Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0897314	09/25/2020
Name of Provider or Supplier	**Street Address, City, State**	
Litholink Corporation	150 Spring Lake Dr - Ste A, Itasca, IL	

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
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, patients' test records, and interview with the Technical Project Specialist, the laboratory failed to have a written or electronic request for patient testing from an authorized person for its Stone Analysis Testing. Findings include: 1. There were no procedures that described the laboratory's process for how Stone Analysis Tests are ordered. 2. Review of patients test records revealed the following information: a. There were written test request for Urinalysis Testing on a form with the Litholink Logo in the corner. b. Corresponding test results for the requested Urinalysis were reported and the name and address location of Litholink as documented on the report. c. There was no documentation to show that a test request for Stone Analysis Testing was submitted. d. Test reports for Stone Analysis Tests were documented with the name and address location of LabCorp, not Litholink. 3. On September 25, 2020 at 2:30 PM, the Technical Project Specialist confirmed the surveyor's findings.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) 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.

	This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, patient test records, and interview with the Technical Project Specialist, the laboratory failed to establish and follow written policies and procedures for specimen processing of Stone Analysis Testing. Findings include: 1. There were no written policies and procedures that describes how it receives and processes specimens for Stone Analysis Testing. 2. Review of patients' test records revealed that Stone Analysis Testing results were documented as being reported by LabCorp and not Litholink. 3. On September 25, 2020 at 2:30 PM, the Technical Project Specialist, confirmed the surveyor's findings.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review laboratory procedures manuals, patients test reports, and interview with the Technical Project Specialist, the test report did not include the name and address of the laboratory location where the test was performed for its Stone Analysis Testing. Finding include: 1. Review of laboratory procedures revealed that there is a page with the name "LabCorp" as the logo on the heading of the page titled, "Stone Types in Descending Order of Frequency." It gives the estimated percentages of identified stone components identified by infrared spectroscopy. 2. Review of patients test reports for stone analysis revealed that the name and address location of Litholink was not documented on the report. However, the name and address location of LabCorp was documented on the report instead. 3. On September 25, 2020 at 2:30 PM, the Technical Project Specialist confirmed the surveyor's findings.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and 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 results reporting, and whether consultant or director review is required prior to reporting patient test results.

	This STANDARD is not met as evidenced by: Based on review of Laboratory Personnel Report (FORM 209), personnel records, and interview with the Technical Project Specialist, the laboratory director failed to be specify, in writing the responsibilities and duties of each consultant and each person, engaged in the performance of testing and identify which examinations and procedures each individuals is authorized to perform. Findings include: 1. Review of form 209 revealed the following information: (a) There are 2 persons listed as Technical Supervisors (one of them being the Laboratory Director) (b) There are 2 persons listed as General Supervisors (c) There are 2 persons listed as Clinical Consultants (one of them being the Laboratory Director) (d) There are 21 persons listed as High Complexity Testing Personnel. (e) There is 1 person listed as Moderate Complexity Testing Personnel. 2. Review of personnel records revealed the following: (a) One of the Clinical Consultants was assigned to the position of "Assistant Laboratory Director." No duties assigned. (b) There was no distinction between Technical Supervisor and General Supervisor. Personnel were only identified as "Supervisor." (c) The Technical Project Specialist performed and documented the training and competency of personnel. She is listed on Form 209 as one of the testing personnel. (d) The laboratory director did not specify which test each individual performs. 3. On September 25, 2020 at 11:30 AM, the Technical Project Specialist confirmed the surveyor's findings.