Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0683829	04/02/2018
Name of Provider or Supplier	**Street Address, City, State**	
Morristown Medical Center	100 Madison Avenue, Morristown, NJ	

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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) 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. This STANDARD is not met as evidenced by: Based on the lack of Test Records and interview with the Laboratory Manger (LM), the laboratory failed to retain Instrument Printouts (IP) for Lactic Acid (LA) tests performed on the Siemens Dimension Vista analyzer from October 2017 to the date of the survey. The finding includes: 1. The laboratory was unable to retrieve the IP from the analyzer for LA tests in the timeframe mentioned above. 2. The LM confirmed on 4/2/18 at 4:45 pm that the IP were not retained.
D5313	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b) The laboratory must document the date and time it receives a specimen. This STANDARD is not met as evidenced by: Based on surveyor review of Manufacturers Package Insert (MPI), Order Entry forms and interview with the Laboratory Manager (LM), the laboratory failed to ensure that the laboratory accurately recorded the date and time specimens were received from October 2017 to the date of survey. The findings include: 1. A review of 32 patients revealed that 2 of 32 were received and resulted at the same time. 2. The MPI stated reaction time for Lactic Acid is 8.9 minutes, samples were spun for 5 minutes but 1

	out of 32 was received and resulted before 14 minutes. 3. The LM confirmed on 4/2 /18 at 4:40 pm that the laboratory did not ensure that specimen time was entered accurately.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on surveyor review of the Manufacturers Package Insert (MPI), Final Reports (FR) and interview with the Laboratory Manager (LM), the laboratory failed to follow the MPI for Lactic Acid (LA) tests performed on the Siemens Dimension Vista from October 2017 to the date of the survey. The finding includes: 1. The LA MPI stated "blood collected must be separated from the cells within 15 minutes of collecting" but a review of 32 patients' records revealed 18 out of 32 or 56% were received in the laboratory more than 15 minutes after drawing blood. 2. The LM confirmed on 4/2/18 at 4:10 pm the laboratory did not follow the MPI.