

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0612335	(X3) Date Survey Completed 05/31/2024
Name of Provider or Supplier Sonoma Specialty Hospital	Street Address, City, State 501 Petaluma Ave, Sebastopol, 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
D2088	<p>ROUTINE CHEMISTRY CFR(s): 493.841(b)</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 American Proficiency Institute (API) proficiency testing (PT) records, CASPER report, and interview with the technical supervisor (TS) and general supervisor (GS); it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for various analytes in routine chemistry. The finding included: 1. Based on review of PT and CASPER report records, API reported: Event Analyte Score Q1-2023 AST (SGOT) 60% Q2-2023 Ph Blood Gas 60% Q3-2023 PO2 Blood Gas 40% Q2-2023 PCO2 Blood Gas 60% 2. Based on the laboratory testing declaration submitted at the time of the survey on 05/31/2024 the laboratory analyzed and reported approximately 25,959 routine chemistry tests during the time the laboratory had unsatisfactory proficiency testing results. 3. The TS affirmed 05/31/2024 at approximately 12:15 p.m. that the laboratory received the above unsatisfactory proficiency testing scores.</p>
D2122	<p>HEMATOLOGY CFR(s): 493.851(b)</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 American Proficiency Institute (API) proficiency testing (PT) records, CASPER records, and interviews with the technical supervisor (TS) and</p>

general supervisor (GS); it was determined that the laboratory failed to attain an overall testing event score of at least 80 percent which is unsatisfactory performance for the coagulation Prothrombin Time analyte. The findings included: 1. Based on review of API and CASPER PT records, the laboratory obtained the following unsatisfactory scores: Q3-2021 0% Q2-2023 60% 2. The TS affirmed on May 31, 2024, at approximately 12:30 p.m. that the laboratory obtained the PT scores in 1. 3. According to the laboratory testing declaration submitted on the day of the survey, the laboratory performed approximately 210 Prothrombin Time testing annually.

D2173

COMPATIBILITY TESTING
CFR(s): 493.863(a)

Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance.

This STANDARD is not met as evidenced by:
Based on review of the second event of 2021 (Q2-2021) and second event of 2023 (Q2-2023) of the American Proficiency Institute (API) proficiency testing (PT) records, random patient sampling test results, and interview with the technical supervisor (TS) and general supervisor (GS); it was determined that the laboratory failed to attain a score of at least 100 percent of acceptable responses for Compatibility Testing. 1. The API reported for Immunohematology Q2-2021 event unacceptable performance score of 80% for Compatibility Testing, and for Q2-2023 a score of 60%. 2. The laboratory analyzed and reported compatibility testing during the period wherein the laboratory received an unsuccessful proficiency testing score, and patients' results could not be assured. 3. The TS and GS affirmed on May 31, 2024, at approximately 12:00 p.m. that the laboratory received the above unsatisfactory proficiency testing score. 3. Based on the laboratory testing declaration signed by the laboratory director on May 31, 2024, the laboratory tests 112 samples for Compatibility Testing.

D3027

RETENTION REQUIREMENTS
CFR(s): 493.1105(a)(1)

Test requisitions and authorizations. Retain records of test requisitions and test authorizations, including the patient's chart or medical record if used as the test requisition or authorization, for at least 2 years.

This STANDARD is not met as evidenced by:
Based on the lack of documentation, review of randomly chosen patient test results, and interviews with the technical supervisor (TS) and general supervisor (GS); it was determined that the laboratory failed to provide test requisition and results for two (2) out of five (5) records reviewed for the years 2021 and 2023. Findings included: 1. The laboratory was not able to retrieve documentation to show requisition and final reports for all tests ordered and reported for the years 2021 and 2023. 2. For two (2) out of five (5) randomly chosen patient test results reviewed covering period from 4/27 /2021 to 03/14/2024 documentation was not retained or accessible for all tests performed in the laboratory for the years 2021 and 2023. 3. The TS and GS affirmed on May 31, 2024, at approximately 3:00 p.m. that the laboratory had no

documentation to show for the tests requisition or patient log results for the patients reviewed for the years 2021 and 2023. 4. 5. The laboratory reportedly performs approximately 40,657 tests annually.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on the incomplete laboratory's verification of performance characteristics for high complexity testing for Procalcitonin and C-Reactive Protein (CRP), interview with the laboratory's technical supervisor (TS) and general supervisor (GS), and review of five (5) randomly selected patient test records; the laboratory failed to demonstrate that it established performance specifications comparable to those established by the manufacturer. The findings included: 1. The laboratory had only partial documentation to show for performance specifications, lacking calculation of accuracy and precision testing performance characteristic and documentation. The laboratory must be able to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics and those to be approved by the laboratory director before starting testing patients' samples: (A) Accuracy (B) Precision (C) Reportable range (D) Reference Range 2. The laboratory was unable to provide for review additional documents using patient samples to establish precision performance specification for Procalcitonin and C-Reactive Protein (CRP). 3. The TS affirmed at the time of the survey on 05/31/2024 at approximately 12:15 p.m. that no additional documents could be retrieved to show that performance specification were performed prior to reporting patient test results when the laboratory went live testing and reporting Procalcitonin and C-Reactive Protein (CRP) diagnostic tests. 4. Based on the estimated annual tests volumes signed by the laboratory director on 05/24/2024; the laboratory performed and reported approximately 25,959 routine chemistry diagnostic tests which include Procalcitonin and C-Reactive Protein (CRP). The precision and accuracy of the reported tests results could not be assured.

D5815

TEST REPORT
CFR(s): 493.1291(h)

When the laboratory cannot report patient test results within its established time frames, the laboratory must determine, based on the urgency of the patient test(s) requested, the need to notify the appropriate individual(s) of the delayed testing.

This STANDARD is not met as evidenced by:

Based on the lack of laboratory's policies, review of patient test records randomly selected, and interview with the technical supervisor (TS); it was determined that the laboratory failed to have a policy for turn-around time (TAT) for all tests performed in

the laboratory. 1. The laboratory failed to provide TAT of testing for five (5) out of five (5) randomly chosen patients at the time of the survey (May 31, 2024). The laboratory did not provide a TAT policy which may adversely impact patient management. 2. The laboratory TS on May 31, 2024, at approximately 12:30 p.m. affirmed that the laboratory did not have a TAT policy to notify any delay on testing to the physician. 3. The laboratory's testing declaration form, signed by the laboratory director on 5/24/2024, stated that the laboratory performs 40,657 tests annually for which a TAT policy was not available.

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 surveyor's tour of the laboratory, review of the laboratory's records and interviews with the laboratory's technical supervisor, general supervisor, and testing personnel on May 31, 2024; it was determined that the laboratory director is cited herein due to failure to ensure that several aspects of the preanalytic, analytic, and postanalytic phases of the laboratory testing were monitored. See D2088, D2122, D3027, and D5815.

D6087

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(3)(iii)

The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:
Based on interviews with the technical supervisor and general supervisor, review of proficiency test reports documents, verification of performance specifications, and policies and procedures record on May 31, 2024; the laboratory director failed to ensure that laboratory personnel are properly trained and competent when performing the test methods as required for accurate and reliable results. See D2173 and D5421.