Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0330647	05/24/2019
Name of Provider or Supplier	**Street Address, City, State**	
Ohiohealth Marion General Hospital	1000 Mckinley Park Drive, Marion, OH	

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
D0000	A complaint survey was completed on May 24, 2019. On June 7, 2019 , it was determined that Immediate Jeopardy (IJ) existed for the following condition-level deficiencies: Cytology- 42 CFR 493.1221 Laboratory Director- 42 CFR 493.1441 Laboratory Technical Supervisor- 42 CFR 493.1447
D5032	CYTOLOGY CFR(s): 493.1221 If the laboratory provides services in the subspecialty of Cytology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1274, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interviews it was determined that the laboratory failed to establish written policies and procedures to ensure optimum patient specimen integrity (refer to D5203); failed to establish written policies and procedures for a program to determine the causes of discrepancies between the cytology diagnosis and the histopathology diagnosis (refer to D5623); failed to establish written policies and procedures for the review of all prior negative gynecologic specimens for each patient with a current high-grade squamous intraepithelial lesion (HSIL) or malignancy (refer to D5625); failed to establish written policies and procedures for the annual evaluation and comparison of six of six laboratory statistics, and failed to document three of six required annual statistics (refer to D5629); failed to establish written policies and procedures to ensure that unsatisfactory gynecologic cytology slide preparations were identified and reported as unsatisfactory, and failed to identify and report five gynecologic cytology cases as being "Unsatisfactory for Interpretation" (refer to D5655); and failed to establish written policies and procedures for the nomenclature used for reporting

	gynecologic cytology test results (refer to D5657). The cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results in the subspecialty of Cytology.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, specimen slides and interview it was determined that the laboratory failed to establish written policies and procedures to ensure the accurate specimen description of patient's specimens. The laboratory failed to ensure that the number of slides and the method of slide preparation was accurately reported for five of 62 random non-gynecologic specimens from January 2019 to March 2019. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that the total number and type of slide preparation is accurately documented for each specimen. 2. The Survey Team reviewed 62 non-gynecologic final test reports and the corresponding slides from January 2019 to March 2019. The Survey Team observed that five of the 62 specimens provided by the laboratory, were not the same as the specimen description that was documented on the final test reports. Specimen descriptions include: -NM19-0002 Report: ThinPrep and Cell Block Specimen: ThinPrep, Cell Block Two Diff Quik stained Cytospin slides -NM19-00004 Report: ThinPrep and Cell Block Specimen: ThinPrep and Cell Block Two Diff Quik stained Cytospin slides -NM19-00037 Report: ThinPrep and Cell Block Specimen: ThinPrep and Cell Block One Diff Quik stained Cytospin slide -NM19-00024 Report: ThinPrep and Cell Block Specimen: ThinPrep and Cell Block Two Diff Quik stained Cytospin slides -NM19-00076 Report: ThinPrep and Cell Block 1 Diff Quik Smear Specimen: ThinPrep and Cell Block 1 Diff Quik stained Cytospin slide 3. The Laboratory Director and Staff A confirmed these findings during an interview on 5/22/19 at 10:00 AM.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, glass slide preparations and interview it was determined that the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the general laboratory systems. Cross Refer to D5203.
D5403	PROCEDURE MANUAL

	CFR(s): 493.1251(b) 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. This STANDARD is not met as evidenced by: Based on review of five laboratory policies and procedures and interview it was determined that the laboratory failed to establish written policies and procedures for two laboratory processes. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe how the stain maintenance for two Diff Quik stain processes was documented. 2. The Survey Team requested and the laboratory failed to provide written policies and procedures for the required cytology proficiency testing of personnel that perform gynecologic cytology testing. 3. Staff A confirmed these findings during an interview on 5/23/19 at 8:15 AM.
D5623	CYTOLOGY CFR(s): 493.1274(c)(2) (c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c) (2) Laboratory comparison of clinical information, when available, with cytology reports and comparison of all gynecologic cytology reports with a diagnosis of high-grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasms with the histopathology report, if available in the laboratory (either on-site or in storage), and determination of the causes of any discrepancies. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interview it was determined that the laboratory failed to establish written policies and procedures to ensure that the cytology diagnosis and the histopathology diagnosis were compared to determine the causes of any discrepancies. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's process to determine the causes of discrepancies between the cytology diagnosis and the histopathology diagnosis. 2. The Survey Team requested

