

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0183697	(X3) Date Survey Completed 08/16/2018
Name of Provider or Supplier Warren General Hospital	Street Address, City, State 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
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory quality assurance (QA) policy, College of American Pathologists (CAP) Non-Gynecologic Cytopathology (NGC) proficiency testing (PT) record, and interview with the cytology general supervisor (GS), the laboratory failed to record PT review in 2017. Findings include: 1. The laboratory QA policy, the laboratory director signed on 05/23/2018, states "Proficiency testing is important to keep a record of each screener's ability to diagnosis different cases ..." 2. The 2017 NGC-A PT report reads as follows: Cumulative Case 4 Response Individuals* Ref Interpretation Adenocarcinoma 55 Site/Your Answer Metastatic Malignancy 17 (other than those listed) *Total 94 participants 3. Of all participants, 59% (55 of 94) responded "Adenocarcinoma" (reference interpretation) versus 18% (17 of 94) responded "Metastatic Malignancy-Other than those listed" (your answer). 4. The laboratory did not document Case 4 PT evaluations in 2017. 5. The laboratory had no other 2017 PT Case 4 verification records. 6. The cytology GS confirmed above findings on 08/15/2018 at 09:00 AM.</p> <p>=====</p>
D5791	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p>

This STANDARD is not met as evidenced by:
 Based on review of laboratory quality assurance (QA) policy, Nitrazine/Actim PROM Correlation Study record, and interview with the technical consultant (TC) #3, the laboratory failed to look into uncorrelated test results in 2018. Findings include: 1. The laboratory QA policy, the laboratory director signed on 05/23/2018, states "Laboratory tests are systematically monitoring for any factor that would affect the accuracy ..." 2. The laboratory 03/10/2018 Nitrazine/Actim PROM correlation study reads as follows: Patient Test Result Number PROM Nitrazine Comparison 1 Positive Positive Agree 2 Positive Positive Agree 3 Positive Negative Disagree 4 Negative Positive Disagree 3. Of these 4 comparison analyses, 2 (patient 3 and 4) disagreed. 4. The laboratory did not address these (2 of 2) discordant test results in 2018. 5. The laboratory had no other follow-up records. 6. The TC # 3 confirmed above findings on 08/13/2018 at 02:30 PM. =====

D6094

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1445(e)(5)

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.

This STANDARD is not met as evidenced by:
 Based on review of laboratory quality assurance (QA) policy, quality management (QM) committee meeting record, and interview with the technical consultant (TC) #3, the laboratory director (LD) failed to ensure QM committee meetings take place bi-monthly in 2018. Findings include: 1. The laboratory QA policy, the LD signed on 05/23/2018, states "This Committee shall meet 6 times per calendar year." 2. The laboratory did not hold any (4 of 4) QM committee meetings from January through August 2018. 3. The laboratory had no other 2018 QM committee gathering records. 4. The TC # 3 confirmed above findings on 08/14/2018 at 11:30 AM. =====