

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>MOA-0014</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____  B. WING _____	(X3) DATE SURVEY COMPLETED  <b>03/31/2015</b>
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NAME OF PROVIDER OR SUPPLIER  
**REPRODUCTIVE HEALTH SERVICES / PLANNI**

STREET ADDRESS, CITY, STATE, ZIP CODE  
**4251 FOREST PARK AVENUE  
SAINT LOUIS, MO 63108**

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L 000	Initial Comments  An on-site, unannounced, state licensure survey was conducted from 03/30/15 to 03/31/15. An onsite complaint investigation for complaint MO00100367 was also conducted and the complaint was found to be unsubstantiated. See below for findings:	L 000		
L1128	19 CSR 30-30.060(1)(B)(8) The facility shall establish a program  The facility shall establish a program for identifying and preventing infections and for maintaining a safe environment. Infectious and pathological wastes shall be segregated from other wastes at the point of generation and shall be placed in distinctive, clearly marked, leak-proof containers or plastic bags appropriate for the characteristics of the infectious wastes. Containers for infectious waste shall be identified with the universal biological hazard symbol. All packaging shall maintain its integrity during storage and transport.  This regulation is not met as evidenced by: Based on nationally-recognized standards, policy review, observation, and interview, the facility failed to: - Restrict multi-dose vials to a centralized medication area separate from the patient treatment area; - Ensure expired medications were not available for patient use; - Have accessible and follow manufacturer's instructions for use; - Monitor the humidity in the clean and dirty instrument processing area; - Protect sterile items from dust and moisture by placing a solid barrier on the bottom shelves;	L1128		

Missouri Department of Health and Senior Services  
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

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L1128	<p>Continued From page 1</p> <ul style="list-style-type: none"> <li>- Ensure staff wore personal protective equipment (PPE) appropriate to the task performed;</li> <li>- Replace worn or deteriorating patient-care items with functional easily cleanable surfaces that would not harbor and transmit infections; and</li> <li>- Clean dirty/dusty surfaces.</li> </ul> <p>The Abortion Facility does an average of 462 cases per month. On the first day of the survey, there were 40 cases.</p> <p>Findings included:</p> <p>1. Review of the facility's, "Infection Prevention Manual," dated 09/09/13, showed the Infection Prevention Committee responsibilities and program components included:</p> <ul style="list-style-type: none"> <li>- Surveillance, investigation, control and prevention of infection;</li> <li>- Review, revision, and approval of infection prevention policies and procedures;</li> <li>- Take appropriate action to correct deficiencies relating to infection prevention as they are reported;</li> <li>- Use of standard precautions including personal Protective Equipment (PPE);</li> <li>- Injection safety (i.e., if multi-dose vials will be used for more than one patient, the vials should be restricted to a centralized medication area);</li> <li>- Environmental cleaning;</li> <li>- Handling of contaminated furniture/equipment/linen/instruments/ supplies;</li> <li>- Medical equipment; and</li> <li>- Ongoing program evaluation of program.</li> </ul> <p>(Note: The facility's policy titled, "Pharmaceutical Services," dated 07/01/13, did not address that multi-dose medications should be restricted to a centralized medication area as shown in the facility's, Infection Prevention Manual .)</p>	L1128		

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L1128	<p>Continued From page 2</p> <p>2. Review of the Centers for Disease Control and Prevention (CDC), document titled, "Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care," dated 2014, showed to dedicate multi-dose vials to a single patient whenever possible. If multi-dose vials will be used for more than one patient, they should be restricted to a centralized medication area and should not enter the immediate patient treatment area (e.g., OR, patient room/cubicle).</p> <p>3. Review of the facility's policy titled, "Pharmaceutical Services," dated 07/01/13, showed:</p> <ul style="list-style-type: none"> <li>- On the first clinic session of each month, a delegated staff reviews the inventory to ensure that stock is being properly rotated and has not expired.</li> <li>- Expired inventory must be removed from active stock and marked as expired to ensure it is not available to patient care.</li> <li>- Controlled substances must be destroyed by two nurses and documented on the Controlled Substance Dispensing or Administration Log Sheet.</li> <li>- A daily count at the beginning and at the end of the clinic day must be taken on days when controlled substances are administered or prescribed.</li> <li>- Syringes taken from multi-dose vials must be labeled with date, time, and staff initials. If not used within 24-hours, it must be discarded no later than 24-hours.</li> <li>- Manufacturer's recommendations for storage of opened and unopened multi-dose vials must be followed.</li> </ul> <p>(Note: The policy did not address that multi-dose medications should be restricted to a centralized medication area as shown in the facility's Infection Prevention Manual.)</p>	L1128		