	and the laboratory failed to provide records for cytology and histopathology correlation to document the review and the causes of any discrepancies. 3. Staff A confirmed these findings during an interview on 5/23/19 at 8:15 AM. Based on review of laboratory policies and procedures and interview it was determined that the laboratory failed to establish written policies and procedures to ensure that the cytology diagnosis and the histopathology diagnosis were compared to determine the causes of any discrepancies. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's process to determine the causes of discrepancies between the cytology diagnosis and the histopathology diagnosis. 2. Staff A confirmed during an interview on 5/23/19 at 8:15 AM that there were no laboratory procedures to describe the laboratory's process to ensure that the review, along with the cause for discrepancies, was performed and documented.
D5625	CYTOLOGY CFR(s): 493.1274(c)(3) (c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c)(3) For each patient with a current HSIL, adenocarcinoma, or other malignant neoplasm, laboratory review of all normal or negative gynecologic specimens received within the previous 5 years, if available in the laboratory (either on-site or in storage). If significant discrepancies are found that will affect current patient care, the laboratory must notify the patient's physician and issue an amended report. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interview it was determined that the laboratory failed to establish written policies and procedures to ensure that the search and review of prior negative gynecologic specimens received within the previous five years, for each patient with a current High Grade Lesion (HSIL) or Malignancy was performed. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's process for the search and review of all prior negative gynecologic specimens received within the previous five years, for each patient with a current HSIL or Malignancy. 2. Staff A confirmed during an interview on 5/23/19 at 8:15 AM that there were no written laboratory procedures to describe the laboratory's process to ensure the review was performed and documented.
D5629	CYTOLOGY CFR(s): 493.1274(c)(5) (c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c)(5) An annual statistical laboratory evaluation of the number of - (c)(5)(i) Cytology cases examined; (c)(5)(ii) Specimens processed by specimen type; (c)(5)(iii) Patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation); (c)(5)(iv) Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison; (c)(5)(v) Gynecologic cases where cytology and histology are discrepant; and (c)(5)(vi) Gynecologic cases where any rescreen of a normal or

	negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures for the annual evaluation and comparison of six of six laboratory statistics. The laboratory failed to document three of six required annual statistics for 2017 and 2018. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for the annual statistical evaluation of six of six required laboratory statistics. 2. The Survey Team requested and the laboratory failed to provide records of three of six required annual statistics for 2017 and 2018 for this facility. -Gynecologic cases with a diagnosis of High Grade Squamous Lesion (HSIL), Adenocarcinoma, or other malignant neoplasm for which histology results were available; -Gynecologic cases where cytology and histology are discrepant; -Gynecologic cases where a rescreen of a negative specimen results in reclassification to Low Grade Squamous Lesion (LSIL), HSIL, Adenocarcinoma, or other malignant neoplasm. 3. Staff A confirmed these findings during an interview on 5/23/19 at 8:15 AM.
D5655	CYTOLOGY CFR(s): 493.1274(e)(4) (e) Slide examination and reporting. The laboratory must establish and follow written policies and procedures that ensure the following: (e)(4) Unsatisfactory specimens or slide preparations are identified and reported as unsatisfactory. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, interview and review of gynecologic cytology slides it was determined that the laboratory failed to establish written policies and procedures to ensure that unsatisfactory gynecologic cytology slide preparations were identified and reported as unsatisfactory. The laboratory failed to identify and report five gynecologic cytology cases from April 2017 to March 2019 as being "Unsatisfactory for Evaluation." Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to define the criteria for reporting unsatisfactory gynecologic specimens. a. Staff A confirmed during an interview on 5/24/19 at 8:15 AM that there was no written procedure for reporting gynecologic specimens as unsatisfactory. 2. The Survey Team reviewed 66 unsatisfactory gynecologic cases. The laboratory failed to report 5 of the 66 cases as unsatisfactory. Cases include: -GM17-207069 -GM18-201950 -GM18-206387 -GM18-206162 -GM19-201150 3. The Survey Team Pathologist confirmed on 5/24/19 that the laboratory failed to identify and report five gynecologic cases as "Unsatisfactory for Evaluation."
D5657	CYTOLOGY CFR(s): 493.1274(e)(5) (e) The laboratory must establish and follow written policies and procedures that ensure the following: (e)(5) The report contains narrative descriptive nomenclature for all results.

