

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D0900020	<b>(X3) Date Survey Completed</b>  11/17/2022
<b>Name of Provider or Supplier</b>  Castle Family Health Centers, Inc At Castle	<b>Street Address, City, State</b>  3605 Hospital Rd, Atwater, 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>D2100</b>	<p><b>ENDOCRINOLOGY</b> CFR(s): 493.843(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by: Based on review of 2021 proficiency testing reports from CMS [report 155D, Individual Laboratory Profile] and AAB [American Academy of Bioanalysts], the lack of laboratory proficiency testing records, and interview with Testing person-1, it was determined the laboratory failed to participate in proficiency testing for serum HCG [pregnancy test]. Findings included: 1. CMS and AAB reported scores for HCG, as follows: 2021: Event 2 Event 3 ----- 0% 0% 2. The laboratory failed to have records of testing for the aforementioned events, and failed to have records notifying AAB of the circumstances for not testing; and thus, resulted in scores of 0%. 3. Testing person-1 affirmed (11/17/22 at 1pm) the laboratory didn't participate in proficiency testing of serum HCG in 2021, events 2 and 3. 4. The reliability and quality of serum HCG results reported after 2/17/21 [event 1] could not be assured.</p>
<b>D6029</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(11)</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. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on review of Personnel Reports [forms CMS209, LAB116; 11/15/22] and laboratory test records, the lack of laboratory training records, and interview with Testing persons 2, 3, and 4, it was determined that the Laboratory Director was deficient in establishing policy and records to monitor and ensure all personnel were trained and demonstrated satisfactory operation of laboratory analyzers and manual tests performances prior to testing patients' specimen. Findings included: 1.

Laboratory Personnel Reports documented four testing persons. 2. Laboratory test records documented testing persons, as follows: Date ID Testing person

----- 7/29/20 0729:H00006R 2 11/04/20  
1104:H00003R 2 2/08/21 0208:C00005R 2 6/23/21 0623:H00056R 2 5/26/22 0526:  
H00023R 2, 3 8/10/22 0810:H00001R 2, 3 11/03/22 1103:H00005R 2, 3, 4 3. Testing  
person-2 affirmed (11/17/22 at 5pm) the hire date in 2020, but was unable to provide  
records of training and demonstrating reliable testing prior to testing patients'  
specimen. 4. Testing person-3 affirmed (11/17/22 at 5pm) the hire date of 3/21/22 and  
provided a record of training in chemistry testing only, but no records for  
demonstrating reliable testing prior to testing patients' specimen. 5. Testing person-4  
affirmed (11/17/22 at 5pm) the hire date prior to 2020, but was unable to provide any  
records of training and demonstrating reliable testing prior to testing patient's  
specimen. 6. And thus, the reliability and quality of training and subsequent test  
results reported could not be assured.