiency testing score of 80% for Compatibility test.

D3031

RETENTION REQUIREMENTS
CFR(s): 493.1105(a)(3)

Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.

This STANDARD is not met as evidenced by:
Based on review and the lack of documentation for International Normalized Ratio (INR) Mean PT (MNPT) calculation, random patient sampling test results, and interview with the technical consultant (testing personnel), it was determined that the laboratory failed to follow manufacturer's (Siemens Healthcare Diagnostics)test system instructions regarding Prothrombin (PT, INR .) The findings included: a. The laboratory has no documentation of the PT INR, MNPT calculation based on the manufacturer's instruction stated on the Siemens Healthcare Diagnostics product insert page 1/8. b. For six (6) out of six (6) random patient test results reviewed covering period from 1/1/2016 to 2/2/2018, the laboratory analyzed and reported PT INR results without the MNPT calculation needed. c. The technical consultant (testing personnel) affirmed (2/16/2018, 10AM) that the laboratory has no MNPT calculation performance documentation to show.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:
Based on review of the American Proficiency Institute (API) proficiency testing records, and interview with the technical consultant, it was determined that the laboratory failed to at least verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. The findings included: General Immunology a. API reported an unsatisfactory score of 0% for Anti-HBc analyte for Q1-2017. b. Based on the laboratory's annual testing declaration submitted for 2017-2017, the laboratory analyzed and reported 299 Anti-HBc tests. c. The technical supervisor affirmed (2/16/2018, 10AM), that the laboratory received the above unsatisfactory proficiency testing score of 0% for Anti-HBc analyte. Bacteriology a. API reported an unsatisfactory score of 0% for C. difficile Toxin for Q3-2017. b. Based on the laboratory's annual testing declaration submitted for 2017-2017, the laboratory analyzed and reported 61 C. difficile Toxin test. c. The technical supervisor affirmed (2/16/2018, 10AM), that the laboratory received the above unsatisfactory proficiency testing score of 0% for C. difficile Toxin. Chemistry a. API reported unsatisfactory scores for the following analytes. Analyte: Score: Event/Year: Vit B-12

	<p>50% 2/2016 Vit B-12 50% 3/2016 Vit B-12 67% 1/2017 PSA 50% 3/2016 25-OH Vit D 67% 3/2016 Ferritin 0% 3/2016 Folate 0% 3/2016 Ammonia 67% 2/2017 b. Based on the laboratory's annual testing declaration submitted for 2017-2017, the laboratory analyzed and reported 106,873 Routine Chemistry tests which included the above analytes. c. The technical supervisor affirmed (2/16/2018, 10AM), that the laboratory received the above unsatisfactory proficiency testing scores for the above analytes. Hematology a. API reported an unsatisfactory score of 50% Mononuclear (CSF/Body Fluid) for Q1-2017. b. Based on the laboratory's annual testing declaration submitted for 2017-2017, the laboratory analyzed and reported 6 Mononuclear (CSF/Body Fluid) tests. c. The technical supervisor affirmed (2/16/2018, 10AM), that the laboratory received the above unsatisfactory proficiency testing score of 50% for Mononuclear (CSF/Body Fluid) tests.</p>
<p>D5405</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(c)</p> <p>Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory.</p> <p>This STANDARD is not met as evidenced by: Based on review and the lack of documentation for International Normalized Ratio (INR) Mean PT (MNPT) calculation, random patient sampling test results, and interview with the technical consultant (testing personnel), it was determined that the laboratory failed to follow manufacturer's (Siemens Healthcare Diagnostics)test system instructions regarding Prothrombin (PT, INR .) The findings included: a. The laboratory has no documentation of the PT INR, MNPT calculation based on the manufacturer's instruction stated on the Siemens Healthcare Diagnostics product insert page 1/8. b. For six (6) out of six (6) random patient test results reviewed covering period from 1/2/2016 to 2/2/2018, the laboratory analyzed and reported PT INR results without the MNPT calculation needed. c. The technical consultant (testing personnel) affirmed (2/16/2018, 10AM) that the laboratory has no MNPT calculation performance documentation to show.</p>
<p>D5411</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on review and the lack of documentation for International Normalized Ratio (INR) Mean PT (MNPT) calculation, random patient sampling test results, and interview with the technical consultant (testing personnel), it was determined that the laboratory failed to follow manufacturer's (Siemens Healthcare Diagnostics)test system instructions regarding Prothrombin (PT, INR .) See D5405.</p>
<p>D5439</p>	<p>CALIBRATION AND CALIBRATION VERIFICATION</p>

CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on review and the lack of Serofuge calibration performance documents for (2016 and 2017), interview with the technical supervisor, it was determined that the laboratory failed to establish and follow written policies and procedures for the Serofuge calibration performance. The findings included: a. The laboratory' uses IEC Centra-W Cell washer for Blood Bank Serofuge. b. During the survey (2/15-2/16 /2018) there were no documentation shown for the Serofuge Calibration performances for the years 2016 and 2017. c. Based on the laboratory's annual testing declaration for 2016-2017, the laboratory analyzed and reported Unexpected antibody detection and Compatibility testing approximately 161 tests. d. The technical supervisor affirmed (2/16/2018, 10AM), that there was no performance documentation to show for the years 2016 and 2017 for the Serofuge Calibration.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on review and the lack of documentation for Serofuge calibration, PT/INR patient mean population data studies and interview with the technical consultant, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems. See D 5411 and D5439.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on review and the lack of documentation for Serofuge calibration (D 5439), PT /INR patient mean population data studies (D 5405), (D 5411), retention policy (D 3031) and interview with the technical consultant, it was determined that the laboratory director failed to ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.