POC ACCEPTABLE
YES ☑ NO ☐
Reviewed By: Name

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

Facility Notified
Name:
Date:
Time:
Notified By: Name

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050057	A. BUILDING _____ B. WING _____	12/24/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
Kaweah Delta Medical Center	400 W. MINERAL KING, VISALIA, CA 93291 TULARE 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
	The following reflects the findings of the Department of Public Health during an inspection visit: Complaint Intake Number: CA00253068 - Substantiated Representing the Department of Public Health: Surveyor ID # 27709, 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 1279.1(b)(4)(C) (b) For purposes of this section, "adverse event" includes any of the following: (4) Care management events, including the following: (C) Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a facility, including events that occur within 42 days post delivery and excluding deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy or cardiomyopathy. DEFICIENCY CONSTITUTES IMMEDIATE JEOPARDY		This Plan of Correction constitutes Kaweah Delta Medical Center's (KDMC) written allegation of compliance for the deficiencies cited. The statements made on this plan of correction are not an admission and do not constitute agreement with the alleged deficiencies herein. Specifically, Kaweah Delta Medical Center (KDMC) disputes the facts contained in the notice of deficiency, including, but not limited to, statements attributed to RN 3,MD2 and the Chief of Obstetrics (MD 9). KDMC has taken actions to prevent reoccurrence, including: Immediate Action and Systemic Changes: 1) Pursuant to KDMC's Quality Assurance/ Performance Improvement (PI) program and in compliance with AP.87 "Sentinel Event and Adverse Event Response and Reporting" policy, a "Case Review Committee" (CRC) was convened on 12/20/10. Members of the CRC included the Chief of Staff, CMO, CNO, COO, Director of Maternal-Child Health, OB Nurse Manager, Director of PI, and Director of Risk Management. The CEO notified the President of the Board of Directors by 12/20/10. 2) A thorough and credible Root Cause Analysis (RCA) was conducted. Meeting dates were 12/21/10, 1/6/11 and 2/11/11. MD 1, MD 2, MD 9 (Chief of Obstetrics), CEO, CNO, CMO, Medical Director for Anesthesia, Director of Maternal-Child Health, L&D Nurse Manager, Clinical Educators, Registered Nurses, the Director of PI and the Director of Risk Management participated in the RCA process. The event was reported to the California Department of Public (CDPH) as an "adverse event" pursuant to H&S Code 1279.1 on 12/22/10. The RCA findings and plan of correction were reported to the Board of Directors on 1/17/11. The findings of the RCA were presented to Medical Care Review Committee (MCRC) on 3/2/11 and the Patient Safety Committee (PSC) on 3/22/11.	12/20/10 12/21/10 1/6/11 2/11/11 12/22/10 1/17/11 3/2/11 3/22/11

Event ID:E81511 7/21/2011 10:20:09AM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Lindsay K. Munn | TITLE: CEO | (X6) DATE: 8/15/11

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AUG 15 20[illegible]
DEPT OF HEALTH SERVICES
LICENSING & CERTIFICATION - FRESNO

