

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0240925	(X3) Date Survey Completed 04/20/2018
Name of Provider or Supplier Tremont Medical Center	Street Address, City, State 8312 Creedmoor Road, Raleigh, NC	
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
D5787	<p>TEST RECORDS CFR(s): 493.1283(a)</p> <p>The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).</p> <p>This STANDARD is not met as evidenced by: Based on review of 2017 temperature and humidity logs during the survey on 4/20/18, testing personnel #1 and #2 deleted the temperature and humidity readings using white out and re-wrote the temperatures over the initial readings documented on the Daily Temperature and Humidity logs. Review of the 2017 Daily Temperature and Humidity Logs revealed 12 days when the initial temperature and humidity readings were deleted using whiteout and were re-written over the deleted temperature and/or humidity readings: Refrigerator temperature readings that were deleted using white-out were noted on 1/23/17, 5/24/17, 8/21/17, 10/12/17, 10/13/17, 10/17/17, 11/21/17, 12/12/17, 12/13/17, 12/14/17, 12/15/17, and 12/19/17. One freezer temperature reading on 1/23/17 was deleted using white-out.</p>
D6010	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(2)</p> <p>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)(2) Ensure that the physical plant and environmental conditions of</p>

the laboratory are appropriate for the testing performed.

This STANDARD is not met as evidenced by:

Based on the deficiency cited at D5787 and review of the laboratory's "2017 Daily Temperature and Humidity Logs" the laboratory director failed to ensure the environmental conditions in the laboratory were appropriate for the testing performed.

Findings: Review of the 2017 Daily Temperature and Humidity Logs revealed 12 days when the initial temperature and humidity readings were deleted using whiteout and were re-written over the deleted temperature and/or humidity readings:

Refrigerator temperature readings that were deleted using white-out were noted on 1/23/17, 5/24/17, 8/21/17, 10/12/17, 10/13/17, 10/17/17, 11/21/17, 12/12/17, 12/13/17, 12/14/17, 12/15/17, and 12/19/17. One freezer temperature reading on 1/23/17 was deleted using white-out. Review of the 2017 Daily Temperature and Humidity logs revealed that the laboratory director reviewed and signed all of the Daily Temperature and Humidity logs listed above.