Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0505053	11/28/2018
Name of Provider or Supplier	**Street Address, City, State**	
Ascension Seton Medical Center- Lab/Rt	1201 W 38th Street, Austin, TX	

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
D3043	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(7) The laboratory must retain cytology slide preparations for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception). The laboratory must retain histopathology slides for at least 10 years from the date of examination. The laboratory must retain pathology specimen blocks for at least 2 years from the date of examination. The laboratory must preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen. This STANDARD is not met as evidenced by: Based on observation and interviews it was determined that Facility C (CLIA #45D0505053) failed to retain gynecologic cytology slide preparations for at least five years. Findings include: 1. During an observation of the slide storage room on November 27, 2018 at 8:20 AM, the Anatomic Pathology (AP) Laboratory Manager failed to identify for the Survey Team, the retention of any gynecologic cytology slide preparations prior to July 10, 2017. 2. During an interview on November 27, 2018 at 8: 20 AM, the AP Laboratory Manager stated, "you have all the slides we have. We do not have any more." 3. These findings were reviewed with and confirmed by the AP Laboratory Manager and Laboratory Director/Technical Supervisor A during survey overviews on November 27, 2018 at 4:15 PM and November 28, 2018 at 12:15 PM.
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, record review, observation and interviews it was determined that Facility C (CLIA #45D0505053) failed to follow written policies and procedures for the evaluation and comparison of two of six laboratory statistics, and failed to document two of six required statistics for 2016 and 2017 (refer to D5629); failed to ensure that two of two unsatisfactory cases were identified and reported as unsatisfactory for evaluation (refer to D5655); failed to establish written policies and procedures to ensure that corrected reports indicated the basis for the correction on the report (refer to D5659); failed to ensure that slides were available upon request (refer to D5663); and failed to ensure that six final gynecologic test reports indicated the name and address of the laboratory location where the test was performed (refer to D5805). 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.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of thirty-two laboratory policies and procedures, observation and interviews it was determined that Facility C (CLIA #45D0505053) failed to follow one written procedure. Cross refer to D3043 and D5473 Findings include: 1. The laboratory failed to follow the written procedure titled "Retention of Laboratory Records and Materials" which stated that gynecologic glass slides "will be retained for five years." 2. These findings were reviewed with and confirmed by the AP Laboratory Manager and Laboratory Director/Technical Supervisor A during survey overviews on November 27, 2018 at 4:15 PM and November 28, 2018 at 12:15 PM.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of thirty-two laboratory policies and procedures and interviews it was determined that Facility C (CLIA #45D0505053) failed to ensure that nineteen written procedures were approved, signed, and dated by the Laboratory Director prior to the start of the survey on November 26, 2018. Findings include: 1. The Laboratory Director failed to sign and date nineteen laboratory procedures. Procedures include: - GYNECOLOGIC CYTOLOGY RANDOM QC MINIMUM REQUIREMENT - GYNECOLOGICAL MONTHLY REPORTS - HISTOLOGY/CYTOLOGY SPECIMEN HANDLING GUIDE - RESCREEN OF PAP CASES WITH A HIGH PROBABILITY FOR DEVELOPING CERVICAL CANCER - SUBMITTING SPECIMENS TO THE CYTOLOGY LABORATORY - PATIENT IDENTIFICATION PROCEDURE - PROCESSING TEST IN QUESTION AND

