| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 39D0183697 | 10/22/2020 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Warren General Hospital | 2 Crescent Park, Warren, 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 |
|---|---|
| **D5209** | PERSONNEL COMPETENCY ASSESSMENT POLICIES<br>CFR(s): 493.1235<br><br>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the histology competency policy and interview with the testing personnel (TP) #17, the laboratory failed to follow their histology competency policy to assess the competency of 1 of 1 testing personnel (TP) who performed grossing and Inking of histology specimen from 08/13/2018 to the date of survey. Findings Include: 1. The histology competency policy states, " Once a year, each employee that works in Histology will perform competency." 2. On the day of survey 10/22/2020, TP #17 could not provide competency assessment records for 1 of 1 TP who performed grossing and Inking of histology specimen from 2018, 2019, and 2020. 4. TP# 17 confirmed the finding above on 10/22/2020 around 09:15 am. |
| **D5217** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(c)(1)<br><br>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.<br><br>This STANDARD is not met as evidenced by:<br>Based on peer review records and interview with the TP #17, the laboratory failed to verify the accuracy of the histology slides read on site in 2018 and 2019. Findings |

| | |
|---|---|
| | include: 1. On the day of survey, 10/22/2020, TP #17 could not provide verification of accuracy of histology slides examined in 2018 and 2020. 2. TP #17 confirmed the finding above on 10/22/2020 at 10:00 am. |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation of the laboratory and interview with the Technical Consultant (TC), the laboratory failed to monitor and document room temperatures for the Cytology and Histopathology reagent and stain storage area from 08/13/2018 to the date of survey. Findings include: 1. On the day of survey, 10/22/2020, observation of the Cytology and Histopathology laboratory areas revealed, the storage area where 2 of 2 flammable cabinets reside, housed the Cytology and Histopathology reagents and stains were not monitored for temperature from 08/13/2018 to 10/22/2020. 2. The laboratory could not provide documentation of room temperature from 2018, 2019 and 2020. 3. The flammable cabinets housed the following reagents and stains on 10 /22/2020, stated to be stored at "15 to 30 degrees Celsius": - 1 of 1 pint of Richard Allen Scientific EA-36 Stain, Lot# 536261, expiration date: 4/2022. - 4 of 4 pints of Richard Allen Scientific EA-36 Stain, Lot# 539051, expiration date: 5/2022. - 1 of 1 pint of Richard Allen Scientific OG-6 Stain, Lot# 534458, expiration date: 4/2022. - 946 ml bottles of Richard Allen Scientific Thin Prep Cytological Solution: - 2 of 2 bottles of Lot# 9070EB, expiration date: 03/11/2021. - 3 of 3 bottles of Lot# 9157EA, expiration date: 06/03/2021. - 4 of 4 bottles of Lot# 9294EA, expiration date: 09/06 /2021. - 4 of 4 bottles of Lot# 0006EA, expiration date: 12/19/2021. 4. In 2018 (08/13 /2018 to 12/31/2018) the following number of slides were examined: - Cytology: 1163 - Histology: 9909 5. In the 2019 - Cytology: 3243 - Histology: 19451 6. In 2020 (01 /01/2020 to 10/22/2020) the following number of slides were examined. - Cytology: 2128 - Histology: 12478 7. The TC confirmed the findings above 10/22/2020 at 1:00 p.m. |
| **D5423** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(2)<br><br>Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. |

| | |
|---|---|
| | This STANDARD is not met as evidenced by:<br>Based on observation of laboratory test kits and interview with the Technical supervisor (TS) #2 and #3, the laboratory failed to establish verification of performance on the AIMTab substance reducing tablets that are not subject to FDA clearance or approval, before reporting patient test results in 2020. Findings include: The AIM Tab Substance Reducing Tablets box states, "for forensic use only". 2. On the day of survey, 10/22/2020, observation of laboratory kits revealed, the laboratory was performing diagnostics tests on the AIM Tab substance reducing tablets, meant to be used for forensic use only. 3. Before patient tests were analyzed, the laboratory did not establish and perform verification of performance of the AIMTab substance reducing tablets that have been cleared by the FDA for diagnostic use. 4. In 2020 (01 /01/2020 to 10/22/2020) The laboratory analyzed 96 patients for the AIMTab substance reducing tablets test. 5. The TS #2 and #3 confirmed the finishing above on 10/22/2020 around 1:00 pm. |
| **D5449** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(3)(ii)(g)<br><br>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the Cepheid Xpert Xpress SARS-CoV-2 quality control (QC) records, and interview the technical supervisor (TS) #2 and #3, the laboratory failed to document QC procedures each day of patient testing for 724 patient specimens examined for SARS - CoV-2 in 2020. Findings Include: 1. The Cepheid Xpert Xpress SARS-CoV-2 emergency use authorization (EAU) states, "Your product also includes in the cartridge the following controls, or other authorized controls, that are processed along with the patient samples when tested with your product. The controls listed below must generate expected results in order for a test to be considered valid, as outlined in the Instructions for Use". 2. The Xpert Xpress SARS-CoV-2 Instructions for use, under 15.2 External controls, states, "External controls should be used in accordance with local, state, and federal accrediting organizations as applicable". 1. On the day of survey, 10/21/2020 to 10/22/2020, review of the Xpert Xpress SARS-CoV-2 QC records revealed, the laboratory did not perform QC each day of patient testing from 05/05/2020 to 10/22/2020. 2. In 2020, 724 Xpert Xpress SARS-CoV-2 tests were analyzed. 5. The TS #2 and #3 confirmed on 10/22/2020 around 12:00 PM. |
| **D6094** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5)<br><br>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.<br><br>This STANDARD is not met as evidenced by: |

| | |
|---|---|
| | Based on review of the The Laboratory Quality Management (QM) Plan Policy, review of QM documents and interview with technical supervisor (TS) #2 and #3, the LD failed to ensure quality assessment (QA) programs were followed to assure the quality of laboratory services provided from 2018 to the day of survey. Findings Include: 1. The Laboratory Quality Management Plan Policy states, "The committee shall meet 3 times per year". 2. On the date of survey, 10/21/2020, review of the Quality Management Plan committee meeting minutes revealed, the committee did not meet 3 times a year in 2018, 2019 and 2020. In 2018 the committee met 2 of 3 times. In 2019, the committee met 2 of 3 times. In 2020, the committee met once. 3. The TS #2 and #3 confirmed the findings above on 10/06/2020 around 11:00 am. ** Repeat Deficiency*** |