Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 04D2159576	**(X3) Date Survey Completed** 08/08/2019
Name of Provider or Supplier Natural State Laboratories	**Street Address, City, State** 1514 Market Street, B100, Little Rock, AR	
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**
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Through review of quality control records, review of computerized batch documentation, lack of documentation and interview with laboratory staff it was determined that the laboratory failed to document the performance of quality control before reporting patient results on three of thirteen days of testing in June 2019. Findings follow: A) Review of quality control records revealed that quality control procedures were succesfully performed for drug testing by mass spectrometry on 6/7 /19, 6/18/19, 6/19/19, 6/20/19, 6/21/19, 6/24/19, 6/25/19, 6/26/19, 6/27/19, and 6/28 /19. B) Review of computerized batch performance documentation revealed that drug testing was performed on 6/10/19, 6/12/19 and 6/13/19. C) Review of specimen logs revealed that eight procedures were performed and reported on 6/10/19 for patients identified as numbers one through eight on the separate specimen identification list. D) Review of specimen logs revealed that twenty-three procedures were performed and reported on 6/12/19 for patients identified as numbers nine through thirty-one on the separate specimen identification list. E) Review of specimen logs revealed that twenty-six procedures were performed and reported on 6/13/19 for patients identified as numbers thirty-two through fifty-seven on the separate specimen identification list. F) Upon request, the laboratory was unable to provide documentation of succesful quality control results performed on 6/10/19, 6/12/19 and 6/13/19. G) In an interview on 08/08/19 at approximately 01:30 PM, the technical supervisor, identified as number nine on the CMS 209 form, confirmed that no documentation could be found for mass spectrometry quality control performed on June 10, 2019, June 12, 2019 and June 13, 2019 and that testing was performed on those dates.

D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Through a review of personnel records for laboratory personnel, lack of documentation, and interviews with laboratory staff, it was determined the Laboratory Director failed to specify in writing the procedures six of six testing personnel are authorized to perform and whether supervision is required. Survey findings follow: A) Review of personnel records of testing personnel performing highly complex drug testing by mass spectrometry, identified as numbers three through eight inclusive on the CMS 209 form, did not include written authorization to perform testing signed by the laboratory director. B) Upon request, the laboratory was unable to provide authorization to perform testing for the personnel identified above. C) In an interview at approximately 10:30 AM on 8/8/19, the technical supervisor , identified as number nine on the CMS 209 form, confirmed the authorizations to perform testing signed by the laboratory director were not provided for the testing personnel identified above.