	REJECTING SPECIMENS - ROUTINE HANDLING AND DISPOSAL OF INFECTIOUS MATERIALS - PAPANICOLAOU (PAP) STAIN PROCEDURE - CYTOTECHNOLOGIST PERFORMANCE ASSESSMENT - FIVE YEAR RETROSPECTIVE REVIEW - CYTOLOGY QUALITY ASSURANCE PROGRAM - CYTOLOGY STATISTICAL REPORTS - CYTOLOGY/HISTOLOGY CORRELATIONS FOR ABNORMAL PAP TEST - CYTOLOGY AND TISSUE CORRELATION - CYTOLOGY SCREENING PROCEDURE AND DIAGNOSTIC GUIDELINES - PAPANICOLAOU (PAP) SLIDE HIERARCHICAL REVIEW WORKFLOW - CRITERIA FOR PAP ADEQUACY AND ENDOCERVICAL COMPONENT - CYTOLOGY TRAINING AND COMPETENCY ASSESSMENT 2. During an interview on November 26, 2018 at 11:20 AM, the AP Laboratory Manager stated that the Laboratory Director was "in the process of signing the procedures" and confirmed that the Laboratory Director did not approve the procedures prior to the start of the survey. 3. These findings were reviewed with and confirmed by the AP Laboratory Manager and Laboratory Director/Technical Supervisor A during survey overviews on November 27, 2018 at 4:15 PM and November 28, 2018 at 12:15 PM.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory records and interviews it was determined that Facility C (CLIA #45D0505053) failed to test staining materials for intended reactivity to ensure predictable staining characteristics for three of three stain processes each day of use in 2017 and to the date of the survey in 2018. Findings include: 1. The Survey Team requested and the laboratory failed to provide Diff-Quick stain assessment records. a. The procedure titled "Diff-Quick Stain Procedure" stated that the laboratory would "review a minimum of one Diff-Quick stained slide per day for stain quality, and make note on the Staining Quality Control Check Sheet." b. The laboratory failed to document the staining characteristics of one of one Diff-Quick stain process from January 2017 to the date of the survey on the "Staining Quality Control Check Sheet." 2. The Survey Team requested and the laboratory failed to provide H&E stain assessment records. a. The procedure titled "Rapid H&E Stain Procedure" stated that the laboratory would "review a minimum of one Hematoxylin and Eosin (H&E) stained slide per day for stain quality, and make note on the Staining Quality Control Check Sheet." b. The laboratory failed to document the staining characteristics of two separate H&E stain processes from January 2017 to the date of the survey on the "Staining Quality Control Check Sheet." 3. During an interview on November 27, 2018 at 10:45 AM, the AP Laboratory Manager confirmed that there were no laboratory records to document the staining characteristics of the one Diff Quick and two H&E stain processes performed for each day of use in 2017 and to the date of the survey in 2018. 4. These findings were reviewed with and confirmed by the AP Laboratory Manager and Laboratory Director /Technical Supervisor A during survey overviews on November 27, 2018 at 4:15 PM and November 28, 2018 at 12:15 PM.

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 interviews it was determined that Facility C (CLIA #45D0505053) failed to follow written policies and procedures for the evaluation and comparison of two of six laboratory statistics, and failed to document two of six required annual statistics for 2016 and 2017. Findings include: 1. The laboratory failed to follow the procedure titled CYTOLOGY STATISTICAL REPORTS which stated: - "cytology department must document and evaluate statistics annually" - "Monthly reports are printed and collected as part of annual statistics." - "Annually record the sum of all monthly totals for each statistic." 2. The Survey Team requested and the laboratory failed to provide two required annual statistics. a. The number of gynecologic cytology cases examined, and b. The number of gynecologic cytology cases reported by diagnosis. 3. During an interview on November 26, 2018 at 1:30 PM, the AP Laboratory Manager confirmed that the laboratory statistics titled, "Specimen Count and Statistics" included negative gynecologic cases that were not reported at Facility C (CLIA #45D0505053). a. The statistics included cases reported at Facility A (CLIA# 45D1062976). 4. During an interview on November 26, 2018 at 1:30 PM, the AP Laboratory Manager explained that statistics for cases evaluated at Facility C (CLIA #45D0505053) for Facility E (CLIA# 45D0505003) were maintained at Facility E. The Laboratory Manager stated "they are getting them together to send." a. The AP Laboratory Manager confirmed that there was no compilation of statistics for all cases evaluated at Facility C (CLIA #45D0505053). 5. These findings were reviewed with and confirmed by the Laboratory Director/Technical Supervisor A during survey overviews on November 27, 2018 at 4:15 PM and November 28, 2018 at 12:15 PM.
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 written policies and procedures, gynecologic cytology slides and interviews it was determined that Facility C (CLIA #45D0505053) failed to follow

