

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2119781	(X3) Date Survey Completed 02/06/2019
Name of Provider or Supplier Reliance Diagnostics	Street Address, City, State 353 Us 46, Fairfield, NJ	
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
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 surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to enroll in an approved PT program for Complete Blood Count (CBC) tests from August 2017 to the date of survey. The TP # 1 listed on CMS form 209 confirmed on 2/6/19 at 11:45 am the laboratory was not enrolled in PT for CBC tests.</p>
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation of the Laboratory equipment and interview with the Laboratory Director (LD), the laboratory failed to ensure protection from physical</p>

	<p>hazards at the time of the survey. The finding includes: 1. Observation of the Power Spin centrifuge revealed the table it was placed on was not level, the table had a downward slant and the centrifuge was placed at the low end. 2. The LD confirmed on 2/5/19 at 1:10 pm that the laboratory did not ensure protection from physical hazards.</p>
<p>D3029</p>	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(2)</p> <p>Test procedures. Retain a copy of each test procedure for at least 2 years after a procedure has been discontinued. Each test procedure must include the dates of initial use and discontinuance.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Coagulation Tests and interview with the Testing Personnel (TP), the laboratory failed to retain the test procedure for Prothrombin Tests (PT) performed on the Sysmex CA 600 Series Analyzer from 8/8/ 17 to 1/29/19. The finding includes: 1. The test procedure includes the International Sensitivity Index (ISI) used to calculate the International Normalized Ratio (INR) for PT tests. 2. The laboratory used an ISI value of .99 to calculate the INR in the time period stated above but there was no documented evidence found to verify the value. 2. The TP confirmed on 2/5/19 at 1:00 pm that test procedures were not retained.</p>
<p>D5209</p>	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on lack of the Competency Assessment (CA) records, review of the personnel files and interview with the Laboratory Director (LD), the laboratory failed to perform a CA on one out of one Testing Personnel (TP) in the calendar year 2018. The LD confirmed on 2/6/19 at 11:25 am that CA was not performed on TP.</p>
<p>D5215</p>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing records and interview with the Laboratory Director (LD), the laboratory failed to evaluate coded results obtained for Endocrinology tests in 2 and 3 event of 2018 performed with the College of American Pathologists (CAP). The findings include: 1. The laboratory did not evaluate code 20 (No appropriate target) for Triiodothyronine, Free Triiodothyronine and Thyroxine</p>

	<p>tests. 2. The LD confirmed on 2/6/19 at 10:50 am that the laboratory failed to evaluate coded results.</p>
<p>D5309</p>	<p>TEST REQUEST CFR(s): 493.1241(e)</p> <p>If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Test Requisitions (TR), Procedure Manual (PM) and interview with the Laboratory Director (LD), the laboratory failed to ensure that information from the TR was transcribed accurately into the laboratory information system from November 13, 2018 to December 29, 2018. The findings include: 1. A review of 29 out of 29 TR revealed that all 29 TR were not reviewed by another technical staff. 2. The plan of correction of 8/8/17 and the "Specimen Processing" procedure was not followed. 3. The LD confirmed on 2/6/19 at 11:00 am it was not done all the time. Note: This deficiency was cited on the survey report of 8/8/17.</p>
<p>D5401</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: a) Based on surveyor review of the Procedure Manual (PM), review of Quality Control (QC) data and interview with the Testing Personnel (TP), the laboratory failed to follow the procedure for "Establishment of Control Ranges" in the calendar year 2018. The findings include: 1. The PM stated " Control materials are tested as patients for 5 time in different shifts running with current QC". 2. There was not documented evidence QC used for the Advia 560 or Excyte Min-Vital was tested 5 times before use. 3. The TP confirmed on 2/5/19 at 2:50 pm that the QC procedure stated above was not followed. b) Based on surveyor review of the PM and interview with the TP, the laboratory failed to follow the procedure to verify calculated results from 8/8/17 to the date of the survey. The finding includes: 1. The PM stated "The result of any calculated test must be verified using a calculator or online web site but there was no documented evidence the International Normalized Ration (INR) was verified. 2. The TP confirmed on 2/5/19 at 1:50 pm that the PM was not followed. c) Based on surveyor review of the PM and interview with the TP, the laboratory failed to follow the Quality Monitor Report (QMR) procedure to submit a QMR from 8/8/17 to the date of the survey. The TP confirmed on 2/5/19 at 2:40 pm that a QMR was not submitted and the PM was not followed.</p>
<p>D5417</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other</p>

supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on surveyor observation of Quality Control (QC) material in use, review of the Acu-Sed Plus (ASP) Normal and Abnormal ESR Control Kit Manufacture Package Insert (MPI) and interview with the Testing Personnel (TP), the laboratory used expired QC material for the Excyte Mini Vital ESR analyzer from June 1, 2018 to the date of survey. The findings include: 1. The MPI stated open vial stability was for 31 days. 2. ASP QC material in use was dated with an open date of 5/1/18. 3. Approximately 45 patients were run and reported with expired QC . 4. The TP confirmed on 2/6/19 at 11:00 am that the laboratory used expired QC material.