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L1128	<p>Continued From page 3</p> <p>4. Observation of the pre-operative medication area on 03/30/15 at 2:15 PM showed: - An expired EpiPen ([brand] epinephrine autoinjector-medical device used to inject a measured dose or doses of epinephrine used for the treatment of allergic reaction), expiration 02/15. - A pre-drawn syringe labeled Fentanyl (narcotic pain medication) 50 micrograms, dated 03/28/15. Staff failed to dispose of the Fentanyl within 24-hours. - Staff failed to count the syringe of Fentanyl at the end of the day on 03/28/15.</p> <p>During an interview upon the observations, Staff C, Registered Nurse, Clinical Manager confirmed the EpiPen was expired.</p> <p>5. Observation on 03/30/15 at 2:35 PM of procedure room #2 showed an opened, multi-dose vial of Lidocaine (numbing medication).</p> <p>6. Observation on 03/30/15 at 2:40 PM of procedure room #3 showed an opened, multi-dose vial of Lidocaine.</p> <p>7. Observation on 03/30/15 at 2:50 PM, of the clean side of the sterilization area showed two, Tuttnauer 3870-M autoclaves. Staff were unable to find the manufacturer's instructions for use (IFU).</p> <p>8. Review of requested information on 03/31/15 at approximately 9:30 AM, showed the facility failed to provide the autoclave manufacturer's IFU. The information was requested again.</p> <p>9. During an interview on 03/31/15 at 10:40 AM,</p>	L1128		

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L1128	<p>Continued From page 4</p> <p>Staff H, Health Center Assistant (HCA), explained the cleaning and sterilization process. She stated that she could not locate the autoclave manufacturer's IFU.</p> <p>10. During an interview on 03/31/15 at 1:40 PM, Staff I, Practim Coordinator, stated they were still looking for the autoclave manufacturer's IFU.</p> <p>11. During an interview on 03/31/15 at 1:45 PM, Staff J, Training and Quality Systems Coordinator, provided a copy of the autoclave manufacturer's IFU and stated they had just printed them off the Internet as they had not been able to locate the facility copy.</p> <p>12. Review of the newly printed autoclave manufacturer's IFU showed:            - Clean the door gasket daily;            - Clean the autoclave airjet weekly;            - Once every month, clean and check the safety valve;            - Replace the door gasket every 12 months, or as needed; and            - Once a year, inspect the locking device for excessive wear.            The facility failed to provide documentation they or the biomedical company performed these services.</p> <p>13. Review of a document provided by the facility titled, "PSS Biomedical Service," dated 08/07/14, showed they documented the manufacturer, model, and serial number for the autoclaves but failed to document what service they provided.</p> <p>14. Review of the CDC, "Guideline for Disinfection and Sterilization in Healthcare Facilities," dated 2008, showed:            - The American Institute of Architects 959</p>	L1128		

