Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D2258804	(X3) Date Survey Completed 11/10/2022
Name of Provider or Supplier Advanced Biomedical Dba Udl At Southaven	**Street Address, City, State** 8727 Northwest Dr Ste C, Southaven, MS	

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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) 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. This STANDARD is not met as evidenced by: Based on review of the laboratory Blood Sample Handling and Processing procedure and interview with a phlebotomist who collects samples for the facility, the owner of the laboratory and the laboratory director listed on the Centers for Medicare & Medicaid Services (CMS) 209 form at 1:00 p.m. on 11/10/2022, the phlebotomist did not follow the facility's sample handling procedure for correct centrifuging of samples after collection. Findings include: 1. Review of the Blood Sample Handling and Processing procedure states "In general for a horizontal, swing-bucket centrifuge, the recommended spin time is 10 minutes. For a fixed-angle centrifuge, the recommended spin time is 15 minutes". The phlebotomist interviewed was using the fixed-angle centrifuge. 2. Observation of the LW Scientific centrifuge secured in the back seat of the phlebotomist's vehicle on 11/10/2022 revealed the centrifuge had an on/off switch along with a timer dial that extended from 0 - 30 minutes. 3. Interview with the phlebotomist at 1:00 p.m. on 11/10/22 revealed the timer was not used in the centrifugation process for specimens. The centrifuge was turned on without setting the time on the dial. Specimens were routinely centrifuged for an unknown amount of time. 4. An interview with the laboratory director and laboratory owner revealed they were unaware of how the centrifuge procedure was being followed for specimen centrifugation. The director and owner confirmed there are eleven phlebotomists. It was unclear how many of the eleven have centrifuges in their vehicles.
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 review of records for the Clinitek 500 Urine analyzer, lack of documentation of verification of performance specifications, and interview with testing personnel (TP) #1 and the technical consultant/ laboratory director (TC/LD) at 5:30 p.m. on 11/10/2022, the laboratory failed to ensure that performance specifications including comparison studies were performed prior to testing patients. The Clinitek 500 Urine analyzer was put in use on 1/18/2022. Findings: 1. Review of the Clinitek 500 Urine analyzer records put into use on 01/18/2022 revealed no documentation of verification of performance specification or method comparison study performed. According to surveyor notes the Clinitek 500 is used by the laboratory to test glucose, bilirubin,, ketones, specific gravity, blood, pH, protein, urobilinogen, nitrite and leukocytes on patients' urine specimens. 2. Interview with TP #1 and the TC/LD at 5:30 p.m. on 11/10/2022 revealed no performance specification or validation had been performed for urine testing on the Clinitek 500 Urine analyzer before testing patients on 10/04/2022. Approximately 50-60 patients had been tested in that time period according to the machine printouts available for review. .
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 review of quality control (QC) logs, patient testing printouts and interview with both TC/LD and TP#1 as listed on the Centers for Medicare and Medicaid Services (CMS) 209 personnel form on 11/10/22 at 5:30 p.m., the laboratory failed to include a positive (abnormal) and negative (normal) control on each day of patient testing for the Clinitek 500 Urine analyzer when performing patient testing between 10/04/2022 through 11/10/2022. Findings Include: 1. Interview with the LD/TC and TP #1 at 5:30 p.m. on 11/10/2022 confirmed that testing personnel (TP) were not performing two levels of QC (normal and abnormal) each day of patient testing when testing on the Clinitek 500 Urine analyzer. They confirmed QC was performed once a month. 2. There was no IQCP (Individualized Quality Control Plan) available for review on the day of survey. An IQCP is required after 01/01/2016 if two levels of quality control (QC) are not performed each day of use for moderate/high complexity testing. 3. Review of the Clinitek 500 QC log from 01/18/2022 through 11/05/2022 and the patient urine analyzer printouts from 10/4/2022 through 11/10/2022 revealed

	no QC was performed on the days patient urine samples were tested and reported. Approximately 50-60 patient specimens were tested during that time period according to the analyzer printouts.
D6056	CLINICAL CONSULTANT CFR(s): 493.1415 The laboratory must have a clinical consultant who meets the qualification requirements of 493.1417 of this part and provides clinical consultation in accordance with 493.1419 of this part. This CONDITION is not met as evidenced by: Based on review of the Centers for Medicare & Medicaid Services (CMS) 209 Personnel Report, lack of qualifying documentation for a clinical consultant available, and confirmation by the laboratory director at 11:00 p.m. on 11/10/2022, the laboratory did not have a qualified individual designated as clinical consultant who qualified in accordance with 493.1417.
D6057	CLINICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1417 The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493. 1405(b)(1), (2), or (3)(i); or (b) Be a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine and possess a license to practice medicine, osteopathy or podiatry in the State in which the laboratory is located. This STANDARD is not met as evidenced by: Based on review of the CMS (Centers for Medicare and Medicaid Services) 209 personnel form, review of personnel records, lack of qualifying documentation, and confirmation by the laboratory director at 11:00 a.m. on 11/10/2022, the laboratory did not have an individual qualified to perform the duties of the clinical consultant.