

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2066470	(X3) Date Survey Completed 07/24/2023
Name of Provider or Supplier Desert Star Institute For Family Planning	Street Address, City, State 5501 N 19th Ave Ste 420, Phoenix, 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
D0000	An onsite recertification survey was performed on April 26, 2023. It was determined that Immediate Jeopardy (IJ) existed for the following condition-level deficiencies: 42 C.F.R. 493.1217 Condition: Immunohematology
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on lack of Proficiency Testing (PT) records for 2023 and interview with the facility personnel, the laboratory failed to enroll in an HHS approved PT program for the regulated analyte, D(RHO), under the subspecialty of ABO Group and Rh Group, which is included in subpart I . Findings include: 1. No documentation was presented for review during the survey conducted on April 26, 2023 to indicate the laboratory was enrolled in a CMS-approved PT program for 2023 for the regulated analyte, D (RHO), for which the laboratory performed patient testing. 2. The facility personnel interviewed via email on July 3, 2023 at 3:25 PM confirmed that the laboratory was not enrolled in an HHS approved PT program for the regulated analyte, D(RHO), at the time of the survey conducted on April 26, 2023. 3. The laboratory's annual test volume reported on the CMS-116 form provided during the survey is 500.</p>
D2015	TESTING OF PROFICIENCY TESTING SAMPLES

CFR(s): 493.801(b)(5)(6)

(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

This STANDARD is not met as evidenced by:

Based on lack of Proficiency Testing (PT) records for review from 2022 and interview with the laboratory director, the laboratory failed to maintain a copy of all PT records for a minimum of 2 years from the date of the proficiency testing event. Findings include: 1. The laboratory performs D(RHO) testing in the specialty of Immunohematology, with an approximate annual test volume of 500. 2. During the survey conducted on April 26, 2023, the laboratory failed to produce evidence of the following PT documentation from the second testing event of 2022: - Attestation statements signed by the Laboratory Director and testing personnel - Copy of the PT program report form used by the laboratory to record PT results 3. The laboratory director interviewed on April 26, 2023 at 10:20 AM confirmed that the PT records indicated above could not be located during the survey.

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 2022 sent to the State Agency by the PT provider, the laboratory failed to successfully participate in a PT program for the subspecialty of ABO/Rh Group and the regulated analyte, D (RHO), under the specialty of Immunohematology. Findings include: 1. The laboratory's PT

	<p>performance was unsatisfactory for the second event of 2022 for the subspecialty, ABO/Rh Group, with a score of 0%. 2. The laboratory's PT performance was unsatisfactory for the second event of 2022 for the regulated analyte, D (RHO), with a score of 0%. 3. The laboratory's PT performance was unsatisfactory for the third event of 2022 for the subspecialty, ABO/Rh Group, with a score of 80%. 4. The laboratory's PT performance was unsatisfactory for the third event of 2022 for the regulated analyte, D (RHO), with a score of 80%.</p>
D2153	<p>ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(a)</p> <p>Failure to attain a score of at least 100 percent of acceptable responses for each analyte or test in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of Proficiency Testing (PT) reports for 2022 sent to the State Agency by the PT provider and interview with the laboratory director, the laboratory failed to attain a score of at least 100 percent of acceptable responses for each analyte/test in each testing event for testing performed under the specialty of Immunohematology. Findings include: 1. The laboratory's PT performance was unsatisfactory for the third event of 2022 for the regulated analyte, D (RHO), with a score of 80% . 2. The laboratory director interviewed on 4/26/2023 at 10:12 AM acknowledged the unsatisfactory PT score of 80% for D (RHO) for the third PT event of 2022. 3. The laboratory's reported annual test volume in the specialty of Immunohematology is 500.</p>
D2159	<p>ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(d)</p> <p>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of Proficiency Testing (PT) reports for 2022 sent to the State Agency by the PT provider and interview with the laboratory director, the laboratory failed to return proficiency testing results to the proficiency testing program within the time frame specified by the program resulting in a score of 0 for the second testing event of 2022. Findings include: 1. Review of the laboratory's PT records from American Proficiency Institute (API) indicated the laboratory received a score of 0% for the second testing event of 2022 for the regulated analyte, D (RHO), resulting in unsatisfactory performance. 2. The laboratory director interviewed on 4/26/2023 at 10:10 AM stated, "the laboratory failed to submit the PT results (for the second testing event of 2022) by the deadline" resulting in a score of 0 for the second testing event of 2022.</p>
D2160	<p>ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(e)</p> <p>(1) For any unsatisfactory testing event for reasons other than a failure to participate,</p>

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 unsatisfactory 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 for 2022, the laboratory failed to undertake appropriate training, technical assistance and remedial action necessary to correct problems associated with proficiency test failures for the regulated analyte, D (RHO), and for the subspecialty, ABO/Rh Group. See D2016 for findings.