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L1128	<p>Continued From page 5</p> <p>recommends the sterile storage area should be a limited access area with a controlled temperature (may be as high as 75° Fahrenheit (F) and relative humidity (30-60% in all work areas except sterile storage, where the relative humidity should not exceed 70%).</p> <p>15. Review of the facility's document titled, "Affiliate Risk Management Services (ARMS) Infection Prevention Manual," (a corporate document) dated 2010 showed :</p> <ul style="list-style-type: none"> <li>- Guidelines for the storage of sterile supplies:               <ul style="list-style-type: none"> <li>*Store supplies 8 to 10 inches from the floor; and</li> <li>*Relative humidity must be controlled at 35-50%.</li> </ul> </li> </ul> <p>16. Review of the facility documentation log for the sterilization area showed staff failed to document the humidity levels of the clean and dirty side of the sterilization area.</p> <p>17. Observation on 03/30/15 and 03/31/15 of the clean and dirty side of the sterilization area showed there was no humidistat to monitor the humidity level.</p> <p>18. During an interview on 03/31/15 at approximately 10:30 AM, Staff H stated that they monitored the temperature but did not monitor the humidity.</p> <p>19. Review of the American National Standards Institute (ANSI) and Association for the Advancement of Medical Instrumentation (AAMI) document titled, "ANSI/AAMI ST79:2010," Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities," dated 09/24/10, showed:</p> <ul style="list-style-type: none"> <li>- Sterile items should be stored in a manner that</li> </ul>	L1128		

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L1128	<p>Continued From page 6</p> <p>reduces the potential for contamination.</p> <ul style="list-style-type: none"> <li>- Shelving or carts used for sterile storage should be maintained in a clean and dry condition.</li> <li>- For sterile or clean supplies stored on the bottom shelf of an open-shelf (wire) cart, there should be a physical barrier between the shelf and traffic or housekeeping activities.</li> </ul> <p>20. Observation on 03/31/15 at approximately 10:15 AM of the clean room showed a metal storage rack for sterile instrument sets. There was no protective barrier on the bottom shelf. (Note: There is a potential risk for splash onto the sterile items on the lower shelves without the barrier.)</p> <p>During an interview upon the observation, Staff H stated that they did not store instruments on the bottom shelf.</p> <p>21. Review of the Occupational Health and Safety Administration standards titled, "Bloodborne Pathogens," dated 04/03/12, showed:</p> <ul style="list-style-type: none"> <li>- The employer shall ensure that the employee uses appropriate Personal Protective Equipment (PPE); and</li> <li>- Masks, Eye Protection, and Face Shields. Masks in combination with eye protection devices, such as goggles or glasses with solid side shields, or chin-length face shields, shall be worn whenever splashes, spray, spatter, or droplets of blood or other potentially infectious materials may be generated and eye, nose, or mouth contamination can be reasonably anticipated.</li> </ul> <p>22. Review of the facility's document titled, "ARMS Infection Prevention Manual," dated 2010 showed:</p> <ul style="list-style-type: none"> <li>- PPE is the clinic workers last line of defense</li> </ul>	L1128		

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L1128	<p>Continued From page 7</p> <p>against blood borne pathogens. PPE included face shields/masks, goggles, and safety glasses.</p> <p>- Masks, Eye Protection, Face Shields shall be worn whenever splashes, spray splatter, or droplets of blood or other potentially infectious material may be generated and eye, nose, or mouth contamination can be reasonably anticipated. Examples included washing soiled instruments. References for the document included CDC.</p> <p>23. Review of the facility's documents titled, "Infection Prevention Compliance Audit," (tool) dated 01/09/14, showed staff identified eye protection/face shields were not consistently used in the decontamination area. Review of the audit tools dated 04/10/14, 07/10/14, 10/09/14, and 01/08/15, showed staff failed to identify any issues with eye protection/face shields.</p> <p>24. Review of the facility's, "Infection Prevention Surgical Ad Hoc Committee Meeting," minutes, dated 06/18/14, showed recommendations for the decontamination area included to continue with wearing PPE including face shield.</p> <p>25. Observation on 03/31/15 at 10:15 AM showed Staff H cleaned surgical instruments. She did not wear protective goggles or a face mask.</p> <p>During an interview upon the observation, Staff H stated that she could not see without wearing her glasses and could not wear her glasses with the goggles. Staff F, Licensed Practical Nurse, directed her to put on a face shield.</p> <p>26. Review of the facility's policy titled, "Surgical Abortion Services," dated 10/10/14, showed:</p> <p>- Supplies must be checked monthly to ensure adequate amount for anticipated care and to</p>	L1128		



