

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2158118	(X3) Date Survey Completed 06/10/2019
Name of Provider or Supplier Delta Pathology Group At Cytogenetics Solutions	Street Address, City, State 1912 Haring Road, Metairie, 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	An Initial survey was performed on June 10, 2019 at Delta Pathology Group, LLC at Cytogenetics Solutions, CLIA ID # 19D2158118. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: I. Based on record review and interview with personnel, the laboratory failed to ensure written policies and procedures to address competency for General Supervisor were complete. Findings: 1. Review of the laboratory's "Competency Assessment" policy revealed the laboratory did not include competency assessment criteria or frequency of performance for personnel serving as the General Supervisor. 2. Review of personnel records for the General Supervisor revealed the laboratory did not perform a competency assessment for her duties as General Supervisor. 3. In interview on June 10, 2019 at 9:23 am, the General Supervisor confirmed the Laboratory Director did not perform a competency assessment for her duties as General Supervisor. II. Based on record review and interview with personnel, the laboratory failed to establish and follow procedures for testing personnel competency assessments. Findings: 1. Review of the laboratory's "Competency Assessment" policy revealed the laboratory did include the tasks evaluated. 2. Further review of the laboratory's "Competency Assessment" policy revealed a "Competency Assessment Checklist" as the form utilized for evaluations. 3. Review of the competency assessment for the Testing Personnel revealed the laboratory utilized a "Delta Pathology Group Competency Checklist," not the "Competency Assessment</p>

Checklist" included in the policy manual. 4. Further review of the "Delta Pathology Group Competency Checklist" revealed the laboratory included 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 of 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. 5. In interview on June 10, 2019 at 9:43 am the General Supervisor, who also serves as Testing Personnel, stated she serves as a first or second reader for cytogenetic specimen slides. The General Supervisor further stated at 12:03 pm, Delta is in the process of updating the personnel competency forms.

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 record review and interview with personnel, the laboratory failed to establish complete policies and procedures. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not establish complete policies for the following: a) Twice a year verification for accuracy of Cytogenetic testing to include frequency, acceptability criteria, and corrective action plan b) Record retention 2. In interview on June 10, 2019, the General Supervisor confirmed the above policies were not included.

D5407

PROCEDURE MANUAL
CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the laboratory failed to have the policy and procedure manual approved and signed by the Laboratory Director. Findings: 1. Review of the laboratory's Policy and Procedure Manual revealed the manual was not approved and signed by the Laboratory Director. 2. In interview on June 10, 2019 at 12:30 pm, the General Supervisor stated she did not have documentation that the Laboratory Director reviewed the manual. The General Supervisor further stated the Laboratory Director was in the process of reviewing all policies.

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 policies and procedures were followed for assessing personnel competency. Refer to D5209 I and D5209 II.

D6106

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(14)

The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Findings: 1. The laboratory failed to establish complete policies and procedures. Refer to D5401. 2. The laboratory failed to have the policy and procedure manual approved and signed by the Laboratory Director. Refer to D5407.

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:

Based on record review and interview with personnel, the Laboratory Director failed to specify in writing the duties and responsibilities of personnel involved in all phases of testing. Findings: 1. Review of the laboratory's policies and procedures and personnel records revealed a job description related to the duties of Laboratory Director was not included. 2. In interview on June 10, 2019, the General Supervisor confirmed the laboratory did not have written job duties and responsibilities for the Laboratory Director.