Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0099891	09/11/2018
Name of Provider or Supplier	**Street Address, City, State**	
St Marys Hospital Laboratory	56 Franklin Street, Waterbury, 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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on record review and staff interview, laboratory testing personnel failed to follow laboratory policy and procedures for reporting critical values. Findings include: 1. Record review on 08/23/18 of the laboratory's procedure, "Critical Laboratory Test Results Warranting MD Alerts" effective November 2014 revealed "The following test results warrant immediate notification (regardless of the delta checks) to the physician, nurse, or other appropriate health professional within thirty minutes of being completed. After each result has been rechecked by a technologist, he /she will document in the LIS and on the department copy of the report (if applicable) the name of the person(s) notified, date and time called, verification of "read-back" results and the initials of the person making the call. The initials indicate that the person receiving the critical results have read back to the caller the patient's full name and complete results." 2. Record review on 08/23/18 of the laboratory's "Evaluation of Patient Data" procedure number Chem 22.0 approved on 10/12/17 revealed the following: a. "Fail verify" results that have been determined to be critical will immediately be called to the healthcare provider. Follow laboratory procedure of documentation. b. "Absurd Value" an absurd message will be sent when a result is entered that has been defined according to the Min/Max value to be non-compatible. The result must be rerun and verified before being accepted. 3. Record review of the laboratory testing personnel 1 (TP1) written statement on 8/23/18 revealed the following: a. A patient was admitted into the emergency room (ER) on 8/5/18 b. A Basic metabolic panel (BMP) along with other tests were ordered on 8/5/18. c. TP1

	called the ER but a critical potassium result value of 9.7 meq/l obtained was not reported or entered in the LIS. d. TP1 stated to the ER unit coordinator to recollect due to the sample being questionable and cancelled the BMP test. 4. Telephone interview with TP1 on 9/11/18 at 7:55 PM confirmed the ER was notified on 8/5/18 at 4:56 PM that the test result was questionable and to redraw the patient with no mention of critical potassium result. TP1 also stated that the critical laboratory procedure was not clear on how to report questionable critical values. 5. Staff interview with the laboratory manager on 9/11/18 at 10:30AM confirmed TP1 failed to follow laboratory policies and procedures for the reporting of critical values.
D5813	TEST REPORT CFR(s): 493.1291(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values. This STANDARD is not met as evidenced by: Based on record review and interview with testing personnel (TP) and the laboratory manager (LM), the laboratory failed to follow its policy for reporting critical results to the requesting physician. Findings include: 1. Record review on 08/23/18 of the laboratory's procedure, "Critical Laboratory Test Results Warranting MD Alerts" effective November 2014 revealed the following: "The following test results warrant immediate notification (regardless of the delta checks) to the physician, nurse, or other appropriate health professional within thirty minutes of being completed. After each result has been rechecked by a technologist, he/she will document in the LIS and on the department copy of the report (if applicable) the name of the person(s) notified, date and time called, verification of "read-back" results and the initials of the person making the call. The initials indicate that the person receiving the critical results have read back to the caller the patient's full name and complete results." 2. Record review conducted on 8/23/18 of the above procedure revealed that all potassium (K) results over 6.0 meq/l were critical and the physician, nurse, or other appropriate health professional must be notified. 3. Record review on 9/11/18 of patient test report for specimen sample number X125502 collected on 08/05/18 at 15:40 and received by the laboratory on 08/05/18 at 15:59 revealed that the Basic Metabolic Panel was deleted and noted the "specimen unsuitable. Please re- order or resubmit. IV fluid contamination." 4. Telephone interview with TP1 on 9/11/18 at 7:55 PM confirmed the ER was notified on 08/5/18 at 4:56 PM that the test result was questionable and to redraw the patient with no mention of critical potassium result . TP1 also stated that the critical laboratory procedure was not clear on how to report questionable critical values. 5. Staff interview with the LM on 9/11/18 at 10:30AM confirmed TP1 failed to follow laboratory procedures for the reporting of critical values
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 record review and staff interview the laboratory director (LD) failed to ensure laboratory testing personnel (TP) reported critical test results according to established policies and procedures and that TP maintain competency to promptly report critical test results. The cumulative effect of these cited deficiencies resulted in the laboratory's inability to provide accurate and timely reporting of critical test results. Refer to D6087, D6103 and D6122
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory director failed to ensure that laboratory testing personnel report critical test results according to established policies and procedures. Refer to D5401 and D5813.
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 record review and staff interview, the laboratory director (LD) failed to ensure that testing personnel (TP) are competent and maintain competency to report critical test results promptly and proficiently. Findings include: 1. Record review of TP1 training documentation on 8/23/18 revealed the following: a. No direct observation of reporting critical values was documented. b. TP1 checked the box on the training form that he/she fully understood and felt competent to perform critical Values/Documentation for the Beckman Coulter AU5800 instrument on 5/8/18. c. The laboratory manager signed off TP1 was fully trained on 5/12/18. 2. Telephone interview with TP1 on 9/11/18 at 7:55 PM stated the following: a. TP1 felt he/she wasn't properly trained. b. TP1 was not shown laboratory policies or asked to sign any policies. 3. Staff interview with laboratory manager (LM) on 9/6/18 at 9:45 AM stated that TP are competent if the training documentation is signed. 4. Record review conducted on 8/23/2018 of the of the laboratory's procedure, "Critical Laboratory Test Results Warranting MD Alerts" effective November 2014 stated that potassium (K) results over 6.0 meq/l were critical, and the physician, nurse, or other appropriate health professional must be notified. 5. Record review on 9/11/2018 of patient test report for specimen sample number X125502 collected on 08/05/18 at 15:40 and received by the laboratory on 08/05/2018 at 15:59 revealed that the Basic Metabolic Panel was deleted and noted that "specimen unsuitable. Please re- order or resubmit. IV fluid contamination." 6. Telephone interview with TP1 on 9/11/18 at 7:55 PM confirmed the ER was notified on 08/5/18 at 4:56 PM that the test result was questionable and to redraw the patient with no mention of critical potassium result.

