Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D1056551	(X3) Date Survey Completed 12/10/2019
Name of Provider or Supplier Delta Pathology Group, Llc - Mandeville	**Street Address, City, State** 229 West Causeway Approach, Mandeville, LA	

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	A Certification Survey was performed on December 10, 2019 at Delta Pathology Group, LLC-Mandeville, CLIA ID # 19D1056551. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to establish complete competency policies for testing personnel. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not include the following six (6) procedures as a minimal requirement for assessing the competency of all personnel performing laboratory testing: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting or test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f) Assessment of problem solving skills. 2. Further review of the laboratory's policy and procedure manual revealed the frequency and how testing personnel competency will be assessed was not included. 3. In interview on December 10, 2019, the Laboratory Director confirmed the laboratory's policy and procedure manual did not include competency assessment for testing personnel.

D5609	HISTOPATHOLOGY CFR(s): 493.1273(e)(f) (e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to ensure testing personnel documented the stain quality for Hematoxylin and Eosin (H&E) stains. Findings: 1. Review of the laboratory's CMS 209 form (Laboratory Personnel Report) revealed the Laboratory Director serves as the testing personnel. 2. Review of random selection of patients and quality control (QC) records from March 2018 through December 2019 revealed the laboratory did not have documented QC assessment performed for the following dates: Report Date: March 20, 2018 Patient: JS18-08061 Report Date: June 6, 2018 Patient: JS18-19334 Report Date: October 17, 2018 Patient: JS18-37693 Report Date: January 29, 2019 Patient: JS19-03720 Report Date: June 3, 2019 Patient: JS19-23537 Report Date: October 21, 2019 Patient: JS19-47113 Report Date: November 25, 2019 Patient: JS19-59081 Report Date: December 2, 2019 Patient: JS19-60365 3. In interview on December 10, 2019 at 9:15 am, the Laboratory Director stated he does not document acceptable stain quality for H&E stains. The Laboratory Director further stated if the stain quality is unacceptable he documents and notifies the processing location. The Laboratory Director confirmed for H&E stains acceptable stain quality was not documented. 4. Review of the laboratory's test menu revealed the laboratory performs 3,566 H&E stains annually.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that a quality control program was established to assure the quality of laboratory testing. Refer to D5609.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed

	to ensure complete policies and procedures were established for assessing personnel competency. Refer to D5209.