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 surveyor review of the Performance Specification (PS) records and interview with the Testing Personnel (TP), the laboratory failed to verify the Manufacturer's Reference Interval (MRI) for routine chemistry and endocrinology tests performed on Siemens Dimension EXL 200 and Tosho AIA-900 analyzer respectively from March 2017 to the date of survey. The findings include; 1. The TP stated that the test volume was too low to verify the MRI 2. The plan of corrections stated "Due to low specimen volume, average 5-7 weekly, the lab did not have sufficient specimens to complete MRI. Specimens will be frozen to have sufficient volume to complete MRI." 3. The Plan of Corrections (POC) had citation completion date for 9/21/17 but it was not corrected on the day of survey. 4. The TP confirmed on 2/5/19 at 11:10 am that MRI was not verified for routine chemistry and endocrinology testing. NOTE: This deficiency was previously cited on the survey conducted 8/8/17.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Maintenance Record (MR) and interview with the Testing Personnel (TP), the laboratory failed to perform and document maintenance as specified by the manufacturer on the Sysmex CA - 600 analyzer used in Coagulation Testing in the calendar year 2018. The findings include: 1. MR records revealed

maintenance was not performed as below: a. Weekly Maintenance - Not performed in July and December 2018. b. Weekly maintenance - Not performed weekly in April and May 2018. c. Quarterly Maintenance - Clean DI Water Rinse bottle - 2018. b. Quarterly Maintenance - Perform LED calibration - not performed for 3 quarters of 2018. 2. The TP confirmed on 2/5/19 at 2:30 pm that maintenance as specified by the manufacturer was not performed.

D5469

CONTROL PROCEDURES
CFR(s): 493.1256(d)(10)(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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Quality Control (QC) records, Manufacturer's Package Inserts (MPI) and interview with the Testing Personnel (TP), the laboratory failed to establish statistical parameters for the QC material used for Endocrinology tests performed on the Tosho IAI-900 from 8/8/17 to the date of the survey. The findings include: 1. A Biorad Lyphocheck Immunoassay Plus Control insert did not have Thyroid Stimulating Hormone (TSH) QC ranges for the Tosho AIA-900 analyzer. 2. The laboratory did not establish statistical Parameters before putting into use from 8/8/17 until the date of survey. 3. The laboratory performed and reported approximately 100 patients results. 4. The TP confirmed on 2/6/19 at 11:45 am failed to establish statistical parameters for the QC material.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Final Reports (FR) and interview with the Testing Personnel (TP), the laboratory failed to ensure the FR included all tests performed from March 2017 to the date of survey. The finding includes: 1. The FR reported a

	<p>test as Part Thromboplastin Time but the test performed was A Partial Thromboplastin Time. 2. The TP confirmed on 2/5/19 at 1:00 pm that the laboratory did not have all the required information on the FR.</p>
D5891	<p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a)</p> <p>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 postanalytic systems specified in 493.1291.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Laboratory Director (LD), the laboratory failed to establish a procedure for verifying manually entered results from August 2017 to the date of survey. The LD confirmed on 2/6/19 at 10:30 am that the laboratory did not have the procedure mentioned above.</p>
D6074	<p>TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(5)</p> <p>Each individual performing moderate complexity testing must be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the technical consultant, clinical consultant or director.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the Technical Supervisor (TS), the TS failed to identify problems that may affect test performance by not reviewing and evaluating trends and/or shifts for tests performed on the Advia 560 analyzer from July 2018 to the date of the survey. The TS confirmed on 2/5/19 at 1:45 pm that trends and shifts were not reviewed.</p>
D6177	<p>TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(3)</p> <p>Each individual performing high complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records, Manufactures Package Insert (MPI), Levy Jennings Charts (LJC) and interview with the testing Personnel (TP), the TP failed to ensure the LJC were reviewed correctly for routine chemistry tests performed on the Siemens Dimension EXL 200 from 8/8/17 to the date of the survey. The findings include: 1. Review of 14 analytes LJC revealed that the LJC did not have QC lot numbers. 2. LJC's did not have MPI or peer group QC values. 3. The TP was unsure from where the LJC's values were derived. 4. The TP confirmed on 2/6/19 at 1:30 pm that LJC did not include all information.</p>