

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 05D0896064	<b>(X3) Date Survey Completed</b> 10/24/2022
<b>Name of Provider or Supplier</b> Kindred Hospital Brea	<b>Street Address, City, State</b> 875 N Brea Blvd, Brea, 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>D2164</b>	<p>UNEXPECTED ANTIBODY DETECTION CFR(s): 493.861(a)</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 proficiency testing (PT) third event for 2021 (Q3-2021) of the American Proficiency Institute (API) proficiency testing, random patient sampling test results, and interview with the technical supervisor (TS); it was determined that the laboratory failed to attain an overall testing event score of at least 80 percent performance on the Direct Antiglobulin Test (DAT). The findings included: 1. API reported an unsatisfactory PT score of 50% on the DAT for Q3-2021. One (1) out of two (2) PT samples tested obtained an unsatisfactory score as follow: Sample Reported Expected Performance DAT-05 Positive Positive Acceptable DAT-06 Negative Positive Unacceptable 2.. For one (1) out of five (5) randomly chosen patients sampling test results reviewed covering from period 4/27/2021 to 7/20/2022, the laboratory analyzed and reported DAT test results during the time the PT had an unsatisfactory score. 3. The TS affirmed on October 24, 2022, at approximately 12:50 p.m., that the laboratory received the above unsatisfactory PT score of 50% for DAT. 4. Based on the laboratory's test volume declaration signed by the laboratory director on 10/24/2022, the laboratory performs and reports approximately 395 DAT annually.</p>
<b>D6094</b>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p>

This STANDARD is not met as evidenced by:  
Based on review of the laboratory proficiency testing results, policies and procedures, and interview with the laboratory technical supervisor and testing personnel; it was determined that the laboratory director failed to ensure the quality assessment programs were established and maintained to provide accuracy and reliability of the proficiency reporting results to assure the quality of laboratory services provided and to identify failures in quality as they occur. The findings included See D2164.