CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 051332	(X2) MULTIPLE CONSTRUCTION A. BUILDING ______ B. WING ______	(X3) DATE SURVEY COMPLETED 11/15/2013
NAME OF PROVIDER OR SUPPLIER: **Mark Twain Medical Center**		STREET ADDRESS, CITY, STATE, ZIP CODE: **768 Mountain Ranch Rd, San Andreas, CA 95249-9707 CALAVERAS COUNTY**	

POC accepted 4/17/14 [illegible] HFES

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The following reflects the findings of the Department of Public Health during an inspection visit:

Complaint Intake Number:
CA00359050, CA00359061 - Substantiated

Representing the Department of Public Health:
Surveyor ID # 29108, 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.

Health and Safety Code Section 1279.1 Retention of a Object in a Patient
(b) For purposes of this section, "adverse event" includes any of the following:
(1) Surgical events, including the following:
(D) Retention of a foreign object in a patient after surgery or other procedure, excluding objects intentionally implanted as part of a planned intervention and objects present prior to surgery that are intentionally retained.

The adverse event was detected on [redacted]/13.
The facility reported the adverse event on [redacted]/13.
The patent and/or responsible party was notified of the adverse event on [redacted]/13.

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: [signature] Vice President, Chief Nurse Executive
TITLE
(X6) DATE: April 16, 2014

By signing this document, I am acknowledging receipt of the entire citation packet, Page(s). 1 thru 10

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	Adverse Event Notification - Informed Health and Safety Code Section 1279.1 (c), "The facility shall inform the patient or the party responsible for the patient of the adverse event by the time the report is made." The CDPH verified that the facility informed the patient or the party responsible for the patient of the adverse event by the time the report was made. CCR Title 22 DIV 5 CH1 ART 3 70223 Surgical Service General Requirements (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. This rule is not met as evidenced by: Based on observations, interviews, medical record and document review, the facility failed to ensure facility policy and procedure for surgical services "Prevention of Retained Surgical Items Policy - Sponge counts" were followed. This failure resulted in the retention of a blue surgical towel left in Patient 1 during an open right hemicolectomy (surgical removal of part of the colon) and a left inguinal hernia repair (protrusion of an anatomical structure in the groin) performe[redacted]3.		ID 70223 ((b)2) 06/14/13 Blue surgical towels removed from Operating Room (OR) and Sterile Processing Department (SPD) store. White towels with Raidopaque markers (ROT) replaced. Observational audits of Surgical count and compliance with policy and procedure initiated 06/14/13, two random audits per week until 100% compliance for 30 days; then observational audits once per week for 90 days until 100%; then random observational audits monthly until 100% for three months. Report audit results and actions to bi-monthly Department of Surgery Meetings Director Perioperative Service responsible. Informed Sacramento Central Supply Chain Management and MedLine representative to remove blue towels from prepackaged materials for kits, replace with ROT internally. Custom ordered packs to be ordered specifically with ROT. Director Perioperative Services responsible.	Completed 06/14/13 and ongoing Completed 06/14/13 Custom kits in process