	This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, final test reports and interview it was determined that the laboratory failed to establish written policies and procedures to describe the laboratory's nomenclature for reporting unsatisfactory gynecologic specimens in 2017, 2018 and 2019 to the date of the survey. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's nomenclature system for reporting unsatisfactory gynecologic cytology test results. 2. The Survey Team reviewed 10 random final gynecologic test reports from cases reported as unsatisfactory for interpretation in 2017, 2018 and 2019 to the date of the survey. Ten of ten reports had an interpretation of both "Abnormal" and "Unsatisfactory smear - no diagnosis." Reports include: -GM19-201095 Interpretation (Abnormal) Unsatisfactory smear - No diagnosis -GM19-201046 Interpretation (Abnormal) Unsatisfactory smear - No diagnosis -GM19-200297 Interpretation (Abnormal) Unsatisfactory smear - No diagnosis -GM18-201214 Interpretation (Abnormal) Unsatisfactory smear - No diagnosis -GM17-203896 Interpretation (Abnormal) Unsatisfactory smear - No diagnosis -GM17-203917 Interpretation (Abnormal) Unsatisfactory smear - No diagnosis -GM17-203935 Interpretation (Abnormal) Unsatisfactory smear - No diagnosis -GM17-205156 Interpretation (Abnormal) Unsatisfactory smear - No diagnosis -GM17-204999 Interpretation (Abnormal) Unsatisfactory smear - No diagnosis -GM17-205094 Interpretation (Abnormal) Unsatisfactory smear - No diagnosis 3. Staff A confirmed during an interview on 5/23/19 at 8:15 AM that all reports on unsatisfactory gynecologic cases stated both "Abnormal" and "Unsatisfactory."
D5659	CYTOLOGY CFR(s): 493.1274(e)(6) (e) The laboratory must establish and follow written policies and procedures that ensure the following: (e)(6) Corrected reports issued by the laboratory indicate the basis for correction. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interview it was determined that the laboratory failed to establish written policies and procedures for issuing a corrected report. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for issuing a corrected report. 2. Staff A confirmed these findings during an interview on 5/24/19 at 8:10 AM.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, review of laboratory records

	and interviews it was determined that the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and correct problems in the analytic phases of cytology testing. Cross Refer to D5403, D5623, D5625, D5629, D5655, D5657, D5659.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: A. Based on review of three random fine needle aspiration test reports and interview it was determined that the laboratory failed to ensure the accuracy of one test report. Findings include: 1. The Survey Team reviewed three fine needle aspiration reports from 2019. One report had conflicting specimen sources. -FM19-00032 Specimens A Lymph Node (Subcarinal) B Lung Upper Lobe, Left Final Diagnosis: A. Lung, left upper lobe B. Subcarinal lymph node 2. Staff B confirmed these findings during an interview on 5/23/19 at 12:45 PM. B. Based on review of 302 random non-negative gynecologic test reports and interview it was determined that the laboratory failed to ensure the accuracy of one test report. Findings include: 1. The Survey Team reviewed 302 non-negative gynecologic reports from April 2017 through March 2019 and identified one report with a diagnosis of both "Negative" and "Abnormal." - GM18-202830 Interpretation (Abnormal) Atypical Squamous Cells of Undetermined Significance General Categorization Negative for intraepithelial lesion of malignancy 2. The Laboratory Director and Staff A confirmed these findings during an interview on 5/22/19 at 10:00 AM.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems in the postanalytic phases of cytology testing. Cross Refer to D5805.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493.

