| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 39D0181633 | 08/21/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Punxsutawney Area Hospital | 81 Hillcrest Drive, Punxsutawney, PA | |

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

| (X4) ID Prefix Tag | Summary Statement of Deficiencies |
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| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of Semen Analysis Procure manual and interview of the Laboratory Manager (LM), the laboratory failed to include Quality Control (QC) measures for post vasectomy testing from 2017 to 2018. Findings Include: 1. On the days of survey, 08/20/2018 and 08/21/2018, review of the Semen Analysis Procure manual revealed that the procure did not include QC measures to evaluate semen post vasectomy testing. 2. When asked to show documentation of QC for post vasectomy testing performed in 2017 (02/15/2017 to 12/31/2017) and 2018 (01/01/2018 to 08/21/2018), the LM stated QC is not perform for this test. 3. In 2017, 11 post vasectomy |

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| | examinations were performed. 4. In 2018, 10 post vasectomy examinations were performed. 5. The LM confirmed the findings above on 08/21/2018 around 9:00 am. |
| **D5415** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(c)<br><br>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.<br><br>This STANDARD is not met as evidenced by:<br>Based on tour of the laboratory, observation of Tissue Marking Dye bottles, Interview with the Laboratory Manager (LM) and Assistant Manager, the laboratory failed to label 5 of 5 bottles of Cancer Diagnostics (CDI) Tissue Marking Dyes with open and expiration dates. Findings Include: 1. On the days of survey, 08/20/2018 to 08/21 /2018, while on tour of the Tissue pathology laboratory, it was discovered that the laboratory does not write the open and expiration date of Cancer Diagnostics (CDI) Tissue Marking Dyes in use. 2. 5 of 5 bottles were found on site were: 1 of 1 Cancer Diagnostics (CDI) Tissue Marking Dye Applicator Series, Blue. 1 of 1 Cancer Diagnostics (CDI) Tissue Marking Dye Applicator Series, Red. 1 of 1 Cancer Diagnostics (CDI) Tissue Marking Dye Applicator Series, Yellow. 2 of 2 Cancer Diagnostics (CDI) Tissue Marking Dye Applicator Series black. 2. In 2017 (02/15 /2018 to 12/31/2018), 60 Histopathology tissues specimens were processed that used the Cancer Diagnostics (CDI) Applicator, Series Tissue Marking Dyes. 3. In 2018 (01 /01/2018 to 08/21/2018), 33 Histopathology tissues specimens were processed that used the Cancer Diagnostics (CDI) Applicator, Series Tissue Marking Dyes. 4. The LM confirmed the findings above on 08/21/2018 around 01:00 PM. |
| **D6046** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(8)<br><br>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of personnel competency assessment records and interview with the Laboratory Manager (LM), the laboratory failed to assess the competency of the Testing Personnel (TP) #2 in 2017 for histopathology slides read onsite. Findings Include: 1. On the days of survey, 08/20/2018 to 08/21/2018, the LM could not provide the 2017 competency assessment document for TP#2. 2. TP#2 read 116 histopathology slides in 2017. 3. The LM confirmed the findings above on 08/21/2018 around 12:00 pm. |