Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2024969	05/23/2019
Name of Provider or Supplier	**Street Address, City, State**	
Gipson Specialty Center, Pllc	6005 Park Ave Ste 400, Memphis, TN	

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
D3001	FACILITIES CFR(s): 493.1101(a)(1) The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process. This STANDARD is not met as evidenced by: Based on observation of the laboratory and interview with the lead testing personnel, the laboratory failed to have adequate space for performing patient testing and all laboratory processes. The findings include: 1) Observation of the laboratory on May 23, 2019 at 9:20 am revealed laboratory space that was very small. The countertop was overcrowded with no adequate space to perform specimen processing, accessioning, paperwork, or computer work. There was limited space for storage of laboratory records. 2) Interview with the lead testing personnel on May 23, 2019 at 9: 30 am confirmed the laboratory space was not adequate to carry out all laboratory testing procedures, required paperwork and storage of laboratory records.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) 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). This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records and interview with the lead testing personnel, the laboratory failed to evaluate the accuracy of non-graded

	proficiency testing results for 2018 event one. The findings include: 1) Review of the laboratory's 2018 event one proficiency testing records revealed a non-graded score for sample number UDS-02 for opiates. There was no documentation that the result had been evaluated against the proficiency testing program expected results to determine the laboratory's accuracy. 2) Interview with testing personnel number one on May 23, 2019 at 3:00 pm confirmed the laboratory failed to evaluate non-graded proficiency testing results for opiate in 2018 event one.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assessment plan, quality assessment monitors schedule, patient test management records and interview with the lead testing personnel, the laboratory failed to follow the quality assessment plan for patient test management in 2017 and 2018. The findings include: 1) Review of the laboratory's quality assessment plan revealed that patient test management would be performed to monitor accuracy from pre-analytic through post-analytic phases of testing. 2) Review of the quality assessment schedule revealed that patient test management monitors would be performed for the 2nd and 4th quarters of the year. 3) Review of the laboratory's patient test management records revealed that no records were present documenting patient test management monitoring for the 4th quarter of 2017 and the 2nd quarter of 2018. 4) Interview with the lead testing personnel on May 23, 2019 at 3:00 pm confirmed the laboratory failed to follow the quality assurance plan for patient test monitoring in the 4th quarter of 2017 and the second quarter of 2018 with patient testing performed.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, technical supervisor's job description, validation studies for the Medica Easy RA instrument, quality assessment documents, laboratory director's personnel records, the general supervisor's job description, testing personnel records, patient number six's test report and interview

	with testing personnel number one, the laboratory director failed to ensure the technical supervisor and general supervisor performed delegated duties in 2017, 2018, and 2019. The findings include: 1) Review of the laboratory's procedure manual revealed the laboratory director's duties were delegated to a consulting group for the positions of technical supervisor, general supervisor and testing personnel. 2) Review of the technical supervisor's job description revealed the following statements: "Verification of the test procedures performed and establishment of the lab performance specifications, including the precision, accuracy and reportable range." "Monitors and review all department functions including: quality control, maintenance, training/competency, proficiency testing, test performance, correction actions." 3) Review of the validation studies performed for the Medica Easy RA instrument used for performing tests for toxicology revealed no documented review by the technical supervisor for the initial validation performed in 2017 or the validation performed in February 2019 for additional urine drug screen analytes. 4) Review of quality assessment documents for the months of June 2017, November 2017, March 2018, and June 2018 through April 2019 revealed review of monthly quality control documents by the laboratory director. There was no review of quality assessment documents by the technical supervisor. No documentation was present in the laboratory director's personnel records that qualified the laboratory director as a technical supervisor. 5) Review of the general supervisor's job description revealed "Provide orientation and training to all testing personnel." 6) Review of testing personnel number one's personnel records revealed a start date of 05.30.2018 with initial training and competency assessment for performance of urine drug screen testing performed on 09.05.2018. 7) Review of patient number six's test report revealed urine drug screen testing performed by testing personnel number one on 07.24.2018, prior to initial training. 8) Interview with testing personnel number one on May 23, 2019 at 1:40 pm confirmed the laboratory director failed to ensure the technical supervisor and general supervisor performed the delegated duties in 2017, 2018 and 2019.