

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0698417	(X3) Date Survey Completed 12/14/2021
Name of Provider or Supplier Adc, Pllc, Extended Care At Cedar Bend, The	Street Address, City, State 2400 Cedar Bend Drive 1st Floor, Austin, TX	
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
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Review of manufacturer's instructions, patient final reports and interview of facility personnel found the laboratory failed to follow the manufacturer's instructions when using the Abbott ID NOW Covid-19 test kits for testing 5543 patients tested between December 1, 2020 and December 13, 2021. The findings included: 1. Review of the manufacturer's instructions found on page 21 under the heading CONDITIONS OF AUTHORIZATION FOR LABORATORY " Authorized laboratories using your product must include with the test result reports, all authorized Fact Sheets." 2. Review of patient results found no fact sheets included with the final report for three of three patient reports reviewed. 3. Interview of the Technical Consultant conducted December 14, 2021, 2021 at 09:41 AM confirmed that the authorized Fact Sheets were not included with the patient test results for Covid -19 testing using the Abbott ID NOW test kits.</p>