

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2104014	(X3) Date Survey Completed 10/07/2022
Name of Provider or Supplier Wonderful Center	Street Address, City, State 1701 S Lexington St, Delano, 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
D2016	<p>SUCCESSFUL PARTICIPATION 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 proficiency testing (PT) and patient sample testing records, and interview with the laboratory testing person on October 7, 2022, at 12:52 pm, the laboratory failed to successfully participate in the proficiency testing program for the subspecialties of bacteriology and virology. The findings include: 1. The laboratory participated in the American Proficiency Institute (API) PT testing program for the subspecialties of bacteriology and virology in the year 2022. However, it received an unsatisfactory score of 0 at the 1st and 2nd events, resulted in an unsuccessful PT participation. Therefore, the accuracy of the patients' test results rendered by the laboratory during that time cannot be assured. 2. The laboratory</p>

testing person on October 7, 2022, at 12:52 pm, affirmed that the laboratory did not receive a satisfactory score for the subspecialties of bacteriology and virology at the 1st and 2nd events of PT in 2022. 3. The laboratory's testing declaration form, signed by the laboratory director on 10/6/2022, stated that the laboratory performs approximately 100 tests, annually.

D2028

BACTERIOLOGY
CFR(s): 493.823(e)

Failure to achieve an overall testing event score of satisfactory performance 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 proficiency testing (PT) records, and interview with the laboratory testing person on October 7, 2022, at 12:52 pm, the laboratory failed to achieve satisfactory performance for the subspecialty of bacteriology in two consecutive testing events. The findings include: 1. The laboratory participated in the American Proficiency Institute (API) PT testing program for the subspecialty of bacteriology in the year 2022. However, it failed to return proficiency testing results to the proficiency testing program within the time frame specified by the program for the 1st event and received an unsatisfactory score of 0 at the 1st event. It also failed to participate to the 2nd event and received a 0 score. Laboratory's failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events resulted in an unsuccessful PT performance in bacteriology. Therefore, the accuracy of the patients' test results rendered by the laboratory during that time cannot be assured. 2. The laboratory testing person on October 7, 2022, at 12:52 pm, affirmed that the laboratory did not receive a satisfactory score for the subspecialties of bacteriology at the 1st and 2nd events of PT in 2022. 3. The laboratory's testing declaration form, signed by the laboratory director on 10/6/2022, stated that the laboratory performs approximately 100 tests in bacteriology, annually.

D2064

VIROLOGY
CFR(s): 493.831(e)

Failure to achieve an overall testing event score of satisfactory performance 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 proficiency testing (PT) records, and interview with the laboratory testing person on October 7, 2022, at 12:52 pm, the laboratory failed to achieve satisfactory performance for the subspecialty of virology in two consecutive testing events. The findings include: 1. The laboratory participated in the American Proficiency Institute (API) PT testing program for the subspecialty of virology in the year 2022. However, it failed to return proficiency testing results to the proficiency testing program within the time frame specified by the program for the 1st event and received an unsatisfactory score of 0 at the 1st event. It also failed to participate to the 2nd event and received a 0 score. Laboratory's failure to achieve an overall testing event score of satisfactory performance for two consecutive testing

	<p>events resulted in an unsuccessful PT performance in virology. Therefore, the accuracy of the patients' test results rendered by the laboratory during that time cannot be assured. 2. The laboratory testing person on October 7, 2022, at 12:52 pm, affirmed that the laboratory did not receive a satisfactory score for the subspecialties of virology at the 1st and 2nd events of PT in 2022. 3. The laboratory's testing declaration form, signed by the laboratory director on 10/6/2022, stated that the laboratory performs approximately 100 tests in virology, annually.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on Surveyor review of laboratory's proficiency testing (PT) and patient sample testing records, and interview with the laboratory testing person during an onsite survey of the laboratory on October 7, 2022, at 12:52 pm, and the severity and the number 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 moderate 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 assure compliance with the applicable regulations. (See D6004) 2. The laboratory director failed to ensure that PT samples were tested as required under Subpart H of this Part. (See D6016) 3. The laboratory director failed to ensure that the PT results are returned within the timeframes established by the proficiency testing program. (See D6017)</p>
<p>D6004</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b)</p> <p>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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's proficiency testing (PT) and patient sample testing records, and interview with the laboratory testing person on October 7, 2022, at 12:52 pm, the laboratory director failed to assure laboratory's compliance with the applicable regulations and potentially harm patients. The findings include: See D2016 and D2017.</p>
<p>D6016</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES</p>

CFR(s): 493.1407(e)(4)(i)

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)(4)(i) Ensure that 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 proficiency testing (PT) records, and interview with the laboratory testing person on October 7, 2022, at 12:52 pm, it was determined that the laboratory director failed to ensure that PT samples were tested as required under subpart H. of this part. The findings include: For the subspecialties bacteriology and virology, the laboratory failed to achieve satisfactory performance in two consecutive testing events, resulting in unsuccessful PT performance due to non-participation and failure to test and return proficiency testing results to the proficiency testing program within the time frame specified by the program. (See D2028 and D2064).

D6017

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(ii)

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)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program.

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's proficiency testing (PT) records, and interview with the laboratory testing person on October 7, 2022, at 12:52 pm, the laboratory director failed to ensure that the laboratory test and return proficiency testing results to the proficiency testing program within the time frame specified by the program. The findings include: See D2028 and D2064.