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	Continued From page 1 T22. DIV5.CH1. ART 3. 70203(a)(2) Developing, maintaining, and implementing written policies and procedures in consultation with other appropriate health professional and administration. Policies shall be approved by the governing body. Procedures shall be approved by the administration and medical staff where such is appropriate. Based on staff interview, clinical record and administrative document review, the facility failed to ensure the physician staff implemented and followed Medical Staff By-laws, Medical Staff Rules and Regulations, and the Rapid Response Team policy & procedure requiring physicians to seek additional advice and to request consultation from a qualified consultant (senior staff obstetrician) when indicated. This occurred when MD 1 and MD 2 failed to request assistance when Patient 1's blood loss exceeded 1500 cc's (measure of volume - 1 1/2 liters) during a normal vaginal delivery. The Rapid Response Team (RRT) was called and not allowed access to Patient 1. These failures in combination delayed life saving measures to Patient 1 and led to her death. Findings: On 12/27/11 Patient 1's clinical record was reviewed. The record indicated Patient 1 arrived at the hospital on [redacted]/10 at 2:10 a.m., to deliver a full term baby via a routine vaginal delivery. Patient 1 presented in no acute distress with no known health risks and was at a full term pregnancy with ruptured membranes. The medical record indicated Patient 1 had progressed through labor in a normal manner in a		Members of the MCRC include, the chair/ designee of all clinical departments, the Peer Review Committee (PRC) chair and the Medical Director of PI. Other MCRC attendees include the CEO, CMO, COO, Director of PI, Director of RM and other KDHCD and medical staff as determined by the chair. MCRC presented to Quality Council on 3/23/11. The care of Patient 1 was presented to the Medical Executive Committee (MEC) on 3/2/11. 3) The matter was referred for medical staff peer review for both MD 1 and 2. The care provided by MD 1 and 2 was peer reviewed on 12/29/10 and 1/10/11, respectively. i. Persons Responsible: Chief of Staff, Peer Review Committee (PRC) and MEC for oversight and ensuring proper adherence to Medical Staff bylaws, rules & regulations. ii. Monitoring process: Results and actions of peer review are confidential, privileged and protected pursuant to California Evidence Code 1157. 4) Consistent with KDMC's commitment to patient safety and quality care, on 1/3/11, the Post-Partum Hemorrhage (PPH) H.2 policy was immediately reviewed and revised. Immediate education of nursing staff was completed by L&D Clinical Nurse Educator via 1:1 stand-up in-service meetings on unit and L&D Nurse staff meeting on 1/13/11. Immediate education of OB physicians was completed at OB Committee meeting on 1/3/11. Changes included: i. If the patient continues to bleed and blood loss equals 750 cc or more for a vaginal delivery or 1500cc or more for a C-Section, the patient will be transferred to the Main OR for further intervention/evaluation and possible surgical intervention.	3/23/11 3/2/11 12/29/10 1/10/11 1/3/11 1/13/11 1/3/11

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Lindsay K. Mann | TITLE: CEO | (X6) DATE: 8/15/11

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	Continued From page 2 regular labor and delivery room. According to the documentation on the Labor and Delivery (L D) Flowsheet dated [redacted]10 at 11:26 a.m., the membrane (bag of fluid in the uterus) was ruptured by artificial (broken open with a sterile pointed instrument) method. After delivery of the baby at 3:18 p.m. and following the expelling of the placenta, Patient 1 sustained a 1500cc (1 1/2 liters) blood loss and continued to bleed over a one hour time frame (from 3:18 p.m. to 4:20 p.m.). According to the Operative Report dated 12/17/10 at 9:22 p.m., MD1 attempted to stop the bleeding by repair of the cervical laceration, fractional dilation and curettage and the placement of a Bakri Balloon (a tube with a balloon used vaginally to provide temporary reduction of postpartum uterine bleeding). The attempts to stop the bleeding were unsuccessful. LD Flowsheet indicated the patient was moved from the labor and delivery room to the Operating Room because of the continued bleeding at 4:20 p.m. Patient 1 continued to bleed in the OR for the next 41 minutes. According to the Intraoperative Record dated [redacted]/10 at 5 p.m., RN 8 requested a "senior proctoring obstetrician" to come to the OR. RN 9 repeated the request to call for a Senior Staff Obstetrician to come to the OR. MD 8 (Senior Staff Obstetrician) responded to the call by the nursing staff to the Operating Room. At this time period Patient 1 had been bleeding (bright red constant trickle) for1hour and 41 minutes. The Intraoperative Record under comments dated [redacted]/10 at 5:25 p.m., indicated that RN 9 asked MD 2(Anesthesiologist) if another Physician or the		If blood loss exceeds 750cc for vaginal delivery or 1500cc for a C-Section before patient can be transferred to OR but bleeding has stopped and patient is stable, the physician may determine no further intervention is necessary. ii. If Main OR does not have a room available or if the patient is too unstable to wait for transfer to the Main OR, the patient will be transferred to the OBOR and the Rapid Response Team and Main OR Team will be called to help support the patient and the L&D staff. iii. Persons Responsible: L&D Nurse Manager and Director of Maternal Child Health for ensuring L&D staff are competent in understanding & complying with policies & procedures and monitoring is completed. MEC, PRC, Chief of Staff and Chief of Obstetrics for oversight and ensuring proper adherence to Medical Staff bylaws, rules & regulations. iv. Monitoring process: Pursuant to the California Maternal Quality Care Collaborative's (CMQCC –described below) "OB Hemorrhage Toolkit", a "de-brief" is promptly completed in 100% of all OB hemorrhages using the CMQCC "Team de-briefing form", which includes the primary nurse and the primary physician. The de-brief form provides an opportunity for the Department of OB/GYN to review then document the sequence of events and identify opportunities for improvement. In addition, 100 % of PPH occurrences are monitored monthly by the PI department. Results will be reported to MCRC and PSC Committee for a minimum of 4 months to assure compliance with the revised policy. 5) On 1/6/11, the implementation of a Communication "White Board" in cases of PPH was implemented pursuant to the California Maternal Quality Care Collaborative's (CMQCC –described below).	1/6/11