D2162

ABO GROUP AND D(RHO) TYPING
CFR(s): 493.859(f)

Failure to achieve satisfactory performance for the same analyte in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:
Based on review of Proficiency Testing (PT) reports for 2022 sent to the State Agency by the PT provider, the laboratory failed to achieve satisfactory performance for the regulated analyte, D (RHO), in two consecutive testing events resulting in unsuccessful PT performance. See D2016 for findings.

D2163

ABO GROUP AND D(RHO) TYPING
CFR(s): 493.859(g)

Failure to achieve an overall testing event score of satisfactory for two consecutive testing 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 an overall testing event score of satisfactory performance for the subspecialty of ABO Group and Rh Group for the second and third events of 2022, resulting in unsuccessful PT performance. See D2016 for findings.

D5026

IMMUNOHEMATOLOGY
CFR(s): 493.1217

If the laboratory provides services in the specialty of Immunohematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1271, and 493.1281 through 493.1299.

This CONDITION is not met as evidenced by:
Based on the number and severity of deficiencies cited for services provided in the

specialty of Immunohematology, the laboratory failed to meet the requirements specified in 493.1230 through 493.1256 and 493.1281 through 493.1299. See D5211, D5403, D5441, D5445 and D5791 for findings.

D5211

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:

Based on review of Proficiency Testing (PT) records from 2022 and interview with the laboratory director, the laboratory failed to provide a documented review of PT results from the 3rd testing event of 2022. Findings include: 1. The laboratory participates in PT for the regulated analyte, D(RHO), in the specialty of Immunohematology. The laboratory's reported annual test volume of 500. 2. No evidence, either by written comment or signature, was presented during the survey conducted on April 26, 2023 to indicate the laboratory director or other laboratory personnel reviewed the PT results for the 3rd testing event of 2022. 3. Review of the laboratory's PT scores for the 3rd testing event of 2022 revealed the laboratory received a unsatisfactory score of 80% for the analyte, D(RHO), and 80% for the subspecialty, ABO Group and Rh Group. 4. The laboratory director interviewed on April 26, 2023 at 10:23 AM confirmed the PT results indicated above were not reviewed by laboratory personnel.

D5403

PROCEDURE MANUAL

CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on review of the EldonCard Rhesus D Blood Type System procedure manual and interview with the laboratory director, the laboratory's procedure manual failed to include the type of control materials used for control procedures. Findings include: 1. Review of the procedure manual showed no procedure for the type of external

positive and negative control materials used by the laboratory. 2. Interview with the laboratory director on April 26, 2023 at 11:10 AM confirmed the laboratory failed to have a step-by-step procedure for performing external controls.

D5441

CONTROL PROCEDURES
CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's Individualized Quality Control Plan (IQCP), review of Quality Control (QC) documentation and interview with the laboratory director, the laboratory's Quality Control Plan (QCP) failed to include the type of testing control materials used for the EldonCard RhD test kit. Findings include: 1. The laboratory performs Rh testing on patient specimens using the EldonCard RhD test kit under the specialty of Immunohematology, with a reported annual test volume of 500. 2. The laboratory's QCP (included in the IQCP) for the EldonCard Rhesus D Blood Type System reviewed during the survey on April 26, 2023 states, "Control testing is conducted on laboratory test supplies with each new lot number received from the manufacturer; on each new box of tests opened; and once each month even if the test was not used during a specific month". 3. Review of the monthly Quality Control logs from July 2022 through April 2023 revealed the testing personnel performed control procedures using previously tested patient specimens as external positive and external negative control materials. 4. The laboratory's QCP failed to include information regarding the type of external control materials used for the EldonCard Rhesus D Blood Type System. 5. The laboratory failed to determine the acceptable performance level for each set of control materials (previously tested patient specimens) used as external positive and negative control materials for the EldonCard Rhesus D Blood Type System from July 2022 through April 2023. 6. The exact number of patient tests performed by the laboratory from July 2022 through April 2023 could not be determined at the time of the survey. 7. The laboratory director interviewed on April 26, 2023 at 11:48 AM confirmed the laboratory's QCP failed to include the type of control material used for the EldonCard Rhesus D Blood Type System, and the laboratory failed to determine the acceptable performance level for each set of previously tested patient samples used as external positive and negative control material from July 2022 through April 2023.

D5445

CONTROL PROCEDURES
CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified

in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (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 and interview with the laboratory director, the laboratory failed to perform and document control procedures using the number and frequency as required for testing performed in the specialty of Immunohematology. Findings include: 1. The laboratory performs D(RHO) testing on patient specimens using the EldonCard RhD test kit under the specialty of Immunohematology, with a reported annual test volume of 500. 2. The laboratory's Individualized Quality Control Plan (IQCP) for the EldonCard Rhesus D Blood Type System reviewed during the survey on April 26, 2023 stated, "Control testing is conducted on laboratory test supplies with each new lot number received from the manufacturer; on each new box of tests opened; and once each month even if the test was not used during a specific month." 3. The laboratory failed to perform and document external QC using positive and negative control materials for the following months: August 2021 through June 22. 4. The laboratory failed to perform and document external QC using a negative control material during February 2023. 5. Approximately 486 patient tests were performed during the months indicated above. 6. The laboratory director interviewed on April 26, 2023 at 11:25 AM confirmed the laboratory failed to perform and document quality control procedures for the months listed above.

