Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0718558	08/24/2018
Name of Provider or Supplier	**Street Address, City, State**	
Hospital For Special Care	2150 Corbin Ave, New Britain, 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
D5535	ROUTINE CHEMISTRY CFR(s): 493.1267(a)(d) For blood gas analyses, the laboratory must perform the following: (a) Calibrate or verify calibration according to the manufacturer's specifications and with at least the frequency recommended by the manufacturer. (d) Document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to perform calibration verification according to manufacturer's specification. Findings include: 1. Record review of the laboratory's calibration verification records on 8/24/18 revealed calibration verification of two ISTAT instruments was not performed in 2018. 2. Record review of the manufacturer's (ISTAT) package insert for calibration verification (Art:715209-00F) on 8/24/18 revealed calibration verification to be performed every six months to ensure accuracy of test results. 3. Staff interview with the technical consultant on 8/24/18 at 10:00 AM confirmed the above findings. 4. The laboratory performs 3,600 blood gas tests annually.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to adhere to the

	approved individual quality control plan (IQCP) quality assessment (QA) procedures. Findings include: 1. Record review of the laboratory's IQCP-QA procedure (Doc# QAQC.133.Proc-001) on 8/24/18 revealed the following. a. "Every 6 months, results from external liquid control materials are compared across all departments to detect trends in operator and device performance. b. Every 6 months, patient samples are tested and i-STAT results are compared to Laboratory results to detect trends in operator and device performance". 2. Record review of the laboratory's 2018 QA documents on 8/24/18 revealed the above indicated comparison data is not available for review. 3. Staff interview with the technical consultant on 8/24/18 at 10:30 AM confirmed the above findings. 4. The laboratory performs 3,600 blood gas tests annually.
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory's testing personnel (TP) failed to adhere to established quality control (QC) procedures. Findings include: 1. Record review of the laboratory's 2018 QC records on 8/24/18 revealed the TP did not perform external QC when a new lot of reagent cartridge was placed into service. 2. Record review of the laboratory's QC procedure (Document # QAQC.133.Proc) on 8 /24/18 revealed "Two levels of external liquid controls are run at least every 31 days and/or with new cartridge shipments and lots". 3. Staff interview with the technical consultant on 8/24/18 at 10:00 AM confirmed the above findings. 4. The laboratory performs 3,600 blood gas tests annually.