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	Continued From page 3 Rapid Response Team (RRT-critical care team) was needed. MD 2 responded not at this time. On [redacted]/10, according to the clinical record, at 5:30 p.m. the RRT came to the OR and was not allowed inside the OR by MD 2. MD 2 placed a breathing tube in Patient 1 and after placement allowed the RRT to enter the OR at 5:35 p.m. Resuscitative measures (Code Blue) were begun and continued for 72 minutes. On 12/28/10 at 12:30 p.m., during an interview, RN 3 confirmed she was with Patient 1 during the entire active labor and delivery. RN 3 confirmed she updated MD 1 as to Patient 1's condition. RN 3 confirmed giving MD 1 an estimated blood loss of 1500 cc's. RN 3 confirmed Patient 1 was moved from the labor and delivery area to the OR due to excessive bleeding at 4:20 p.m. on [redacted]/10. On 3/16/11 at 1:45 p.m., during a telephone interview, MD 1 confirmed Patient 1 was moved from the normal delivery area to the OR because he could not see where the excessive bleeding was coming from. When asked at what point he would have called for assistance from a consultant and the RRT, MD 1 did not respond. On 5/4/11 at 3:10 p.m., during an interview, MD 2 confirmed knowledge that Patient 1 had excessive bleeding at the time the patient was moved to the OR. MD 2 confirmed she did not keep track of the amounts of fluid and/or blood loss, vital signs, amount of urine output and the amount of fluids given. When asked what she would have done differently, MD 2 stated, in retrospect, she should have called for assistance.		This is a dry erase board that is brought into the rooms on the L&D unit when a PPH occurs. These boards are mounted in each OBOR. These boards are cleaned between patient uses in accordance with Infection Prevention policies and procedures. An in-service to physicians and nursing staff regarding the purpose and use of the white board was presented by L&D Nurse Manager on 1/6/11. The white board was reviewed with L&D nursing staff and physicians at the mandatory CME on 2/16/11. iii. This is a checklist utilized by L&D nursing staff to improve communication between health care providers during a PPH, including: A. Administration of Oxygen B. Vital Signs with O2 saturation every 5 min C. Start 2nd IV D. Insert Foley catheter E. Keep patient warm F. Evaluate blood loss every 5 min during active bleed G. Medications: Methergine, Hemabate, Misoprostol H. Consider Bakri Balloon I. Draw Labs J. Emergency Release Blood Products (PRBC 2 units) K. Fresh Frozen Plasma (if giving more than 2 units PRBC) iv. Persons Responsible: L&D Nurse Manager and Director of Maternal Child Health for ensuring L&D staff are competent in understanding & complying with policies & procedures and monitoring is completed. MEC, PRC, Chief of Staff and Chief of Obstetrics for oversight and ensuring proper adherence to Medical Staff bylaws, rules & regulations.	1/6/11 2/16/11

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Lindsay K. Mann | TITLE: CEO | (X6) DATE: 8/15/11

