

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2090034	(X3) Date Survey Completed 11/16/2022
Name of Provider or Supplier Advanced Diagnostic Labs Llc	Street Address, City, State 11030 N Tatum Blvd, Bldg F, Ste 101b, 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
D5301	<p>TEST REQUEST CFR(s): 493.1241(a)</p> <p>The laboratory must have a written or electronic request for patient testing from an authorized person.</p> <p>This STANDARD is not met as evidenced by: Based on lack of test requisitions for review and interview with the technical supervisor, the laboratory failed to have a written or electronic request for patient testing for two out of two patient records reviewed during the survey. Findings include: 1. The laboratory performs urine drug screen and confirmation testing in the sub-specialty of Toxicology, with an approximate annual test volume of 45,000. It is the practice of the laboratory to perform a drug screen and confirmation test on each specimen received. 2. No written or electronic request for testing was presented for review for two out of two patient records reviewed during the survey (patient ID# PADDAV001 reported on 4/06/2022 and patient ID# SALRUB001 reported on 8/07/2021). 3. During the survey conducted on 11/16/22, the laboratory presented a chart cover as evidence of a test requisition for each patient indicated above, however the chart cover does not include the required information needed for a test requisition, including but not limited to, the test(s) to be performed. 4. The technical supervisor interviewed on 11/16/22 at 11:05am confirmed the laboratory failed to provide evidence of an electronic or written test requisition for drug screen and confirmation testing performed on the patients' indicated above.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's</p>

instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on lack of temperature records for review and interview with the technical supervisor, the laboratory failed to monitor and document the room temperature and humidity of the room where patient testing is performed and failed to monitor and document the temperature of the incubator used in conjunction with patient testing. Findings include: 1. The laboratory performs urine drug screen and confirmation testing in the sub-specialty of Toxicology, with an approximate annual test volume of 45,000. The laboratory utilizes the Agilent LC/MS/MS 6460 QQQ for the drug screen and drug confirmation testing. 2. No room temperature documentation was presented for review from 12/09/2019 through the date of the survey, 11/16/2022, to indicate the laboratory monitored and documented the temperature of the room where the analyzer and test reagents are stored, on each day the laboratory performed patient testing. 3. No documentation was presented for review from 12/09/2019 through the date of the survey, 11/16/2022, to indicate the laboratory monitored and documented the ambient humidity of the room where the analyzer and test reagents are stored, on each day the laboratory performed patient testing. 4. No documentation was presented for review from 12/09/2019 through the date of the survey, 11/16/2022, to indicate the laboratory monitored and documented the temperature of the incubator used in conjunction with patient testing. 5. The number of days the laboratory performed patient testing between 12/09/2019 and 11/16/2022 could not be determined at the time of the survey. 6. The technical supervisor interviewed on 11/16/22 at 12:12pm confirmed that the laboratory failed to monitor and document the temperatures as indicated above since 12/09/2019.