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 review of Quality Assessment (QA) policies and procedures, analytic test records and interview with the laboratory director, the laboratory failed to follow established 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. The laboratory's established QA policy titled 'Quality Assurance' states, "Review all temperature logs monthly for rooms and refrigerator to ensure temperatures were monitored and recorded according to the QCP, and that appropriate corrective actions(s) were taken for any and all temperatures that were out of acceptable range. Review internal QC logs monthly to ensure appropriate corrective action(s) were taken for any unacceptable values." 2. The laboratory failed to document the QA activities indicated above during 2021 through the date of the survey conducted on April 26, 2023, and failed to monitor, assess, and when indicated, correct problems identified in the analytic systems. See D5403, D5441 and D5445 for specific findings. 3. The laboratory director interviewed on April 26, 2023 at 12:10 PM confirmed that the laboratory's QA processes were not effective at monitoring, identifying and correcting problems found in the analytic systems and

	<p>confirmed the laboratory failed to perform and document QA reviews as indicated in laboratory policy.</p>
<p>D6020</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on lack of Quality Control documentation and review of the Quality Control Plan (QCP) for the EldonCard Rhesus D Blood Type System, the laboratory director failed to ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. See D5441 and D5445 for findings.</p>
<p>D6033</p>	<p>TECHNICAL CONSULTANT-MODERATE COMPLEXITY CFR(s): 493.1409</p> <p>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.</p> <p>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: D6041 - failure to ensure that the laboratory was enrolled and participated in an HHS approved Proficiency Testing program for testing performed by the laboratory; D6049 - failure to ensure competency assessments include the evaluation of proficiency testing results and quality control records; D6051 - failure to ensure competency assessments include the evaluation of test performance of external proficiency testing samples; and D6052 - failure to ensure competency assessments include the evaluation of problem solving skills.</p>
<p>D6041</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(3)</p> <p>(b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered;</p> <p>This STANDARD is not met as evidenced by: Based on lack of Proficiency Testing (PT) records from the first testing event of 2023, for D(RHO) testing, and interview with the facility personnel, it was determined that the technical consultant failed to ensure that the laboratory was enrolled and participated in an HHS approved PT program. See D2000 for findings.</p>

<p>D6049</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of testing personnel competency records and interview with the technical consultant, the procedures for evaluation of the competency of the staff failed to include review of quality control records and proficiency testing results. Findings include: 1. Review of annual competency records from 2022 for one out of one testing personnel failed to include review of quality control records and review of proficiency testing results. 2. The laboratory director interviewed on April 26, 2023 at 10:25 AM confirmed the procedures for the evaluation of competency of testing personnel failed to include review of quality control records and proficiency testing results.</p>
<p>D6051</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of testing personnel competency records and interview with the technical consultant, 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 annual competency records from 2021 and 2022 for one out of one testing personnel failed to include the assessment of test performance through testing external proficiency testing samples. 2. The laboratory director interviewed on April 26, 2023 at 10:25 AM confirmed the procedures for the evaluation of competency of testing personnel failed to include the assessment of test performance through testing external proficiency testing samples.</p>
<p>D6052</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(vi)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills.</p> <p>This STANDARD is not met as evidenced by: Based on review of competency evaluation forms and interview with the technical consultant, the procedures for evaluation of the competency of laboratory staff failed to include the assessment of problem solving skills. Findings include: 1. Review of annual competency records from 2021 and 2022 for one out of one testing personnel failed to include the assessment of problem solving skills. 2. The technical consultant</p>

interviewed on April 26, 2023 at 10:25 AM confirmed the procedures for evaluation of the competency of the staff failed to include the assessment of problem solving skills.

D6072

TESTING PERSONNEL RESPONSIBILITIES

CFR(s): 493.1425(b)(3)

Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.

This STANDARD is not met as evidenced by:

Based on review of monthly Quality Control (QC) logs, review of the laboratory's Control Test Log procedure and interview with the laboratory director, the testing personnel failed to adhere to the laboratory's quality control policies. Findings include: 1. The laboratory's established policy titled, "Control Test Log" states, "Instructions for completing the Control Test Log: Control Lot Number and Expiration are documented from the control used. Cassette/Strip Lot Number and C/S Expiration come from the test used." 2. The monthly Control Test Logs reviewed from October 2022 through April 2023 showed the testing personnel failed to document the EldonCard Lot# and EldonCard Expiration Date each month quality control activities were performed. 3. The laboratory director interviewed on April 26, 2023 at 11:55 AM confirmed the testing personnel failed to adhere to the laboratory's quality control policies for documenting test card lot number and expiration date each month of quality control performance.