CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050168	A. BUILDING _____ B. WING _____	02/15/2012

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
ST. JUDE MEDICAL CENTER	101 E Valencia Mesa Dr, Fullerton, CA 92835-3809 ORANGE COUNTY

2012 JUN 28 AM 11 06

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
	The following reflects the findings of the Department of Public Health during an inspection visit: Complaint Intake Number: CA00300836 - Substantiated Representing the Department of Public Health: Surveyor ID # 22779, HFEN The inspection was limited to the specific facility event investigated and does not represent the findings of a full inspection of the facility. Health and Safety Code Section 1280.1(c): For purposes of this section "immediate jeopardy" means a situation in which the licensee's noncompliance with one or more requirements of licensure has caused, or is likely to cause, serious injury or death to the patient. The following reflects the findings of the Department of Public Health during investigation of Complaint No. CA00300836 The inspection was limited to the specific complaint(s) investigated and does not represent the findings of a full inspection of the facility. Representing the Department of Public Health: 22779HFEN. Health & Safety Code Section 1280.1(c): For purposes of this section "immediate jeopardy"		Approved 6/26/12	

Event ID:4PPX11 6/14/2012 8:40:27AM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Brian Hellekad | TITLE: COO | (X6) DATE: 6/26/12

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. Except for nursing homes, the findings above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050168	A. BUILDING _____ B. WING _____	02/15/2012

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
ST. JUDE MEDICAL CENTER	101 E Valencia Mesa Dr, Fullerton, CA 92835-3809 ORANGE COUNTY

2012 JUN 28 AM 11 06

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
	Continued From page 1 means a situation in which the licensee's noncompliance with one or more requirements of licensure has caused, or is likely to cause, serious injury or death to the patient. Deficiency Constituting Immediate Jeopardy T22 DIV5 ART3-70223(b)(2) (b) A committee of the medical staff shall be assigned responsibility for: (2) Development, maintenance and implementation of written policies and procedures in consultation with other appropriate health professionals and administration. Policies shall be approved by the governing body. Procedures shall be approved by the administration and medical staff where such is appropriate. T22 DIV5 ART3-70223(d)(2) (d) Prior to commencing surgery the person responsible for administering anesthesia, or the surgeon if a general anesthetic is not to be administered, shall verify the patient's identity, the site and side of the body to be operated on, and ascertain that a record of the following appears in the patient's medical record: (2) Appropriate screening tests, based on the needs of the patient, accomplished and recorded within 72 hours prior to surgery. The above regulations were NOT MET as evidenced by:		**T22 DIV5 ART-370223(b)(2)** **a) How the corrections will be accomplished, both temporarily and permanently.** The temporary and permanent correction accomplished by revising the Universal Protocol policy to include the language "all relevant images or studies be displayed and reviewed by the surgeon as part of the Time Out". Surgical services staff were provided education on the changed process. **b) The title or position of the person responsible for the correction.** Director of Surgical Services **c) A description of the monitoring process to prevent recurrence of the deficiency.** The universal protocol time out audit form was revised to include the relevant images and studies present at the time of surgery. The "Time Out" audits are conducted with a minimum of 30 cases per month. Variations in any of the policy practices are immediately sent to Physician Peer Review. This information is then aggregated and presented to the Patient Safety Performance Improvement committee. **T22 DIV5 ART-370223(d)(2)**	3-15-12

Event ID:4PPX11 6/14/2012 8:40:27AM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
Brian Hellebrand	COO	6/26/12

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. Except for nursing homes, the findings above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050168	A. BUILDING _____ B. WING _____	02/15/2012

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
ST. JUDE MEDICAL CENTER	101 E Valencia Mesa Dr, Fullerton, CA 92835-3809 ORANGE COUNTY

2012 JUN 28 AM 11 06

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
	Continued From page 2 Based on observation, interview and record review, the hospital failed to follow their policy and procedure to have relevant images and results properly labeled and displayed prior to a patient's surgery. This failure resulted in the removal of the wrong kidney. Findings: On 2/10/12, the hospital notified the Department of a wrong site surgery. The hospital stated they had adopted the Joint Commission's Safety Goals as their policy and procedure. Review of the Joint Commission's Safety Goals for Hospital 2012 showed hospitals should conduct a preprocedure verification process. The pre-procedure verification, usually called a "Time Out" is an ongoing process of information gathering and confirmation. The purpose of the pre-procedure verification process is to make sure that all relevant documents and related information or equipment are: - Available prior to the start of the procedure - Correctly identified, labeled, and matched to the patient's identifiers - Reviewed and are consistent with the patient's expectations and with the team's understanding of the intended patient, procedure, and site. Among items listed by the Joint Commission that should be included in the pre-procedure verification process are labeled diagnostic and radiology test results (for example, radiology images and scans,		**a) How the corrections will be accomplished, both temporarily and permanently.** The temporary and permanent correction plan includes: the surgical services department developed a standardized preoperative checklist to confirm that the relevant documentation, imaging study and pathology reports are available before the start of the procedure. The process for scheduling an operative procedure was standardized to include the requesting of relevant images and studies. **b) The title or position of the person responsible for the correction.** Director of Surgical Services **c) A description of the monitoring process to prevent recurrence of the deficiency.** The universal protocol time out audit form was revised to include the relevant images and studies present at the time of surgery. The "Time Out" audits are conducted with a minimum of 30 cases per month. Variations in any of the policy practices are immediate sent to Physician Peer Review. This information is then aggregated and presented to the Patient Safety Performance Improvement committee.	3-15-12

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
[signature]	COO	6/26/12

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. Except for nursing homes, the findings above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050168	A. BUILDING _____ B. WING _____	02/15/2012

