

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D0612446	<b>(X3) Date Survey Completed</b>  07/21/2021
<b>Name of Provider or Supplier</b>  Sonoma Valley Hospital District	<b>Street Address, City, State</b>  347 Andrieux St, Sonoma, CA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> CFR(s): 493.803(a)(b)(c)</p> <p>(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.</p> <p>This CONDITION is not met as evidenced by: Based on Surveyor review of laboratory's policy &amp; procedure, and proficiency testing (PT) records, and interview with the laboratory technical supervisor on July 21, 2021 at 12:30 pm, the laboratory failed to successfully participate in the proficiency testing program for the compatibility test. The findings include: 1. The laboratory participated in the American Proficiency Institute (API) PT testing program for the compatibility test at the 3rd event in 2020 and 1st event in 2021. However, it received an unsatisfactory score of 80 and 60 at the 3rd and 1st events, correspondingly, resulted in an unsuccessful PT participation. Therefore, the accuracy of the patients' blood cross match test results rendered by the laboratory during that time period can</p>

not be assured. 2. The laboratory technical supervisor on July 21, 2021 at 12:30 pm, affirmed that the laboratory did not receive a satisfactory score for the compatibility test at the 3rd event in 2020 and 1st event in 2021. 3. The laboratory's testing declaration form, signed by the laboratory director on 7/19/2021, stated that the laboratory performs approximately 150 compatibility tests, annually.

**D2181**

**COMPATIBILITY TESTING**  
CFR(s): 493.863(e)

Failure to achieve an overall testing event score of satisfactory for 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 Surveyor review of laboratory's policy & procedure, and proficiency testing (PT) records, and interview with the laboratory technical supervisor on July 21, 2021 at 12:30 pm, the laboratory failed to achieve satisfactory performance for the compatibility (cross match) in two consecutive testing events. The findings include: 1. The laboratory participated in the American Proficiency Institute (API) PT testing program for the compatibility test at the 3rd event in 2020 and 1st event in 2021. However, it received an unsatisfactory score of 80 and 60 at the 3rd and 1st events, correspondingly, resulted in an unsuccessful PT performance. Therefore, the accuracy of the patients' blood cross match test results rendered by the laboratory during that time period can not be assured. 2. The laboratory technical supervisor on July 21, 2021 at 12:30 pm, affirmed that the laboratory did not receive a satisfactory score for the compatibility test at the 3rd event in 2020 and 1st event in 2021. 3. The laboratory's testing declaration form, signed by the laboratory director on 7/19/2021, stated that the laboratory performs approximately 150 compatibility tests, annually.

**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 Surveyor review of laboratory's policy & procedure, random patient sample, quality control (QC) and proficiency testing records, and interview with the laboratory technical supervisor during an onsite survey of the laboratory on July 21, 2021, and the severity of deficiencies found and cited herein, it was determined that the laboratory director failed to provide effective direction over the operation of the laboratory, hence the Condition: Laboratories performing high complexity testing; laboratory director was not met. The laboratory director's failure to provide direction over the laboratory operation has a consequence of potential erroneous test result reporting and patient harm. The findings include: 1. The laboratory director failed to ensure compliance with the applicable regulations. (See D6079) 2. The laboratory director failed to ensure that the testing system used for the compatibility test provided quality laboratory services in the analytical phase of testing. (See D6082) 3. The laboratory director failed to ensure that PT samples were tested as required under Subpart H of this Part. (See D6089)

**D6079**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(a)(b)

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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's policy & procedure, random patient sample, quality control (QC) and proficiency testing records, and interview with the laboratory technical supervisor on July 21, 2021 at 12:30 pm, the laboratory director failed to assure laboratory's compliance with the applicable regulations. The findings include: See D2016 and D2181.

**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 Surveyor review of laboratory's policy and procedure, and proficiency testing records, and interview with the laboratory technical supervisor on July 21, 2021 at 12:30 pm, the laboratory director failed to ensure that the testing system used for the compatibility test provided quality laboratory services in the analytical phase of testing. The findings include: See D2181.

**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 Surveyor review of laboratory's policy & procedure, and proficiency testing (PT) records, and interview with the laboratory technical supervisor on July 21, 2021 at 12:30 pm, it was determined that the laboratory director, high complexity testing, failed to ensure that PT samples were tested as required under subpart H. of this part. The findings include: For the compatibility test, 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 D2096).