	1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, glass slides and interviews it was determined that the laboratory failed to have a Laboratory Director who provides overall management and direction in accordance with 493.1445 of this subpart. The Laboratory Director failed to fulfill the responsibility for the overall operation of the laboratory and failed to ensure compliance with applicable regulations (refer to D6079); failed to ensure that quality control programs were established and maintained (refer to D6093); failed to ensure that quality assessment programs were established (refer to D6094); and failed to ensure written policies and procedures were established to identify needs for remedial training or continuing education to improve upon diagnostic skills of the Technical Supervisors (refer to D6103). The cumulative effect of these systemic problems resulted in the Laboratory Director's inability to provide overall management and direction of cytology in accordance with 493.1445 of this subpart.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, glass slides and interviews it was determined that the Laboratory Director failed to be responsible for the overall operation and administration of the laboratory, to include assuring compliance with the applicable regulations and ensuring that all the duties of the Laboratory Director were performed. Cross Refer to D5203, D5403, D5655, D5657, D5659, D5805.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 policies and procedures, laboratory records and interviews it was determined that the Laboratory Director failed to ensure that quality

	control programs were established and maintained to assure the quality of cytology testing and identify failures in quality as they occur. Cross Refer to D5623, D5625, D5629.
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 policies and procedures, laboratory records and interviews it was determined that the Laboratory Director failed to ensure that quality assessment programs were established and maintained to assure the quality of cytology testing and identify failures in quality as they occur. Cross Refer to D5291, D5791, D5891.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on review of laboratory polices and procedures, laboratory records and gynecologic cytology slides it was determined that the Laboratory Director failed to ensure written policies and procedures were established to identify needs for remedial training or continuing education to improve upon diagnostic skills of the Technical Supervisors, when evaluating gynecologic specimens. Cross Refer to D6115. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to identify needs for remedial training or continuing education to improve upon diagnostic skills of the Technical Supervisors, when evaluating gynecologic specimens. 2. The Survey Team requested and the laboratory failed to provide records to monitor and assess remedial training or continuing education to improve upon diagnostic skills of the Technical Supervisors, when evaluating gynecologic specimens. 3. The Survey Team reviewed 164 cases reported by Technical Supervisor C as Negative for Intraepithelial Lesion or Malignancy (NIL) from April 2017 through December 2018. a. The Survey Team Pathologist confirmed on 5/24/19 that Technical Supervisor C failed to identify and report two of the 164 (NIL) cases as High Grade Squamous Intraepithelial Lesion (HSIL). Cases include: -GM17-203820 -GM17-206312 b. The Survey Team Pathologist confirmed on 5/24/19 that Technical Supervisor C failed to identify and report three of the 164 (NIL) cases as Low Grade Squamous Intraepithelial Lesion (LSIL). Cases include: -GM17-203346 -GM17-206797 -GM18-205810 c. The Survey Team Pathologist confirmed on 5/24/19 that Technical Supervisor C failed to identify and report one of the 164 (NIL) cases as Atypical Squamous Cells cannot rule out a High Grade Squamous

