

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D1086556	(X3) Date Survey Completed 05/29/2018
Name of Provider or Supplier Reliant Medical Group Surgical Specialties At	Street Address, City, State 123 Summer Street, Worcester, MA	
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 CLIA recertification survey was conducted for the Reliant Medical Group Surgical Specialties at Worcester Medical Center laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. .
D8103	<p>BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(b)(c)(d)</p> <p>(b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part.</p> <p>This STANDARD is not met as evidenced by: Based on an interview, the laboratory failed to have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. The laboratory did not provide, upon request, all information and data needed by the CMS agent to make a determination of the laboratory's compliance with the</p>

applicable requirements of this part as evidenced by the following: a) The laboratory's written policy for frozen section slide review is to perform "Quarterly random checks of five slides by pathologists in the Reliant Medical Group Histopathology Lab". b) During the time of the survey the laboratory was unable to provide documentation to verify the laboratory's ongoing quality assessment of histopathology diagnoses for calendar years 2016 and 2017. Based on the lack of records the CMS agent was unable to make a compliance determination regarding the quality assessment of histopathology diagnoses portion of the laboratory operation.