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	Continued From page 4 On 5/4/11 at 3:40 p.m., during an interview, the Chief of Obstetrics and Vice Chair of Medical Staff (MD 9) confirmed knowledge and familiarity with Patient 1's case. MD 9 confirmed that she reviewed the events leading up to Patient 1's death. When asked what went wrong with Patient 1's care, MD 9 stated that MD 1 should have called for assistance when excessive bleeding was recognized. The facilities policy and procedure of the "Medical Staff Rules and Regulations with a board approval date of 5/10/10." was reviewed on 12/27/10. The section titled, "General Conduct of Care, Revised: 3/10," Indicated under number "14. Consultation with a member of The Consulting or Active Medical Staff is required in the following situations: a. ...the diagnosis is obscure after ordinary diagnostic procedures have been completed...c. in unusual complicated situations where specific skills of other practitioners may be needed...f. complex cases for which the attending needs additional advise. 15. ...consultant shall make and sign a record of...findings and recommendations...in every such case...16. The attending practitioner is primarily responsible for requesting consultation when indicated and for calling in a qualified consultant. The facility Policy and Procedure from the Anesthesia Manual reviewed on 3/15/11 titled, "Rules and Regulations" last approved by the board on 5/10/10 indicated, "Intra-anesthetic Care: A. ...Following are safety guidelines that need to be met... 3. Proper and adequate use of monitoring equipment (ECG's, blood pressure...temperature		v. Monitoring process: 100 % of PPH occurrences are monitored monthly by the Maternal Child Health and KDMC PI department. Results will be reported to MCRC and PSC Committee for a minimum of 4 months to assure compliance with the new practice. 6) On 1/6/11, Policy AS.16 Rapid Response Team (RRT) was reviewed by RCA team which led to the addition of an Intensivist to the RRT in Labor & Delivery and OB/GYN Operating Rooms effective immediately. Immediate education of nursing staff was completed by L&D Clinical Nurse Educator and ICU Nurse Manager via 1:1 stand-up in-service meetings on both units as well as, an L&D Nurse staff meeting on 1/13/11. OB, Anesthesia & Intensivist Physicians educated to change in policy on 1/6/11. i. Persons Responsible: L&D Nurse Manager & Director of Maternal Child Health for ensuring L&D staff are competent in understanding & complying with policies & procedures and monitoring is completed. MEC, PRC, Chief of Staff and Chief of Obstetrics for oversight and ensuring proper adherence to Medical Staff bylaws, rules & regulations. Director of Emergency and Critical Care Services and RRT Medical Director for ensuring RRT monitoring is completed. ii. Monitoring process: 100% of RRT occurrences are monitored by the RRT committee (appropriate use of, process outcomes and clinical outcomes), and the KDMC PI Department. Results are reported to MCRC and Patient Safety Committee for a minimum of 4 months to assure compliance. Consistent with the PI plan RRTs in L&D, and throughout KDHCD, are monitored monthly by	1/6/11 January 2011 1/13/11 1/6/11

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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Lindsay K. Munn | TITLE: CEO | (X6) DATE: 8/15/11

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State-2567

AUG 15 2011
DEPT OF HEALTH SERVICES
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	Continued From page 5 probe...) 5. Accurate and careful monitoring of vital signs, medications and main events during anesthesia on the hospitals anesthesia record. 6. Accurate charting and monitoring of fluids, blood transfusions including but not limited to gains or losses On 5/14/11 the facility policy and procedure titled, "Rapid Response Team-..." dated and approved 12/13/10, was reviewed. The policy and procedure indicated, "Policy: Rapid Response Team (RRT) using standard assessment process with Advanced Cardiac Life Support Standard Procedure...purpose is for evaluation of questionable medical conditions...functions under authority of Intensive Care Medical Director...in collaboration with Primary Care Physician...or Alternate physician... Documentation: ...IV. D. The RRT/Intensivist/managing physician/RN shall collaborate on course of treatment with the ultimate goal to be expedited access to care and transport to the proper level of care...VI. ...RRT will document assessment interventions on the Rapid Response Team Form...include reason called, vital signs, symptoms and response to interventions." On 12/31/10 during review of patient 1's clinical record, Final autopsy report indicated the following: "I. Massive blood loss A. Immediate post-partum (after delivery of a baby) uterus with 3 cm laceration...lower uterine segment. B. Hemorrhagic cervix and left parametrium (skin tissue of the lower vagina and the ligaments). II. After resuscitation: A. left thoracotomy incision, 17 cm. A. Sternal fracture. B. Excoriation of the skin over the sternum		the PI Department. 1. An RRT form is completed by an RRT Nurse at the time of the RRT. The data entered into RRT database. All RRT forms are submitted to ICU Nurse Manager or designee for review within the next business day and evaluated for: 1) completeness of form 2) appropriate use of Standardized Procedures based on assessment criteria and SBAR report received 3) timely response of physicians 4) completion of the debriefing with staff involved in the RRT. 2. If discrepancies exist, the ICU Nurse Manager will review with the RRT RN and the RRT Medical Director. 3. Aggregate data is presented at the RRT committee meetings monthly for analysis and actions as needed. 4. Beginning 9/1/11, RRTs that may have identified opportunities for improvement will be presented at the RRT committee monthly meetings to be analyzed for recommended and /or implemented corrective actions. 5. Beginning 9/1/11, findings and actions of the RRT committee will be reported monthly to MCRC. RRT cases will be referred to physician and/or nursing peer review as appropriate. 6. Opportunities for improvement relative to nursing practice will be managed individually by the respective nursing manager with appropriate education and progressive discipline if indicated. 7) On 1/10/11, all Anesthesia providers attended a Mandatory Morbidity and Mortality Review meeting where care of Patient 1 was reviewed, including review of Mass Transfusion Protocol and RRT processes in L&D.	9/1/11 1/10/11