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L1128	<p>Continued From page 8</p> <p>remove any expired supplies from active inventory. - This is done on the last day of the month or the first day of each successive month prior to the start of the clinic session.</p> <p>27. Observation on 03/30/15 at 1:50 PM of the ultrasound room showed a can of hand sanitizer, expiration 12/14.</p> <p>28. Observation on 03/30/15 at 2:15 PM of the medication refrigerator showed a box of Tempa-Dot (brand) thermometers, expiration 02/15.</p> <p>29. During an interview on 03/30/15 at 2:28 PM, Staff C stated that the thermometers had expired.</p> <p>30. Observation on 03/30/15 at 3:12 PM of the second ultrasound room showed a can of hand sanitizer, expiration 02/15.</p> <p>During an interview upon the observation, Staff C stated that the hand sanitizer was expired.</p> <p>31. Observation on 03/30/15 at 3:15 PM of ultrasound room C showed the examination table had a T-shaped tear in the middle of the pad, on the left side of the bed, approximately 6-inches high by 5-inches wide and an approximately 7-inch long linear tear on the right side. The tears exposed the foam core of the pad in several places leaving an uncleanable surface.</p> <p>During an interview upon the observation, Staff C stated that she had ordered a new table top pad approximately two weeks prior.</p> <p>32. During an interview on 03/31/15 at 2:15 PM, Staff C stated that:</p>	L1128		

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L1128	<p>Continued From page 9</p> <ul style="list-style-type: none"> <li>- Approximately two weeks prior another staff member asked for things needed and she had requested a new table top pad.</li> <li>- A large patient sat on the table and the table top pad split but she did not recall when this occurred.</li> <li>- They had not ordered a replacement table top pad.</li> <li>- She could not find any documentation to show they had identified they needed to replace the table top pad.</li> </ul> <p>33. Observation on 03/30/15 at 1:50 PM of the ultrasound room C showed the cloth pillow on the table was covered with a torn, unzipped plastic pillow cover and a cloth pillow case. Approximately 3 inches of the cloth pillow was exposed. The exposed edge of the pillow was discolored gray while the part of the pillow that was protected by the plastic cover was white.</p> <p>34. Observation on 03/30/15 at approximately 3:20 PM of procedure room #1 showed the cloth pillow on the table was covered with an unzipped plastic pillow cover and a cloth pillow case. The exposed end of the pillow was not covered by the plastic pillow case.</p> <p>35. Observation on 03/30/15 at approximately 3:25 PM of procedure room #2 showed the cloth pillow on the table was covered with a cloth pillow case leaving an uncleanable surface.</p> <p>36. During an interview on 03/30/15 at approximately 3:20 PM, Staff E, Sonographer (Ultrasound Technician), stated that she changed the pillow case covers after each patient.</p> <p>37. Review of the CDC and the Healthcare Infection Control Practices Advisory Committee</p>	L1128		

