| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 05D0612335 | 02/24/2021 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Sonoma Specialty Hospital | 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 |
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| **D2025** | BACTERIOLOGY<br>CFR(s): 493.823(c)<br><br>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.<br><br>This STANDARD is not met as evidenced by:<br>Based on the surveyor's review of the laboratory's records for evaluation of proficiency testing performance from CMS, laboratory proficiency reporting from API, and an interview with laboratory Technical Supervisor (TS) on 2/24/2021 between 1:00 p.m. and 4:00 p.m., it was determined that the laboratory did not participate in the Bacteriology proficiency testing for Q3 cycle 2020. Findings include: 1. On 2/24/2021, an inspection was conducted between 1:00 p.m. and 4:00 p. m. 2. During a review of the laboratory documentation from API (agency providing the proficiency specimens), it was noted at approximately 3:45 p.m. that there was not a submission of Bacteriology proficiency results for Q3 cycle 2020. 3. The resulting proficiency score was 0 given no submission 4. The TS affirmed that no Bacteriology results were submitted 5. The laboratory has discontinued any Bacteriology testing, starting with Q1 2021. |
| **D2087** | ROUTINE CHEMISTRY<br>CFR(s): 493.841(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on the surveyor's review of the laboratory's records for evaluation of |

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| | proficiency testing performance from CMS, laboratory proficiency reporting from API, and an interview with the laboratory Technical Supervisor (TS) on 2/24/2021 between 1:00 p.m. and 4:00 p.m., it was determined that there were two unacceptable (below 80 %) proficiency testing (PT) results for CK for Cycle 3 in 2019. Findings include: 1. On 2/24/2021, an inspection was conducted between 1:00 p.m. and 4:00 p. m. 2. During a review of the laboratory documentation from API (agency providing the proficiency specimens), it was noted at approximately 2:30 p.m. that there were two unacceptable PT results for cycle Q3 CK on the 2019 report. The laboratory utilizes the Vitros 5600 instrument for general chemistry testing. The TS recognized these atypical results. 3. The findings and acceptable ranges were as follows: Analyte: CK (2/5 unacceptable) Sample Actual Result Expected Result (range) CM12 497 255-474 CH14 255 129-242 4. The TS affirmed the unacceptable results listed above. _____ The STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's records for evaluation of proficiency testing performance from CMS, laboratory proficiency reporting from API, and an interview with laboratory Technical Supervisor (TS) on 2/24/2021 between 1:00 p.m. and 4:00 p.m., it was determined that there were four unacceptable (below 80 %) proficiency testing (PT) results for Bilirubin, Total (TBIL) for Cycle 1 in 2020. Findings include: 1. On 2/24 /2021, an inspection was conducted between 1:00 p.m. and 4:00 p.m. 2. During a review of the laboratory documentation from API (agency providing the proficiency specimens), it was noted at approximately 3:00 p.m. that there were four unacceptable PT results for cycle Q1 for TBIL on the 2020 report. The laboratory utilizes the Vitros 5600 instrument for general chemistry testing. The TS recognized these atypical results. 3. The findings and acceptable ranges were as follows: Analyte: TBIL (4/5 unacceptable) Sample Actual Result Expected Result (range) CH01 1.6 .3-1.2 CH02 2.4 .9-1.8 CH04 7.9 4.1-6.3 CH05 4.7 2.3-3.6 4. The TS affirmed the unacceptable results listed above. __ The STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's records for evaluation of proficiency testing performance from CMS, laboratory proficiency reporting from API, and an interview with laboratory Technical Supervisor (TS) on 2/24/2021 between 1:00 p.m. and 4:00 p. m., it was determined that there were four unacceptable (below 80 %) proficiency testing (PT) results for ALT/SGPT for Cycle 3 in 2020. Findings include: 1. On 2/24 /2021, an inspection was conducted between 1:00 p.m. and 4:00 p.m. 2. During a review of the laboratory documentation from API (agency providing the proficiency specimens), it was noted at approximately 3:30 p.m. that there were two unacceptable PT results for cycle Q3 for ALT/SGPT on the 2020 report. The laboratory utilizes the Vitros 5600 instrument for general chemistry testing. The TS recognized these atypical results. 3. The findings and acceptable ranges were as follows: Analyte: ALT /SGPT (2/5 unacceptable) Sample Actual Result Expected Result (range) CH12 98 52-80 CH15 71 31-48 4. The TS affirmed the unacceptable results listed above. |
| **D6022** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<br><br>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 the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.<br><br>This STANDARD is not met as evidenced by: |

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| | Based on a review of the proficiency laboratory documentation records and interviews with the TS, it was determined that the laboratory director failed to ensure the verification and accuracy of test results of regulated analytes and to identify failures as they occurred for the previously mentioned Cycles for 2019 and 2020 proficiency testing. The findings include: See D-2087 (3 deficiencies) and D-2025 (one deficiency) |