Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D2139326	02/22/2018
Name of Provider or Supplier	**Street Address, City, State**	
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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
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on record review and laboratory director interview, the laboratory failed to be in compliance with the Connecticut State Clinical Laboratory licensure requirements prior to performing patient testing in the subspecialty of histopathology. Findings include: 1. Record review of the laboratory's pre analytical, analytical and post analytical testing procedures, specimen, maintenance, quality control and temperature logs and patient test reports on 2/22/18 revealed the laboratory had tested 129 patients from 12/12/17 through 2/20/18 prior to obtaining a Connecticut State Clinical Laboratory license issued by the Department of Public Health. 2. Staff interview with the laboratory director (LD) on 2/22/18 at 9:30 AM confirmed the laboratory had tested 129 patient samples since 12/12/17 without a Connecticut State Clinical Laboratory license. LD stated that he/she thought testing could begin when the CLIA certificate of registration was paid and received. 3. The laboratory performs 600 histopathology tests annually.
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by:

	Based on surveyor observation and staff interview, it was determined that the laboratory area was not adequately equipped for proper decontamination in the subspecialty of histopathology. Findings include: 1. Surveyor observation on 2/22/18 at 11:30 AM revealed the laboratory is using 2 chairs with cloth material that could not be properly decontaminated. 2. Staff interview with the laboratory director on 2/22 /18 at 11:30 AM, confirmed the 2 cloth chairs needed to be replaced or removed. 3. The laboratory performs 600 histopathology tests annually.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to provide a complete standard operating procedure (SOP) manual in the subspecialty of histopathology. Findings include: 1. Record review of the laboratory's quality control (QC) slides in 2 /22/18 revealed the slides were labeled with the year and marked as QC with no date to distinguish the day it was prepared. 2. Record review of the laboratory's SOP manual on 2/22/18 revealed the laboratory did not have a procedure available for how to label the QC slides to indicate the actual date it was prepared on. 3. Interview with the laboratory director on 8/9/17 at 11:45 AM confirmed the QC slides are not labeled with the date performed and the SOP manual needs to be updated. 4. The laboratory performs 600 Moh's tests annually.