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L1128	<p>Continued From page 10</p> <p>(HICPAC), "Guidelines for Environmental Infection Control in Health-Care Facilities," dated 2003, showed:</p> <ul style="list-style-type: none"> <li>- Microorganisms proliferate in environments wherever air, dust and water are present; and</li> <li>- Dry conditions favor gram-positive bacteria in dust and on surfaces.</li> </ul> <p>38. Review of the facility's undated policy titled, "Environmental Cleaning of Clinical Areas: Policy and Procedure," showed:</p> <ul style="list-style-type: none"> <li>- At the beginning of each day or prior to the first patient interaction, all environmental clinical care areas will be cleaned and disinfected, including: patient dressing area, recovery rooms and exam/procedure rooms.</li> </ul> <p>39. Review of the facility's, "Infection Prevention Ad Hoc Committee Meeting," minutes, dated 03/13/15 showed:</p> <ul style="list-style-type: none"> <li>- Identified areas of surgical services for daily, weekly, monthly, and periodic cleaning to included ultra sound rooms, procedure rooms; and recovery area.</li> <li>- Need to detail items for cleaning in the ultra sound rooms (i.e., identify equipment and furniture items to clean--exam table, lamps, other furniture, and wall items).</li> </ul> <p>40. Review of the facility's, "Infection Prevention Committee Meeting," minutes, dated 11/12/14, showed staff identified that they needed to include environmental cleaning expectation in the general standard requirement section of their OSHA manual.</p> <p>41. Observation on 03/30/15 at approximately 2:15 PM of the pre/postoperative medication refrigerator showed the front of the refrigerator was dirty and there was tape and adhesive on the</p>	L1128		

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L1128	<p>Continued From page 11</p> <p>refrigerator leaving an uncleanable surface.</p> <p>42. Observation on 03/30/15 at 2:21 PM of the pre/post-operative area nurses' station showed a cabinet with packages of intravenous (IV-small catheter inserted into a vein for administering medication and fluid) administration tubing. There was a layer of dust on the shelves that left a mark when a finger was pulled through.</p> <p>43. During an interview on 03/30/15 at 2:27 PM, Staff C stated that the cabinet shelves were dusty.</p> <p>44. Observation on 03/30/15 at 2:30 PM of the pre/postoperative area showed there was tape, adhesive, and/or peeling labels on the cabinets and clip boards on the wall leaving an uncleanable surface.</p> <p>45. Observation on 03/30/15 at 2:40 PM of procedure room #3 showed a drawer with dust and debris inside and adhesive residue and/or torn labels on the outside of the cabinets and/or drawers leaving an uncleanable surface.</p> <p>46. Observation on 03/30/15 at 2:43 PM of procedure room #1 showed adhesive residue and tape on the cabinet doors and drawers leaving an uncleanable surface.</p> <p>47. During an interview on 03/30/15 at 2:45 PM, Staff C stated that they would have to remove the tape and adhesive residue.</p> <p>48. Observation on 03/30/15 at 2:50 PM of the clean side of the sterilization area showed: - Brownish residue in one cabinet and on the floor in front of the cabinet; - Tape and/or adhesive residue on the cabinet</p>	L1128		

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L1128	<p>Continued From page 12</p> <p>doors ; and</p> <ul style="list-style-type: none"> <li>- A drawer in the corner of the room which contained nonsterile surgical instruments with dust and debris in the drawer.</li> </ul> <p>During an interview upon the observation, Staff C stated that it was obvious no one had been in the drawer in a long time.</p> <p>49. During an interview on 03/31/15 at 10:35 AM, Staff H stated that she did not clean the drawers and the instruments in the drawer were extra instruments.</p> <p>50. Observation on 03/30/15 at 3:12 PM of the ultrasound room showed:</p> <ul style="list-style-type: none"> <li>- A plastic tray holding protective bed pads. The tray had a layer of dust that left a mark when a finger was pulled through.</li> <li>- An ultrasound machine (used to obtain images of the fetuses) with a layer of dust on the control panel that left a mark when a finger was pulled through.</li> <li>- Tape on the side and base of the ultrasound machine.</li> </ul> <p>51. During interviews upon the observation, Staff E stated that she had just dusted the room that morning and dusted constantly but the room got dusty again quickly. Staff A, Chief Operating Officer, stated that the tape could be removed.</p> <p>52. Observation on 03/30/15 at 3:55 PM of the hallway outside the sterilization area showed there was a wheelchair with a layer of dust on the frame that left a mark when a finger was pulled through.</p> <p>During an interview upon the observation, Staff C stated that they often used the wheelchair.</p>	L1128		