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Lindsay K. Manson | TITLE: CEO | (X6) DATE: 8/15/11

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	Continued From page 6 C. Hemorrhagic pericardiac fluid. Clinical summary: ...previous medical history not available. Vaginal delivery...extensive vaginal hemorrhage....Massive blood component transfusions...13 units of RBC's, 5 units of plasma and 1 platelet transfusion...Internal examination ...nearly a complete lack of blood...with incisions..." In summary MD 1 and MD 2 failed to request assistance as required by Medical Staff Bylaws, Medical Staff Rules and Regulations and RRT policies and procedures when Patient 1's medical condition declined as a result of excessive blood loss which ultimately lead to her death. The facility's failure is a deficiency that 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. 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).		i. Persons Responsible: MEC, PRC, Chief of Staff and Medical Director for Anesthesia for oversight and ensuring proper adherence to Medical Staff bylaws, rules & regulations. ii. Monitoring process: 100 % of PPH occurrences are monitored monthly by the Maternal Child Health and KDMC PI department. Results will be reported to MCRC and PSC Committee for a minimum of 4 months to assure compliance with policies and procedures. 8) On 1/10/11, KDMC's administration and clinical department of OB/GYN jointly agreed to participate in the California Maternal Quality Care Collaborative (CMQCC), which aims to improve readiness, recognition, response, and reporting of OB hemorrhage by establishing policies and procedures that implement organized, practiced protocols and guide multi-disciplinary training for cooperative, timely response. The primary aim of this collaborative is to improve California hospital capabilities and resources for responding to OB hemorrhage by increasing the use of protocols and by improving availability of and training in standard and state-of-the-art medical, surgical and blood replacement options. i. Persons Responsible: L&D Nurse Manager & Director of Maternal Child Health for ensuring L&D staff are competent in understanding & complying with policies & procedures and monitoring is completed. MEC, PRC, Chief of Staff and Chief of Obstetrics for oversight and ensuring proper adherence to Medical Staff bylaws, rules & regulations. ii. Monitoring process: L&D Nurse Manager submits to the Director of PI monthly reports of PPH cases for review.	1/10/11

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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Lindsay K. Mmmm TITLE: CEO (X6) DATE: 8/15/11

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	050057	A. BUILDING _____ B. WING _____	12/24/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
Kaweah Delta Medical Center	400 W. MINERAL KING, VISALIA, CA 93291 TULARE 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
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Event ID:E81511 7/21/2011 10:20:09AM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
Lindsay K. Mann	CEO	8-15-11

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CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

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Kaweah Delta Medical Center	400 W. MINERAL KING, VISALIA, CA 93291 TULARE COUNTY

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Event ID: E81511 7/21/2011 10:20:09AM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Lindsay K Munn — TITLE: CEO — (X6) DATE: 8-15-11

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Lindsay K. Mann	CEO	8-15-11

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Lindsay K. Munn	CEO	8-15-11

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CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

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Lindsay K. Munn	CEO	8-15-11

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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Lindsay K. Mamm | TITLE: CEO | (X6) DATE: 8-15-11

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Event ID: E81511 7/21/2011 10:20:09AM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Lindsay K Mann TITLE: CEO (X6) DATE: 8-15-11

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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Lindsay K Mann. TITLE: CEO (X6) DATE: 8-15-11

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