The following reflects the findings of the Department of Health Services during an investigation of complaint #CA00140183.

Inspection was limited to the specific complaint investigated and does not represent a full inspection of the hospital.

Representing the Department of Health Services:

[Redacted], RN, Health Facilities Evaluator

HSC 1280.1 (a)(c)

1280.1 (a) If a licensee of a health facility licensed under subdivision (a), (b), or (f) of Section 1250 receives a notice of deficiency constituting an immediate jeopardy to the health or safety of a patient and is required to submit a plan of correction, the department may assess the licensee an administrative penalty in an amount not to exceed twenty-five thousand dollars ($25,000) per violation.

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.

DEFICIENCY CONSTITUTING IMMEDIATE JEOPARDY

T22 DIV5 ART3-70243(f)(1) Clinical Laboratory Service General Requirements
(f) The director of the clinical laboratory shall assure that:

(1) Examinations are performed accurately and in a timely fashion.

This regulation was NOT MET as evidenced by:

Based on interview, record review and observation, the hospital mislabeled tissue specimens which led to an unnecessary surgery, removal of the prostate and lymph nodes, being performed on Patient A. In addition, the failure to ensure accurate examinations potentially resulted in delayed treatment for Patient B.

Findings:

Review of medical records on 2/8/08, showed two patients, Patient A and Patient B, had needle biopsies of the prostate with tissue samples sent to the laboratory on 10/16/07.

On 2/8/08 at 1350 hours, during interview, the hospital safety officer stated a laboratory processing error of these two patients' tissue samples, from 10/16/07, had been identified. According to the safety officer, Patient A had a radical prostatectomy for adenocarcinoma on 1/28/08. After surgery, Patient A's prostate biopsy tissue came back as negative for adenocarcinoma. The hospital then reviewed Patient A's tissue cassette and slide samples from the prostate needle biopsy performed on 10/16/07. The tissue sample in the patient's cassette was different from...
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the patient's slide tissue, although they were labeled with the same patient identifier. The tissue in Patient A's cassette was negative for adenocarcinoma, but the slide was positive.

On 2/8/08, review of the hospital's policy and procedure for tissue processing in place during October 2007, showed no laboratory procedure for labeling slides when processing tissue. According to the safety officer, at the time of the event on 10/16/07, 28 different cassettes and slides were being processed at one time and he believed the wrong ascension (tracking) number was placed on the slide. The process had since been changed to have the technologist process one patient at a time and to alternate the types of tissue examined. Rounds were conducted in the laboratory on 2/8/08 at 1315 hours. According to the technician on duty, the tissue samples were now processed one at a time and the types of tissue examined were alternated.

On 2/8/08, review of the medical record for Patient A showed documentation, in the Operative Report that the patient had a radical prostatectomy on 1/28/08. The operative report showed the patient's bilateral pelvic lymph nodes, the prostate and seminal vesicles were taken as specimens. The Surgical Pathology Tissue Report showed documentation the specimens taken during Patient A's surgery included four right pelvic lymph nodes, six left pelvic lymph nodes, and the prostate gland. The patient had an estimated blood loss of 3500 ccs (cubic centimeters) and received 2 units of packed cells during the surgery. None of the

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.
specimens showed adenocarcinoma on gross exam.

On 2/8/08, the safety officer stated that after the error with Patient A's tissue sample was found, the hospital subsequently reviewed all of the 10/16/07 tissue cassettes against the slides and identified another mismatch between tissue cassette and slide, Patient B. Patient B had adenocarcinoma positive tissue in the cassette tissue but the tissue in the slide labeled for Patient B was negative. The tissue from Patient A's cassette had been put on the slide for Patient B and Patient B's tissue was placed on the slide labeled for Patient A. As of 2/8/08, Patient B had been notified of the error in processing of his tissue sampling but surgery for his prostate had not been performed.

The violation(s) has caused or is likely to cause, serious injury or death to the patient(s).