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L1128	Continued From page 13  53. Review of the facility's, "OSHA and Laboratory Procedure Manual," dated 12/14/14 showed: - Each employee is responsible to disinfect and decontaminate work surfaces at the end of each shift; and - Work surfaces included countertops, exam tables, mobile medication carts, etc. (Note: There were no directions on when and/or how often to clean the laboratory refrigerator.)  54. Review of the facility's, "Quality Management Checklist," policy dated 12/14/14, showed: - Check refrigerator temperatures daily; and - Clean/disinfect laboratory equipment/furniture. (Note: There were no directions on when and/or how often to clean the laboratory refrigerator.)  55. Observation on 03/30/15 at 3:00 PM of the laboratory refrigerator, showed there were several dark strands of hair and dust on the bottom shelf of the refrigerator.  During an interview upon the observation, Staff C confirmed there was hair in the refrigerator.  56. During an interview on 03/30/15 at 3:10 PM, Staff D, HCA, stated that: - He had been employed approximately 1 and 1/2 years. - He had never cleaned the refrigerator; - He did not recall if it was one of his duties; and - Maybe people that had worked there longer cleaned it.	L1128			
L1136	19 CSR 30-30.060(1)(B)(12) The administrator shall be responsible  The administrator shall be responsible for	L1136			

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L1136	<p>Continued From page 14</p> <p>ensuring that the provisions of Chapter 188, Regulation of Abortions, RSMo 1986 are adhered to.</p> <p>This regulation is not met as evidenced by: Based on policy review and interview the facility failed to ensure that all provisions of Chapter 188 were adhered to regarding the reporting of pathologist's reports and the submission to the Missouri Department of Health. The abortion facility does an average of 462 cases per month. On the first day of the survey, there were 40 cases.</p> <p>Findings included:</p> <ol style="list-style-type: none"> <li>1. Review of the facility's policy titled, "Surgical Abortion Services," dated 10/10/14, showed per Missouri law, all fetal tissue is sent to a pathology laboratory for evaluation.</li> <li>2. Review of Missouri State Statute 188.047 showed that a representative sample of tissue removed shall be submitted to a pathologist who shall file a copy of the tissue report with the state Department of Health and Senior Services.</li> <li>3. During an interview on 03/31/15 at 11:00 AM Staff A, Chief Executive Officer, stated that the pathology service utilized by the facility did not submit pathology specimen reports to the Missouri Department of Health and Senior Services.</li> </ol>	L1136		
L1184	<p>19 CSR 30-30.060(4)(D) The following laboratory procedures shall</p> <p>The following laboratory procedures shall be performed on every abortion patient: hematocrit;</p>	L1184		

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L1184	<p>Continued From page 15</p> <p>urinalysis, including pregnancy test; and Rh typing.</p> <p>This regulation is not met as evidenced by: Based on record review, observation, and interview, the facility failed to date glucometer (device used for testing the blood sugar level) test strips (used to place a drop of blood to test the blood sugar). The Abortion Facility does an average of 462 cases per month. On the first day of the survey, there were 40 cases.</p> <p>1. Review of the facility's undated OneTouch UltraSmart (brand - glucometer) Owner's Booklet showed: - Write the discard date (3 months after first opening the vial) on the vial label when you first open it. Discard remaining OneTouch Ultra Test Strips after the discard date. - Do not use test strips beyond the expiration (printed on the package) or discard date, whichever comes first, because they may cause inaccurate results.</p> <p>2. Review of the facility's laboratory log showed the last blood glucose test had been completed on 03/28/15.</p> <p>3. Observation on 03/30/15 at 3:00 PM in the laboratory showed a OneTouch UltraSmart glucometer. Staff failed to date the bottle of test strips to show when they were to be discarded. Instructions on the bottle showed, "Discard six months after opening." There was a line on the bottle to write the discard date, which had been left blank.</p> <p>During an interview upon the observation, Staff D, Health Center Assistant, who was working in the lab, stated that he had no idea when the test</p>	L1184		



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L1184	Continued From page 16 strips had been opened.	L1184		