Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0863039	01/29/2019
Name of Provider or Supplier	**Street Address, City, State**	
St Bernard Hospital	326 West 64th Street, Chicago, IL	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of procedures manuals and proficiency testing (PT) records and interview with the technical supervisor (TS); the individual testing the samples and the laboratory director did not sign the attestation statement. Findings include: 1. Review of PT records revealed that testing personnel and laboratory director or designee did not sign the PT statement attesting that PT samples were tested in the same manner as patient specimens for the 1st, 2nd, and 3rd PT events of 2018. 2. During survey date 01/29/2019 at 10:30 AM, the TS confirmed the surveyor's findings.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of laboratory policies, procedures, personnel records and interview with the laboratory director (LD); the laboratory failed to establish written policies and procedures to assess employees' competency assessments. Findings include: 1. Review of laboratory policies and procedures revealed that there were no laboratory's

	process for assessing the competency of personnel or documentation to show that competency assessments were performed on the following personnel: a. Laboratory Director b. Clinical Consultant c. Technical Supervisor/Technical Consultant d. General Supervisor 2. During survey date at 3:00 PM on 01/29/19, the LD confirmed the surveyor's findings.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory policies, procedures, personnel records and interview with the laboratory director; the laboratory failed to have a director who provides overall management in accordance with 493.1445 of this subpart. Findings include: 1. The laboratory failed to establish and maintained a quality control program that assures quality of laboratory services provided and to identify failures in quality as they occur. See D6093. 2. The laboratory director failed to ensure that testing personnel were qualified and competent to perform all laboratory services provided. See D6102 and D6103. 3. The laboratory director failed to ensure that an approved procedures manual was available to all testing personnel. See D6106. 4. The laboratory director failed to assign personnel to their positions (titles) held in the laboratory, as well as assign which tests each individual is authorized to perform. See D6107.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review laboratory policies, procedures, quality control (QC) records and interview with the technical supervisor; the laboratory director failed to ensure that the quality control programs are established and maintained to identify failures in quality as they occur. Findings include: 1. Review of the laboratory's policies and procedures revealed that the laboratory's control procedures did not include the following: a. Type of control (e.g., manufacturer or in-house, electronic); b. Identity (e.g., normal, abnormal, level I, II, patient or a control); c. Number and frequency of testing controls; d. Control limits established by the laboratory e. Criteria to determine acceptable control results. f. Corrective action to take when control results fail to meet the laboratory's criteria for acceptability. 2. Review of QC records revealed that the laboratory runs 3 levels of QC material on each shift, each day of testing for Routine Chemistry and Complete Blood Count (CBC) tests. The laboratory accepted failed QC results for both Routine Chemistry and Complete Blood Count testing when one level of QC material failed. There was no documentation to show corrective actions were taken when 1 level of QC material failed. 3. During survey date 01/29/19 at 2:00 PM, the technical supervisor confirmed the surveyor's findings.

D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of laboratory procedures, employee records and interview with the laboratory director (LD); the laboratory failed to have personnel with the appropriate education, experience and training for the type and complexity of laboratory testing performed by the laboratory. Findings include: 1. Review of personnel records revealed that there was no US equivalent education documents for 7 of 49 testing personnel who had foreign degrees. 2. During survey date 01/29/2019 at 3:30 PM, the LD confirmed the surveyor's findings.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on review of laboratory policies, records, procedures, personnel form (CMS 209) and interview with the laboratory director (LD); this laboratory failed to have procedures for the monitoring of competency assessments of individuals who conduct laboratory testing and report test results. Findings include: 1. Review of laboratory policies revealed that there were no procedures to indicate who was responsible for the competency assessments of testing personnel. 2. Review of personnel records revealed that the laboratory failed to perform competency assessment on 49 of 49 testing personnel in 2017 and 2018. 3. During survey date 01/29/2019 at 3:00 PM on 01/29/19, the LD confirmed the surveyor's findings.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures manuals; the laboratory director (LD) failed to ensure that an approved, signed, and dated, procedure manual is available to all personnel responsible for all aspects of the testing process. Findings include: 1. Review of the laboratory's policies and procedures manuals revealed that

	the current laboratory director had not approved the laboratories policies and procedures. 2. During survey date 01/29/2019 at 3:00 PM, the LD confirmed the surveyor's findings.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of laboratory personnel form CMS 209), records, policies, procedures and interview with the laboratory director (LD), this laboratory failed to specify in writing the responsibilities and duties of each laboratory personnel engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform. Findings include: 1. Review of laboratory policies and procedures revealed that there was no documentation to show in writing the duties and responsibilities of the following positions in the laboratory, or test(s) each individual is authorized to perform: a. Laboratory Director b. Clinical Consultant c. Technical Supervisor and or Technical Consultant d. General Supervisor e. Moderate Complexity Testing Personnel f. High Complexity Testing Personnel 2. During survey date 01/29/2019 at 3:00 PM, the LD confirmed the surveyor's findings.