

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2114053	(X3) Date Survey Completed 10/16/2019
Name of Provider or Supplier Dls Research & Ventures	Street Address, City, State 1700 Honey Creek Cmns Se Suite A, Conyers, GA	
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
D0000	An onsite survey was completed on October 16, 2019, to investigate complaint number GA00199634. The allegations were substantiated. Deficiencies were cited.
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP), patient requisition and report review, and staff interview, the laboratory failed to follow written policies and procedures for specimen processing as required. Findings include: 1. SOP review revealed the laboratory did not follow the accessioning quality control (QC) guidelines to ensure proper sample identification and reporting. 2. Patient requisition review and inhouse test report review revealed the patient identifiers assigned by DLS did not match the initial patient requisition. 3. An interview with the technical supervisor on October 16, 2019, in a conference room at approximately 3:30 p.m. confirmed the aforementioned findings.</p>
D6094	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p>

This STANDARD is not met as evidenced by:
Based on review of the laboratory policy and procedure manual (SOP), patient requisition and report review, and staff interview, the laboratory director (LD) failed to ensure the quality assessment program was followed as required. Findings include: 1. SOP review revealed the laboratory did not follow the accessioning quality control (QC) guidelines to ensure proper sample identification and reporting. 2. Patient requisition review and inhouse test report review revealed the patient identifiers assigned by DLS did not match the initial patient requisition. 3. An interview with the technical supervisor on October 16, 2019, in a conference room at approximately 3:30 p.m. confirmed the aforementioned findings.

D6112

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451

The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section.

This STANDARD is not met as evidenced by:
Based on review of the laboratory policy and procedure manual (SOP), patient requisition and report review, and staff interview, the technical supervisor (TS) failed to provide technical oversight over the laboratory as required. Findings include: 1. SOP review revealed the laboratory did not follow the accessioning quality control (QC) guidelines to ensure proper sample identification and reporting. 2. Patient requisition review and inhouse test report review revealed the patient identifiers assigned by DLS did not match the initial patient requisition. 3. An interview with the TS on October 16, 2019, in a conference room at approximately 3:30 p.m. confirmed the aforementioned findings.