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	Patient 1 subsequently died of complications related to the retained foreign object on [redacted]13. Findings: Per the medical record, Patient 1 was a 78 year old man admitted to the facility [redacted]13 with diagnoses including colon cancer and a left inguinal hernia. A document dated [redacted]13 titled "Operative Procedure" revealed Patient 1 underwent an open right hemicolectomy and left inguinal hernia repair performed by Surgeon 1 and an assistant, Surgeon 2. Patient 1's [redacted]13 "Anesthesia Intra-Op Evaluation" form identified Anesthesiologist 1 as the physician who intubated and administered the general anesthesia. Patient 1's [redacted]13 Surgical Case Record was reviewed. On Page 4 of the Record, the list of "Devices" used during surgery included "Towel(s)." The "Operative Screens" of Page 4 indicated the following items were included in the counts: sponges, needles, instruments and "other disposable items." Blue surgical towels were not listed. Per the documentation, the Circulating Nurse (OR RN) and Scrub Technician (OR Tech 1) were involved in the counts (the process of counting the number of surgical items available for use in the OR, before, during and after surgery). The facility 7/25/11 Patient Care Services Policy and Procedure titled "Prevention of Retained Surgical Items Policy" defined a surgical item as a supply, device or piece of equipment used in and		Interviewed and queried staff regarding access to electronic policy. Confirmed accessibility. Added to new hire orientation with competency evaluation, RSI policy incorporated into Medical Staff orientation. Director Perioperative Services responsible. Reviewed process with staff utilizing Sponge Accounting Audit Tool for OR and Procedure Room. (Attachment A). Director Perioperative Services responsible. Reviewed current Retained Surgical Item policy and made minor changes based on most current Dignity Health references. Director Perioperative Services responsible. 06/17/13 OR Staff meeting - reviewed event, revised policy & procedure and use of blue towels on Mayo stand only. Director Perioperative Services responsible.	Completed 06/14/13 and ongoing Completed 06/14/13 and ongoing Completed 06/14/13 Completed 06/17/13

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	around a surgical incision or wound. One of the four classes of surgical items is called "soft goods." Soft goods can be cotton, disposable cloth or gauze items including, "...radiopaque (shows up on x ray) towels (16 inches x 26 inches)". Section VI B. 1. General Rules for Sponge Management, b. states, "All cotton gauze disposables placed in the patient will be white surgical sponges or white radiopaque towels and may contain a separate identifiable label or tag. [See Point of Discussion #5 for additional information about why white?] ... 5. VI B .1. b. Why white? The intent here is to have a unified approach to managing what is safe to go into a patient. If we say and practice that all the soft goods that are safe to go inside a patient are white or will be white and have a radiopaque marker (a radiopaque towel ROT) this may help surgical technologists organize the back tables and everyone account for sponges. If it's a white ROT, it's safe and okay to go in [the patient]. If it's blue or green it should be suspect. ...So white ROTs go in just like all the other white sponges while blue or green drape towels stay out." Surgeon 1 was interviewed on 1/2/14 at 12:05 p.m. Surgeon 1 stated he was always involved in the instrument counts. He acknowledged that during Patient 1's surgery, the blue towels were not included in the count and were not radiopaque. Surgeon 1 said he did not use a towel as a sponge, a drape or sling during Patient 1's surgery. Surgeon 1 added that a wet blue towel had been placed under harmonic scalpel, (a cutting instrument used during surgical procedures to simultaneously cut and stop bleeding at the site of the incision).		Informed Medical Executive Committee of event and received approval of revised RSI policy. Director Perioperative Services responsible. Audit of cases scheduled to confirm adherence to current policy. Observational audits of Surgical count and compliance with policy and procedure initiated 06/14/13, two random audits per week until 100% compliance for 30 days; then observational audits once per week for 90 days until 100%; then random observational audits monthly until 100% for three months. Report audit results and actions to bi-monthly Department of Surgery Meetings. Quality Assurance/Risk Management responsible. 06/19/13 Root Cause Analysis performed by interdisciplinary team. Implemented action items. • Repositioned workstations with screen/keyboard away from field. Allowing RN to face surgical field at all times.	Completed 06/17/13 Completed 06/17/13 and ongoing Completed 06/19/13 and ongoing Completed 06/19/13 and ongoing

