Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0965129	10/17/2023
Name of Provider or Supplier	**Street Address, City, State**	
William H Richardson, Md Pc	5240 E Knight Dr Ste 112, Tucson, 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
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on lack of established quality assessment (QA) policies and procedures and interview with the Laboratory Director (LD), the laboratory failed to establish policies and procedures to monitor, assess and correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. Findings include: 1. No QA documentation was provided for review during the survey conducted on 10/17/2023 to indicate the laboratory established policies and procedures to monitor, assess and, when indicated, correct problems identified in the general laboratory system requirements specified at 493.1231 through 493.1236, including but not limited to, Proficiency Testing policies and procedures. 2. The LD interviewed on 10/17/23 at 3:45 PM confirmed the laboratory failed to provide documentation of an established QA policy and procedure to monitor, assess and correct problems identified in the general laboratory systems requirements.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by:

	Based on review of the EldonCard RhD test procedure and interview with the Laboratory Director (LD), the laboratory failed to have the current laboratory director approve, sign and date the RhD test procedure before use. Findings include: 1. The laboratory began patient testing on 01/28/21 in the specialty of Immunohematology with an annual test volume of 1,447. 2. The EldonCard RhD test procedure presented for review during the survey conducted on 10/17/23 was not approved, signed and dated by the current laboratory director. 3. The LD interviewed on 10/17/23 at 02:45 PM confirmed the RhD test procedure was not approved, signed and dated by the current laboratory director before use.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on lack of performance specification documentation for the EldonCard RhD test kit and interview with the Laboratory Director (LD), the laboratory failed to verify the manufacturer's performance specifications for the RhD test system, including accuracy, precision, reportable range and reference range, prior to reporting patient test results. Findings include: 1. The laboratory uses the EldonCard test kit to perform Rh testing. Patient testing began on 01/28/21. 2. The laboratory failed to demonstrate that it can obtain performance specifications for the RhD test system comparable to those established by the manufacturer prior to reporting patient test results, including accuracy, precision, reportable range and reference range. 3. The LD interviewed on 10/17/23 at 3:00 PM confirmed that no evidence was provided for review to indicate the laboratory verified the manufacturer's performance specifications for the RhD test system prior to testing patients. 4. The laboratory performed 3,690 patient tests from 01/28/21 through the date of the survey conducted on 10/17/23.
D5425	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(3) The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Control (QC) policy and interview with the laboratory director (LD), the laboratory failed to determine the EldonCard RhD test system's control procedures based upon the performance specifications verified under paragraph (b)(1) or (b)(2) of this section. Findings include: 1. The laboratory began patient testing on 01/28/21 using the EldonCard RhD test kit.. 2. The laboratory failed to verify the manufacturer's perfomance specifications for the EldonCard RhD

	test kit, see D5421 for specific findings. 3. The laboratory failed to determine the control procedures for the EldonCard RhD test kit including the type, number, and concentration of control materials used to monitor, detect errors, and evaluate method perfomance. 4. The LD interviewed on 10/17/23 at 3:10 PM confirmed the laboratory failed to establish control procedures based upon the performance specifications verified under paragraph (b)(1) or (b)(2) of this section. 5. The laboratory performed 3,690 patient tests from 01/28/21 through the date of the survey conducted on 10/17 /23.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of quality control (QC) documentation for testing performed on the EldonCard RhD test kit and interview with the Laboratory Director (LD), the laboratory failed to perform a positive and negative control on each day of patient testing. Findings include: 1. The laboratory began RhD testing on patients using the EldonCard RhD test kit on 01/28/21. 2. No documentation was presented for review during the survey to indicate the laboratory performed an external positive and negative control material on each day of patient testing from 1/28/21 through the survey date of 10/17/23. 3. The LD interviewed on 10/17/23 at 2:45 PM confirmed the laboratory failed to perform an external positive and negative control on each day of patient testing. 4. Approximately 3,690 Rh tests were performed on patients from 1/28 /21 through the survey date of 10/17/23.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on lack of quality assessment (QA) policies and procedures and interview with the Laboratory Director (LD), the laboratory failed to establish QA policies and procedures to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. Findings include: 1. No QA documentation was provided for review during the survey conducted on 10/17/23 to indicate the laboratory established policies and procedures to monitor, assess and, when indicated, correct problems identified in the analytic systems specified at 493. 1231 through 493.1236. 2. The LD interviewed on 10/17/23 at 4:06 PM confirmed the laboratory failed to provide documentation of an established QA policy and procedure to monitor, assess and correct problems identified in the analytic systems.

D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: The Condition of Technical Consultant was found to be not met based on the failure of the laboratory to have a Technical Consultant who provides technical oversight as evidenced by: D6040 - failure to verify the laboratory's test procedures performed and failed to verify the performance characteristics, including the precision and accuracy of the EldonCard RhD test system; D6042 - failure to establish a quality control program appropriate for the testing performed and failure to establish the parameters for acceptable levels of analytic performance to ensure that these levels are maintained throughout the entire testing process; D6049 - failure to ensure competency assessments include the evaluation of proficiency testing results and quality control records; and D6051 - failure to ensure competency assessments include the evaluation of test performance of external proficiency testing samples.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on lack of test verification documentation for the EldonCard RhD test kit, the technical consultant failed to verify the laboratory's test procedures performed and failed to verify the performance characteristics, including the precision and accuracy of the EldonCard RhD test system. See D5421 for findings.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on lack of quality control documentation for testing performed on the EldonCard RhD test, the technical consultant failed to establish a quality control program appropriate for the testing performed and failed to establish the parameters for acceptable levels of analytic performance to ensure that these levels are maintained throughout the entire testing process. See D5425 and D5449 for findings.
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES

	CFR(s): 493.1413(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Based on review of 3 out of 3 testing personnel competency records and interview with the Laboratory Director (LD), the procedures for evaluation of the competency of the staff failed to include a review of quality control records. Findings include: 1. Review of semiannual and annual competency records from 2021, 2022, and 2023 for three out of three testing personnel failed to include a review of quality control records. 2. The LD interviewed on 10/27/23 at 1:50 PM confirmed the procedures for the evaluation of competency of testing personnel failed to include review of quality control records.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on review of 3 out of 3 testing personnel competency records and interview with the Laboratory Director (LD), the procedures for evaluation of the competency of the staff failed to include the assessment of test performance through testing external proficiency testing samples. Findings include: 1. Review of semiannual and annual competency records from 2021, 2022, and 2023 for three out of three testing personnel failed to include an assessment of test performance through testing external proficiency testing samples. 2. The LD interviewed on 10/27/23 at 1:50 PM confirmed the procedures for the evaluation of competency of testing personnel failed to include an assessment of test performance through testing external proficiency testing samples.