	Intraepithelial Lesion (ASC-H) and one of the cases as Atypical Glandular Cells (AGC). Cases include: -GM17-202683 -GM17-202595 d. The Survey Team Pathologist confirmed on 5/24/19 that Technical Supervisor C failed to identify and report 20 of the 164 (NIL) cases as Atypical Squamous Cells of Undetermined Significance (ASC-US). Cases include: -GM17-205232 -GM17-203971 -GM17-207048 -GM17-204964 -GM17-203828 -GM17-203704 -GM18-201626 -GM18-206153 -GM18-204847 -GM18-204976 -GM18-205015 -GM18-204667 -GM18-204432 -GM17-202761 -GM18-201833 -GM18-202089 -GM17-203158 -GM17-203162 -GM17-203357 -GM18-205317 4. The Survey Team reviewed 142 cases reported by Technical Supervisor C as ASC-US from April 2017 through December 2018. a. The Survey Team Pathologist confirmed on 5/24/19 that Technical Supervisor C failed to identify and report 47 of the 142 (ASC-US) cases as LSIL and one as HSIL. Cases include: -GM18-205910 -GM18-201775 -GM18-203031 -GM18-203061 -GM18-203072 -GM18-203076 -GM18-203095 -GM18-203293 -GM18-200622 -GM18-200676 -GM18-205381 -GM18-201194 -GM18-204525 -GM18-201489 -GM18-201316 -GM18-206337 -GM18-205053 -GM18-206091 -GM18-205088 -GM18-205103 -GM18-203490 -GM18-202465 -GM18-202476 -GM18-204084 -GM18-206470 -GM17-206553 -GM17-206591 -GM17-206680 -GM17-203439 -GM17-204220 -GM17-205277 -GM17-205521 -GM17-205014 -GM17-203131 -GM17-203069 -GM17-203138 -GM17-204599 -GM17-205271 -GM17-203149 -GM17-203179 -GM17-203258 -GM17-202808 -GM17-202900 -GM17-202629 -GM17-202931 -GM17-202449 -GM17-206273 -GM17-202666 5. The Survey Team reviewed six cases reported by Technical Supervisor C as AGC or Adenocarcinoma from December 2017 through December 2018. a. The Survey Team Pathologist confirmed on 5/24/19 that Technical Supervisor C failed to identify and accurately report three of the six cases as squamous lesions or having a squamous component. Cases include: -GM17-206714 -GM18-200594 -GM18-206547
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on review of gynecologic slides and corresponding final test reports it was determined that the Technical Supervisor failed to verify the accuracy of 17 test reports (refer to D6115). The cumulative effect of these practices resulted in the Technical Supervisor's inability to provide technical supervision requirements of 493.1451 of this subpart.
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: A. Based on review of 256 random negative and unsatisfactory gynecologic cases/290

	slides from April 2017 through March 2019 and confirmation by the Survey Team Pathologist on May 24, 2019, it was determined that the Technical Supervisor failed to verify the accuracy of 15 gynecologic tests. 1. GM17-203820 7/10/17 Imaged ThinPrep Pap Test (I-TPPT) LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: High Grade Squamous Intraepithelial Lesion 2. GM17-206312 11/16/17 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: High Grade Squamous Intraepithelial Lesion 3. GM17-203346 6/7/17 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion 4. GM-17-206797 12/8/17 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion 5. GM18-205810 11/12/18 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion 6. GM19-200087 1/10/19 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion Herpes Simplex Virus SURVEY TEAM PATHOLOGIST DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion Herpes Simples Virus 7. GM17-202683 5/9/17 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Atypical Squamous Cells - cannot rule out High Grade Squamous Intraepithelial Lesion 8. GM19-201184 3/8/19 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Atypical Glandular Cells 9. GM17-202595 5/11/17 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Atypical Glandular Cells 10. GM19-200987 3 /1/19 I-TPPT LABORATORY DIAGNOSIS: Unsatisfactory due to Insufficient Squamous Cells SURVEY TEAM PATHOLOGIST DIAGNOSIS: Atypical Squamous cells of Undetermined Significance cannot rule out High Grade Squamous Lesion 11. GM17-207069 12/20/17 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation Scant Cellularity and Obscuring Inflammation 12. GM18-201950 4/18/18 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation Scant Cellularity and Obscuring Inflammation 13. GM18-206387 12/18/18 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation Scant Cellularity and Obscuring Inflammation 14. GM18-206162 12/17/18 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation Scant Cellularity and Obscuring Inflammation 15. GM19-201150 3/7/19 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation Scant Cellularity and Obscuring Inflammation B. Based on review of 302 random non-negative gynecologic cases/307 slides from April 2017 through March 2019 and confirmation by the Survey Team Pathologist on May 24, 2019 it was determined that the Technical Supervisor failed to verify the accuracy of two gynecologic tests. 1. GM18-200594 2/13/18 Imaged ThinPrep Pap Test (I-TPPT) LABORATORY DIAGNOSIS: Atypical Glandular Cells SURVEY TEAM PATHOLOGIST DIAGNOSIS: High Grade Squamous Intraepithelial Lesion 2. GM18-205910 12/11/18 I-TPPT LABORATORY DIAGNOSIS: Atypical Squamous Cells of Undetermined Significance SURVEY TEAM PATHOLOGIST DIAGNOSIS: High Grade Squamous Intraepithelial Lesion

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