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	On 11/15/13 at noon, Anesthesiologist 1 was interviewed. Anesthesiologist 1 stated blue towels were typically placed around the perimeter of the abdominal wound, within the sterile surgical field. Anesthesiologist 1 explained she had seen towels used to pad retraction or placed underneath instruments. She said she had assumed the count included the blue towels, "[they] normally do." During an interview with the Director of Perioperative Services/Risk Management (DPS/RM) on 10/18/13 at 1:10 p.m., he stated Patient 1's surgery was intended to be laparoscopic (surgery performed using a scope through a small incision) but ended up being "open", (a long incision made on the abdomen to give the surgeon adequate access to the colon). The blue cotton towel wasn't accounted for, he acknowledged. The DPS/RM did not know if towels were used on a regular basis in the Operating Room. An observation was made of the facility's Surgery Department on 10/18/13 at 2 p.m. The DPS/RM retrieved a sterile pack of 4 blue towels from the surgical suite supply room. In a concurrent interview with the DPS/RM, he acknowledged these were the same type of towels used during Patient 1's surgery. Unfolded, one of the cotton blue towels measured approximately 16 inches by 26 inches. The towel did not have a radiopaque marker or identifying tag. Operating Room Registered Nurse (OR RN) who		• Additional magnetic strips for miscellaneous items placed on dry erase board. In order to accommodate additional items counted. • External review by consultant and incorporated into action plan. Director Perioperative Services responsible. 06/25/13 Board of Trustees Notified. Chief Nursing Executive responsible. 07/03/13 Surgical Department Staff Meeting discussed RCA results, audits and shared actions with staff. Director Perioperative Services responsible. 07/12/13 Letter mailed to Department of Surgery to include all surgeons and anesthesiologists, regarding RSI/Sponge Accounting policy.	Completed 07/24/13 and ongoing Completed 07/08/13 - 07/12/13 and ongoing Completed 06/25/13 Completed 07/03/13 Completed 07/12/13

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	was responsible for managing nursing care in the operating room, was interviewed on 12/31/13 at 11:30 a.m. OR RN stated she had counted instruments and supplies with OR Tech 1. She explained blue towels were often located on the "Mayo stand" (an instrument tray that provides a place for sterile instruments and supplies used during surgery). The towels are rolled up and placed under instruments, like scissors for example, to "prop them up." OR RN acknowledged the blue towels were not included in the count. An interview was conducted with OR Tech 1 on 11/15/13 at 1 p.m. OR Tech 1 stated she was present during Patient 1's surgery and participated in the surgical item counts with OR RN. She remembered all items were accounted for after Patient 1's surgery. The counts were documented on the white board and "count sheet." OR Tech 1 stated she never gave a blue towel to the surgeon or placed one on the surgical field during the case. OR Tech 1 stated she had placed a wet blue towel under the harmonic scalpel. She acknowledged the blue towels were never included in the count and were not radiopaque. According to the 2013 AORN (Association of Perioperative Registered Nurses) Perioperative Standards and Recommended Practices, "Recommended Practices for Prevention of Retained Surgical Items (RSIs)" included, "all soft goods used in the surgical field should be radiopaque...Retained surgical towels have resulted in patient injury. Surgical towels found in the abdomen and chest have been reported, as have		Medical Staff manager and Quality Assurance/Risk Management responsible. 07/22/13 Department of Surgery peer review completed. Risk Management and Quality Assurance responsible.	Completed 07/12/13 Completed 07/22/13

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	instances of surgical towels found at autopsy...When placed in a body cavity, an unmarked towel not included in the count may not be detected and increases the possibility of a RSI." During an interview with the Chief Nursing Officer (CNO) on 10/18/13 at 11:50 a.m., the CNO acknowledged there was indication Patient 1 wasn't recovering from surgery as well as expected. The physicians were concerned. The CNO stated Patient 1 experienced nausea and vomiting, vague abdominal pain and a low grade (elevated) fever. On [redacted]13, Surgeon 2 ordered a CT (computed tomography; a specialized x-ray that produces a precise reconstructed image of the area) of Patient 1's abdomen and pelvis. According to the Imaging Report, Radiologist 1 charted, "Impression...Right renal cyst. Some non-specific inflammatory changes in right flank." Surgeon 2 ordered another abdominal/pelvic CT on [redacted]13. The Imaging Report read "mass in the right lower abdomen which may represent an abscess although the relative lack of inflammatory change suggests that this possibly could represent a sterile abscess. Findings discussed with Surgeon 2." In a phone interview with Radiologist 1 on 12/31/13 at 2:30 p.m., he stated he understood at the time, Patient 1 had been "uncomfortable" and so a CT [of the abdomen and pelvis] was ordered on [redacted]13. Radiologist 1 explained that in the right lower quadrant of Patient 1's abdomen, the film showed an area that looked like a "sponge from the ocean." Radiologist 1 stated he discussed the results with			

