

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2150723	<b>(X3) Date Survey Completed</b>  04/15/2021
<b>Name of Provider or Supplier</b>  Cardiovascular Association, Pllc	<b>Street Address, City, State</b>  18450 Hwy 59 N, Humble, TX	
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>D3000</b>	<p>FACILITY ADMINISTRATION CFR(s): 493.1100</p> <p>Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.</p> <p>This CONDITION is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory and patient test records from 2020-2021, and confirmed in interview, the laboratory failed to report 78 SARS-CoV-2 test results as required by 42 CFR 493.41 and 493.1100(a) for 46 of 46 days reviewed from 09/3/2020 to 4/15/2021. Findings were: 1. Review of the Instructions for Use for the Beckman Coulter Access SARS-CoV-2 IgG (C60543 C, July 2020) under CONDITIONS OF AUTHORIZATION FOR THE LABORATORY revealed "authorized laboratories using your product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate." 2. Review of the laboratory test records from 2020 to 2021 revealed the laboratory started SARS-CoV-2 IgG patient testing using Beckman Coulter Access SARS-CoV-2 IgG on the Access DxI chemistry analyzer on 7/24/20. 3. Review of the laboratory policies available revealed no documentation of a policy/procedure related to SARS-CoV-2 test reporting. 4. Review of the laboratory SARS-CoV-2 IgG patient test records from 2020 to 2021 revealed no documentation the laboratory reported 78 of 78 patient test records on the following 46 of 46 days of testing. date accession 09/03/2020 21376 09/03/2020 21410 09/03/2020 21411 09/04/2020 21454 09/08/2020</p>

21520 09/14/2020 21788 09/16/2020 21878 09/21/2020 22022 09/23/2020 22115 09/25/2020 22180 10/06/2020 22549 10/07/2020 22587 10/08/2020 22617 10/12/2020 22684 10/12/2020 22695 10/13/2020 22720 10/15/2020 22859 10/26/2020 23158 11/16/2020 23990 11/20/2020 24010 11/24/2020 24060 11/30/2020 24140 11/30/2020 24150 12/04/2020 24320 12/04/2020 24323 12/04/2020 24328 12/08/2020 24416 12/08/2020 24445 12/08/2020 24450 12/08/2020 24447 12/08/2020 24451 12/08/2020 24452 12/14/2020 24628 12/17/2020 24720 12/17/2020 24751 12/18/2020 24777 12/18/2020 24788 12/31/2020 24967 12/31/2020 24976 12/31/2020 24987 01/04/2021 25025 01/04/2021 25061 01/05/2021 25269 01/07/2021 25228 01/12/2021 25331 01/12/2021 25347 01/13/2021 25402 01/14/2021 25459 01/15/2021 25520 01/15/2021 25527 01/20/2021 25650 01/20/2021 25673 01/21/2021 25682 01/21/2021 25702 01/25/2021 25813 01/25/2021 25815 01/25/2021 25816 01/27/2021 25864 01/27/2021 25881 01/28/2021 25902 01/28/2021 25927 02/03/2021 26148 02/09/2021 26341 03/01/2021 26781 03/04/2021 26952 03/04/2021 26953 03/04/2021 27132 03/08/2021 27045 03/08/2021 27063 03/08/2021 27066 03/22/2021 27576 03/25/2021 27675 03/25/2021 27686 03/25/2021 27708 03/26/2021 27732 03/26/2021 27733 04/08/2021 28129 04/08/2021 28142 5. An interview with the technical consultant on 4/14/21 at 1540 hours in the conference room confirmed the above findings. He was unaware the laboratory was required to report Covid-19 test results.