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
ST. JUDE MEDICAL CENTER	101 E Valencia Mesa Dr Fullerton, CA 92835-3809 ORANGE COUNTY

2012 JUN 28 AM 11 06

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
	Continued From page 3 or pathology and biopsy reports) properly displayed. On 2/14/12, review of the hospital's policy and procedure titled Universal Protocol To Prevent Wrong Person/Procedure; Site/Side Operations Or Procedures, effective 9/5/11, showed for the "Time Out" process "Relevant Images and results are properly labeled and displayed." As a reference for this policy and procedure the hospital used the 2003 Joint Commission Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery which also showed images and diagnostic studies should be available during the preprocedure process. On 2/14/12, review of Patient D's medical record showed the patient was admitted to the hospital, St Jude Medical Center on [redacted]12 with a diagnosis of neoplasm (cancer) of the right kidney. The patient was taken to the OR (operating room) on [redacted]12. The surgical record showed the patient's pre-operative diagnosis was neoplasm of the right kidney and umbilical hernia. The post-operative diagnosis was laparoscopic hand-assisted right nephrectomy (removal of a kidney) and repair of umbilical hernia (a bulging of the abdominal lining at the belly button). During an interview on 2/14/12, the Regulatory Manager stated the pathologist notified MD 1 on [redacted]12 the kidney removed during the surgery was normal. At that time, MD 1 contacted his office staff and asked the staff to read the CAT (computerized axial tomography) scan (a type of x-ray) report from			

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE: COO | (X6) DATE: 6/26/12

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. Except for nursing homes, the findings above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050168	A. BUILDING _____ B. WING _____	02/15/2012

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
ST. JUDE MEDICAL CENTER	101 E Valencia Mesa Dr, Fullerton, CA 92835-3809 ORANGE COUNTY

2012 JUN 28 AM 11 06

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
	Continued From page 4 Hospital B, the hospital where the patient had diagnostic studies done. These results were at MD 1's office at the time of the surgery. At that time it was identified that the neoplasm was in the left kidney. Review of a pathology report, dated [redacted]12, showed the patient's right kidney, received on [redacted]12, was benign renal tissue (normal kidney). After the surgery, the hospital obtained records from Hospital B where the patient had the kidney studies. Review of the diagnostic studies from Hospital B showed on [redacted]11, Patient D had a CAT scan which showed the patient had a left renal mass consistent with renal cell carcinoma. According to the Regulatory Manager this report was not a part of the patient's medical record at St Jude Medical Center, where the surgery was performed. At the time of the surgery, MD 1 had the reports at his office. On 2/14/12 at 0850 hours, RN 1 was interviewed. RN 1 functioned as the circulating nurse during the operation. RN 1 stated she was 10 minutes late starting, so she asked RN 2 to interview Patient D. In the OR, RN 1 wrote the patient name, OR side, allergies. According to RN 1 when the patient arrives in the room this is asked again. The hospital used a digital x-ray system that holds the patient's x-rays. The viewing monitor was in the room and according to RN 1 the only film in the system was a chest x-ray. RN 1 stated about 90% of the time films pertinent to the case are in the room and usually the surgeon and assistant surgeon view the films. RN 1 stated prior to the surgery, the assistant surgeon called in sick so MD 1 was			

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Brian Hellland | TITLE: COO | (X6) DATE: 6/26/12

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. Except for nursing homes, the findings above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050168	A. BUILDING _____ B. WING _____	02/15/2012

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
ST. JUDE MEDICAL CENTER	101 E Valencia Mesa Dr, Fullerton, CA 92835-3809 ORANGE COUNTY

2012 JUN 28 AM 11 06

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
	Continued From page 5 notified to contact another surgeon to function as the assistant surgeon (MD 3). RN 1 stated for some reason she thought the surgery was on the left side but double checked the records and it was the right side. RN 1 added that she had called the MD 1's office prior to the surgery date to confirm the procedure and the side the surgery was to be on. RN 1 stated the team did the time out and all the team members participated, MD 1, MD 2 (the anesthesiologist), the ST (Scrub Technician) and herself. After the initial incision was made, MD 3 who had been called in the assist entered the room. On 2/14/12 at 0945 hours, RN 2 was interviewed, RN 2 stated she had Patient A's medical record and prior to the surgery interviewed the patient. The patient said the right side, the history and physical in the patient's medical record showed the right side and the consent was for the right side. On 2/15/12 MD 2, the anesthesiologist for the case was interviewed. MD 2 stated the time out was extremely thorough. MD 2 stated he asked the patient and the patient said the right side. According to MD 2 preoperatively he looked at labs and general medical health. MD 2 stated he would not meet with the surgeon and review CAT scan results and typically did not review test results (x-rays) as it was not a standard of care. The hospital's failure to follow their policy and procedure for Universal Protocol which resulted in the removal of the wrong kidney is a deficiency that			

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
Susan Hilliard	COO	6/26/12

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. Except for nursing homes, the findings above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050168	A. BUILDING _____ B. WING _____	02/15/2012

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
ST. JUDE MEDICAL CENTER	101 E Valencia Mesa Dr, Fullerton, CA 92835-3809 ORANGE COUNTY

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
	Continued From page 6 has caused, or is likely to cause, serious injury or death to the patient and therefore constitutes an immediate jeopardy within the meaning of Health and Safety Code Section 1280.1(c). This facility failed to prevent the deficiency(ies) as described above that caused, or is likely to cause, serious injury or death to the patient, and therefore constitutes an immediate jeopardy within the meaning of Health and Safety Code Section 1280.1(c).			

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Susan Stellard | TITLE: COO | (X6) DATE: 6/26/12

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. Except for nursing homes, the findings above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.