

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 22D0067542	<b>(X3) Date Survey Completed</b> 09/19/2018
<b>Name of Provider or Supplier</b> Memorial Square Laboratory	<b>Street Address, City, State</b> 2150 Main St, Springfield, MA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A CLIA recertification survey was conducted for the Memorial Square Laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
<b>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on record review and confirmed through interview with the general supervisor on 9/19/18, the laboratory did not retain all quality control records as evidenced by the following: a) A review of quality control records for calendar year 2018 (eight months of testing) revealed that a new lot of urinalysis quality control material (Quantimetrix lot numbers 44451 and 44452) was implemented on 9/18/18 according to the quality control record. b) The laboratory could not provide documentation of the acceptable quality control limits for the above quality control material. c) This was confirmed through interview with the general supervisor on 9/19/18 at 11:25 AM.</p>
<b>D5213</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(b)(1)</p> <p>The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on proficiency testing record review and confirmed through an interview on 9/19/18 with the general supervisor, the laboratory failed to verify the accuracy of analytes listed in subpart I of this part that were not evaluated or scored by a CMS-approved proficiency testing program as evidenced by the following: a) A review of proficiency testing results for for calendar years 2016, 2017 and 2018 (six testing events) revealed the fact that the proficiency testing service had not graded Triglyceride (specimen CH-01) and Free Thyroxine for the first chemistry testing event of 2017. The the proficiency testing service had also not graded Parathyroid Hormone (PTH) for the first testing event of 2018. b) There was no documented self grading by the technical consultant for the ungraded routine chemistry and endocrinology results. c) The general supervisor confirmed in an interview on 9/19/18 at 9:45 am that ungraded proficiency testing results were not being self graded by the laboratory.

**D5817**

**TEST REPORT**  
CFR(s): 493.1291(i)

If a laboratory refers patient specimens for testing-- (i)(1) The referring laboratory must not revise results or information directly related to the interpretation of results provided by the testing laboratory; (i)(2) The referring laboratory may permit each testing laboratory to send the test result directly to the authorized person who initially requested the test. The referring laboratory must retain or be able to produce an exact duplicate of each testing laboratory's report; and (i)(3) The authorized person who orders a test must be notified by the referring laboratory of the name and address of each laboratory location where the test was performed.

This STANDARD is not met as evidenced by:  
Based on record review and interview, the laboratory failed to indicate the address of the laboratory location where reference testing was performed as evidenced by the following: a) A review of 24 test reports for testing performed between 1/11/17 and 8/15/18 was conducted. b) The review revealed the fact that, for reports where reference laboratory testing was performed, the address of one (1) of three (3) reference laboratories was not indicated on the final report for one (1) out of twenty four (24) final reports reviewed (patient number 00037373 for a Troponin I result reported by Life Laboratories on 3/27/18). c) The general supervisor confirmed in an interview on 9/19/18 at 2:30 PM that the address of the one reference laboratory was not included on the final report.

**D6127**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**  
CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:  
Based on record review interview and interview, the technical supervisor failed to evaluate and document the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tested patient specimens as evidenced by the following: a) Review of the CMS 209 Laboratory Personnel Report on 9/19/18 showed that there was one (1) new personnel

hired and performing testing since the last CLIA recertification survey on 9/8/16. b) Review of personnel competencies for calendar year 2017 revealed that there was no documentation of semiannual competency evaluations for the one (1) new laboratory technologist except for manual differential exams. c) The general supervisor confirmed in an interview by phone on 9/21/18 at 11:05 AM that, except for manual differential exams, no semiannual competency evaluations had been performed on the one (1) new laboratory technologist.