Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0721728	03/21/2019
Name of Provider or Supplier	**Street Address, City, State**	
Hartford Healthcare Medical Group	761 Main Avenue, Suite 201, Norwalk, CT	

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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation, record review and staff interview, the laboratory failed to ensure proper storage of reagents and controls in the specialty of chemistry and hematology. Findings include: 1. Surveyor observation on 3/21/19 at 11:45 AM revealed the thermometer being used to record the main laboratory freezer temperature is not working. Patient serum samples are being stored in the main laboratory freezer. 2. Record review of the laboratory's refrigerator/freezer temperature log on 3/21/19 revealed the following: (a) Documentation for main laboratory refrigerator/freezer temperature is missing from 4/7/17 through 4/12/17 and 11/22/17 through 11/30/17. (b) Documentation for refrigerator #2 temperature is missing from 6/23/18 through 6/30/18. 3. Record review on 3/21/19 of the storage requirements of the Streck hematology and Biorad chemistry QC labels indicated they are to be stored at 2-8 degree Celsius. 4. Staff interview with testing personnel #1 (TP#1) on 3/21/19 at 11:30 AM confirmed the above findings. TP#1 stated refrigerator /freezer temperatures were not recorded when TP#1 was on vacation. 5. This is a repeat deficiency. 6. The laboratory performs 299, 477 tests annually.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)

	For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to document maintenance(s) for laboratory equipment(s) to ensure accurate and reliable test results. Findings include: 1. Record review on 3/21/19 of the equipment(s) preventive maintenance (PM) log revealed the following: a. Annual PM of the Olympus BX-41 microscope was not performed or documented after 2016. b. Annual PM policies for laboratory equipment was not available for review. 2. Staff interview with the laboratory director on 3/21/19 at 12:30 PM confirmed that annual PM and function checks for the above laboratory equipment was overlooked and not performed in 2017, 2018 and to-date in 2019. 3. The laboratory performs 2867 histopathology cases annually.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor observation and staff interview, the laboratory failed to document lot to lot verification for new lots of reagents and quality controls (QC) prior to patient testing for chemistry and endocrinology tests performed on the Roche Integra 400+ and the Architect i-1000 instruments. Findings include: 1. Surveyor observation of the reagents and QC currently in use on 3/21/19 at 10:05 AM revealed the laboratory failed to provide evidence or documentation for lot to lot verification of new reagents and QC placed into service prior to patient testing for all tests performed on the Roche Integra 400+ and Architect i-1000 instruments in 2017 and 2018. 2. Staff interview with the laboratory director (LD) on 3/21/19 at 10:30 AM confirmed the above finding. The LD stated policy or procedure was not available for lot to lot verification of reagents and QC performed on the Roche Integra 400+ and Architect i-1000 instruments in 2017 and 2018. 3. The laboratory performs 216, 536 chemistry tests and 9, 086 endocrinology tests annually.