

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D1086556	(X3) Date Survey Completed 10/14/2020
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 laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. .
D5435	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: Based on policy review and interview, the laboratory failed to follow maintenance protocol for laboratory equipment as evidenced by the following: Microscope maintenance: a) Procedure review on 10/14/20 revealed microscope maintenance was to be performed annually. b) Review of microscope maintenance documentation revealed that maintenance was to be performed on 4/13/20 but, as of the date of the survey, had not yet been performed. Airfiltronix ductless fume hood maintenance: a) Review of filter change requirements for the fume hood indicated that filters were to be changed annually. b) Review of documentation for the filter changes revealed that the filter was due to be changed in January of 2020 but, as of the date of the survey, had not yet been performed. The radiology and laboratory site supervisor confirmed in an interview on 10/14/20 at 10:55 AM that maintenance on the microscope and fume hood had not been completed as required. .</p>

D6084

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(2)

The laboratory director must ensure that the physical plant and environmental conditions provide a safe environment in which employees are protected from physical, chemical, and biological hazards.

This STANDARD is not met as evidenced by:

Based on observation, the laboratory director failed to provide a safe environment in which employees are protected from chemical and biological hazards as evidenced by the following: On the day of the survey in the presence of the laboratory director and supervisor of ancillary services, it was observed that there was no permanently mounted eyewash which would provide fifteen minutes of continuously flowing water near the laboratory area. The supervisor of ancillary services confirmed in an interview on 10/14/20 at 11:00 AM that there was no permanently mounted eyewash available in the laboratory area.