	TP1 also stated that the critical laboratory procedure was not clear on how to report questionable critical values. 7. Staff interview with the LM on 9/11/18 at 10:30AM confirmed TP1 failed to follow laboratory procedures for the reporting of critical values
D6122	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(ii) The procedures for evaluation of the competency of the staff must include, but are not limited to monitoring the recording and reporting of test results. This STANDARD is not met as evidenced by: Based on record review and staff interview, the technical supervisor (TS) failed to evaluate and monitor testing personnel (TP) recording and reporting of critical test results. Findings include: 1. Record review of TP1 training documentation on 8/23/18 revealed TP1 was competent to perform and report critical value results 2. Record review on 8/23/18 of TP1 training evaluation form dated 5/8/18 revealed no available documentation for the direct observation of TP1 resulting or reporting critical value test results. 3. Telephone interview with TP1 on 9/11/18 at 7:55 PM confirmed no one had observed TP1 resulting or reporting critical value results. 4. Staff interview with laboratory manager (LM) on 9/6/18 at 9:45 AM stated the following: a. TP1 was hired 3/12/18. b. TP1 signed training documentation on 5/8/18 indicating fully competent to perform and report critical value results. c. LM signed TP1 training documentation on 5/12/18. d. LM stated after TP are trained their competent if training documents are signed. e. TP1 6 month competency was'nt due till November of 2018.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on record review and staff interview testing personnel (TP) failed to report critical test results for potassium (K) according to established laboratory policies and procedures. Refer to D6173 and D6175.
D6173	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495 The testing personnel are responsible for specimen processing, test performance and for reporting test results. This STANDARD is not met as evidenced by: Based on record review and staff interview, laboratory testing personnel failed to report critical test results for potassium (K). Refer to D5813.
D6175	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(1)

	Each individual performing high complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory testing personnel (TP) failed to follow laboratory policies and procedures for critical result reporting and the maintenance of patient test results. Refer to D5401