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	Surgeon 2. "I just knew it didn't belong there," he said. Radiologist 1 continued, saying a second CT was completed [redacted]13 which provided no additional or different information. As the interview continued, Radiologist 1 remembered Patient 1 was transferred to a different facility (Facility 2) on [redacted]13. On [redacted]13, at Facility 2, another CT was performed and Facility 2 staff determined the image was suggestive of a "foreign body." Radiologist 1 (from Facility 1) stated, "Why I didn't think it was a foreign body, I don't know, I just didn't." Radiologist 1 said that in a later discussion with Surgeon 1, they had asked themselves, "How did [the towel] get inside?" "We hadn't a clue," he stated. Patient 1's [redacted]13 Surgical Case Record from the receiving hospital (Facility 2) was reviewed. It revealed that one "retained foreign body (towel x 1)" was removed from the right lower quadrant of the abdomen and sent to the Pathology Lab. In an interview with the Risk Manager (RM) at Facility 2 on 10/7/13 at 1:15 p.m., the RM explained a surgeon at Facility 2 accepted Patient 1 on [redacted]3. A CT scan was ordered at Facility 2 and the physicians suspected "the mass" on the film was a retained surgical item. Patient 1 went to surgery and they found a towel. The RM continued, "On post-operative day #2[redacted]3, [redacted] day after second surgery), a Physical Therapist encouraged him to get up out of bed. When he stood up, he collapsed and coded (stopped breathing). The staff could not revive him."			

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	In an interview with the DPS/RM on 10/18/13 at 1:10 p.m., he stated the autopsy report indicated the retained surgical towel in Patient 1's abdomen had compressed a blood vessel which contributed to the development of blood clots in his lungs and legs and were contributory to his sudden death. Review of the [redacted]13 official document from the San Joaquin County Office of the Coroner which specified Patient 1's cause of death. The document revealed Patient 1 had been "injured" by a surgical towel left inside his abdomen after surgery causing therapeutic complications. The immediate cause of death was an "Acute Pulmonary Thrombo-embolism (life-threatening blood clot in the lung) due to Deep Vein Thrombosis (blood clots) of the Legs due to Systemic Inflammatory Response Syndrome (SIRS) due to Intra-Peritoneal Gossypiboma/Textilloma (unintentionally retained textile, sponge, or towel)." The document was signed by the Supervising Deputy Coroner. In a phone interview with the Supervising Deputy Coroner on 11/12/13 at 1:15 p.m., he described the textilloma as "standard sized surgical towel." "It was [found] wadded up, about the size of a human fist," the Coroner continued. The Coroner confirmed the towel was not radiopaque. The [redacted]13 Autopsy Report of Patient 1 was reviewed by a Forensic Pathologist. The Forensic Pathologist concurred with the Coroner's report, he documented, in his "Opinion [Patient 1] a 78 year old white male, died as a result of Acute			

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	Thrombo-Embolism due to Deep Vein Thrombosis of Legs, due to Systemic Inflammatory Response Syndrome (SIRS) due to Intra-Peritoneal Gossypiboma/Textilloma." In an interview with the Chief Nurse Officer (CNO) at Facility 1, on 10/18/13 at 11 a.m., she stated, "The towels were not counted. It's not standard procedure to count towels." After the incident, the CNO explained that she had asked the operating room staff what may have contributed to the towel being left in the patient; the staff remarked there was the "assumption" everything was okay. The CNO stated the blue towel was not radiopaque; it was a type of greenish blue tray towel generally placed on top of the instruments before the start of the procedure, or used to drape an open body cavity." 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).			