

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2084339	(X3) Date Survey Completed 08/03/2022
Name of Provider or Supplier Desert Laboratories, Llc	Street Address, City, State 1343 N Alma School Rd, Ste 150, Chandler, 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
D5305	<p>TEST REQUEST CFR(s): 493.1241(c)</p> <p>The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.</p> <p>This STANDARD is not met as evidenced by: Based on review of patient test requisitions for urine drug screen testing performed under the specialty of Chemistry and interview with the technical supervisor, two out of two test requisitions failed to include the date and time of specimen collection. Findings include: 1. The laboratory performs urine drug screen and confirmation testing on patient specimens in the specialty of Chemistry with an approximate annual test volume of 61,182. The laboratory utilizes the Beckman Coulter AU400 chemistry analyzer for the drug screen testing and utilizes the Thermo Quantum Access analyzer for the drug confirmation testing. 2. The test requisitions presented for review during the survey for specimen# S0018391 and specimen# S0017500 failed to include the date and time of specimen collection. 3. The technical supervisor interviewed at 1:15pm on 8/03/2022 confirmed the date and time of specimen collection were not documented on the test requisitions referenced above.</p>

D5311

SPECIMEN SUBMISSION, HANDLING, AND REFERRAL

CFR(s): 493.1242(a)

The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:

Based on review of established policies and procedures for specimen rejections and interview with the technical supervisor, the laboratory failed to follow established policies and procedures for rejected specimens. Findings include: 1. The laboratory performs urine drug screen and confirmation testing on patient specimens in the specialty of Chemistry with an approximate annual test volume of 61,182. The laboratory utilizes the Beckman Coulter AU400 chemistry analyzer for the drug screen testing and utilizes the Thermo Quantum Access analyzer for the drug confirmation testing. 2. The laboratory's established policy titled, Quality Assurance Plan Procedure Version 1.1, states, "Pre-Analytical - The attached form will be filled out by the specimen receiving department when any specimen is considered "not acceptable" (to include) 1. QNS specimen; 2. Specimen not properly labeled with three identifiers; 3. Specimen is too old. One week not refrigerated; 4. Incorrect sample." 3. No documentation was presented for review to indicate the laboratory followed the established policy indicated above and documented rejected specimens on a form or log from January 2020 through the date of the survey, 8/3/2022. 4. The technical supervisor interviewed on 8/3/22 at 3:30pm confirmed that the laboratory failed to follow their established policy and document rejected specimens on the Specimen Rejection form.

D5433

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:

Based on lack of an established maintenance policy for the centrifuge and incubator which are used as peripheral equipment involved in patient testing, lack of pipette calibration documentation and interview with the technical supervisor, the laboratory failed to establish and/or follow maintenance protocols for equipment used by the laboratory involved with patient testing. Findings include: 1. The laboratory performs urine drug screen and confirmation testing on patient specimens in the specialty of Chemistry with an approximate annual test volume of 61,182. The laboratory utilizes the following pieces of equipment that are peripherally involved in patient testing: pipettes, a centrifuge and an incubator. 2. No documentation was presented for review

during the survey conducted on August 3, 2022 to indicate the laboratory established a maintenance protocol for the centrifuge and incubator used by the laboratory in conjunction with patient testing. 3. The laboratory's established policy, "Pipette Calibration Policy and Procedure" presented for review during the survey states, "Pipettes are sent out to Pipette.com once a year for calibration". 4. The laboratory failed to follow the established policy listed above and could not produce evidence of annual pipette calibration records for 2020 and 2021 for the pipettes used by the laboratory in conjunction with patient testing. 5. The technical supervisor interviewed on 8/3/22 at approximately 2:45pm acknowledged that the laboratory failed to establish a maintenance protocol for the centrifuge and incubator and confirmed that the pipettes were not calibrated on an annual basis per laboratory policy.

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 review of the laboratory's quality control (QC) records, lack of QC lot correlation documentation and interview with the facility personnel, the laboratory failed to verify the criteria for acceptability of quality control materials. Findings include: 1. The laboratory performs urine drug screen and confirmation testing on patient specimens in the specialty of Chemistry with an approximate annual test volume of 61,182. The laboratory utilizes the Beckman Coulter AU400 chemistry analyzer for the drug screen testing. 2. No documentation was presented for review during the survey conducted on August 3, 2022 to indicate the laboratory verified the criteria for acceptability of each lot of control material used on the analyzer indicated above from January 2020 through the date of the survey. 3. At approximately 2:00pm on August 3, 2022, the testing personnel interviewed confirmed that the laboratory failed to verify and document the criteria for acceptability of control lots used on the analyzers stated above. 4. The number of QC lots used on the analyzer from January 2020 through the date of the survey could not be determined at the time of the survey.

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1299(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 postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:

Based on lack of Quality Assessment (QA) documentation and interview with the technical supervisor, the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems. Findings include: 1. The laboratory's established QA policy, Quality Assurance Plan Procedure Version 1.1 states, "Post-Analytical - The attached form will be used to review the Post-Analytical results. Common errors found in Post-Analytical: 1. Transcription errors of results; 2. Incorrect tests performed due to incorrect ordering of tests; 3. Increased Turn-Around time." 2. During the survey conducted on August 3, 2022, no QA documentation from January 2020 through the date of the survey was provided for review to indicate the laboratory followed the established policy and procedure indicated above to monitor, assess and, when indicated, correct problems identified in the postanalytic systems. 3. The technical supervisor interviewed on 8/03/2022 at 3:45pm confirmed the laboratory failed to provide documentation of completed QA activities indicated above to monitor, assess and correct problems identified with the postanalytic systems.