Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D1059101	05/19/2020
Name of Provider or Supplier	**Street Address, City, State**	
Cardiac Solutions - Sun City West	14420 W Meeker Blvd, Suite A-305, Sun City West, AZ	

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	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (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. This CONDITION is not met as evidenced by: Based on review of Proficiency Testing (PT) reports for 2019 and 2020 sent to the State Agency by the PT provider, the laboratory failed to successfully participate in a PT program for the regulated analytes, (A) Cell ID or WBC Diff and (B) RBC, under the specialty of Hematology. Findings include: A1. The laboratory's PT performance was unsatisfactory for the 3rd event of 2019 for the regulated analyte, Cell ID or WBC Diff, with a score of 67%. A2. The laboratory's PT performance was unsatisfactory for the 1st event of 2020 for the regulated analyte, Cell ID or WBC Diff, with a score of 33%. B1. The laboratory's PT performance was unsatisfactory for

	the 3rd event of 2019 for the regulated analyte, RBC, with a score of 40%. B2. The laboratory's PT performance was unsatisfactory for the 1st event of 2020 for the regulated analyte, RBC, with a score of 0%.
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on information the Proficiency Testing (PT) provider furnishes to the State Agency, it could not be determined if the laboratory underwent training and technical assistance and if remedial action was taken to correct the PT failures for the analytes, Cell ID or WBC Diff and RBC, for the 3rd event of 2019 and 1st event of 2020. See D2016 for findings.
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on information furnished to the State Agency by the Proficiency Testing (PT) provider, the laboratory failed to achieve satisfactory performance for the regulated analytes, Cell ID or WBC Diff and RBC, for the 3rd event of 2019 and 1st event of 2020 resulting in unsuccessful PT performance. See D2016 for findings.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 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. This CONDITION is not met as evidenced by: The Condition of Laboratory Director was found to be not met based on the failure to provide overall management and direction as evidenced by D6016 - ensuring that the proficiency testing samples are tested as required under Subpart H.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES 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 information furnished to the State Agency by the Proficiency Testing (PT) provider, it was determined that the laboratory director failed to ensure that PT samples are tested in a manner that results in successful participation in a proficiency testing program for the regulated analytes, Cell ID or WBC Diff and RBC. See D2016 and D6000 for findings.