	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 two of two gynecologic cases from July 2017 through October 2018 as being "Unsatisfactory for Evaluation." Findings include: 1. The laboratory failed to follow the procedure titled, "Cytology Screening Procedure and Diagnostic Guidelines." a. The procedure stated to "Report all cases using the current Bethesda Terminology." 2. The laboratory failed to follow the procedure titled, "Criteria for Pap Adequacy." a. The procedure stated to use the "Recommendations of Bethesda 2001 for assessing Specimen Adequacy of Gynecological Cytology Samples" which states "a minimum limit of 5,000 well-visualized/preserved squamous cells" for liquid based Pap Test reporting. 3. The laboratory failed to identify and report two of two gynecologic cytology Pap Test cases from July 2017 through October 2018 as being "Unsatisfactory for Evaluation." Cases include: - XC17-27 - XS18-04 4. These findings were reviewed with and confirmed by the AP Laboratory Manager and Laboratory Director/Technical Supervisor A during survey overviews on November 27, 2018 at 4:15 PM and November 28, 2018 at 12:15 PM.
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 interviews it was determined that Facility C (CLIA #45D0505053) failed to establish written policies and procedures to ensure that corrected reports indicated the basis for the correction on the report. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's process to ensure that corrected reports indicated the basis for the correction. 2. During an interview on November 27, 2018 at 11:45 AM, the AP Laboratory Manager confirmed that the written procedures titled, "Pathology Reports" and "Cytopathology Reports" did not include the requirement to include the basis for the correction on a corrected report. 3. These findings were reviewed with and confirmed by the AP Laboratory Manager and Laboratory Director/Technical Supervisor A during survey overviews on November 27, 2018 at 4:15 PM and November 28, 2018 at 12:15 PM.
D5663	CYTOLOGY CFR(s): 493.1274(f)(4) (f) Record and slide retention. (f)(4) All slides must be retrievable upon request. This STANDARD is not met as evidenced by: Based on interview and laboratory record review it was determined that Facility C (CLIA #45D0505053) failed to retrieve seventy-nine of seventy-nine gynecologic cytology slide preparations from January 2014 to July 10, 2017. Cross refer to D3043 Findings include: 1. The Survey Team requested and the laboratory failed to provide seventy-nine gynecologic cytology slide preparations prior to July 10, 2017. a. The laboratory failed to provide slide preparations for nineteen cases from January to July 2017. Cases #XC17-01 to XC17-19 b. The laboratory failed to provide slide

	preparations for thirty-two cases from January to December 2016. Cases #XC16-01 to XC16-32 c. The laboratory failed to provide slide preparations for nineteen cases from January to December 2015. Cases #XC15-01 to XC15-19 d. The laboratory failed to provide slide preparations for nine cases from January to December 2014. Cases #XC14-01 to XC14-09 2. During an interview on November 26, 2018 at 11:05, the AP Laboratory Manager stated "we are looking for the slides but they were moved and we can't find them." 3. The AP Laboratory Manager provided laboratory records titled "SMC Cytology Gynecological" of the number of cases each year but failed to provide the slide preparations for the cases.
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: Based on review of laboratory records and interviews it was determined that Facility C (CLIA #45D0505053) failed to ensure that six of sixty-eight final test reports from January 2017 to October 2018 indicated the name and address of the location where the test was performed. Findings include: 1. The Survey Team reviewed sixty-eight final gynecologic test reports. Six of the sixty-eight final test reports did not indicate the name and address of Facility A (CLIA #45D1062976), where the test was performed. Case numbers on the reports include: - XC17-09 - XC17-22 - XC17-32 - XC17-33 - XC18-06 - XC18-26 2. During an interview on November 26, 2018 at 3:50 PM, the AP Laboratory Manager confirmed the final test reports did not indicate the name and address of Facility A (CLIA #45D1062976). 3. These findings were reviewed with and confirmed by the AP Laboratory Manager and Laboratory Director /Technical Supervisor A during survey overviews on November 27, 2018 at 4:15 PM and November 28, 2018 at 12:15 PM.
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, record review and interviews it was determined that Facility C (CLIA #45D0505053) 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). 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 and interviews it was determined that the Laboratory Director failed to be responsible for the overall operation and administration of Facility C (CLIA #45D0505053), to include assuring compliance with the applicable regulations and ensuring that all the duties of the Laboratory Director were performed. Cross refer to D3043, D5407, D5473, D5663 and D5805
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: Based on the review of thirty-eight (38) routine negative gynecologic cases from July 2017 to October 2018, and confirmation by the Laboratory Director/Technical Supervisor A on November 28, 2018, it was determined that the Technical Supervisor failed to verify the accuracy of three gynecologic tests. 1. XC17-21 07/28/17 SurePath Pap Test (SPPT) LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion; Reactive SURVEY TEAM DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion LABORATORY DIRECTOR/TECHNICAL SUPERVISOR DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion 2. XC17-27 08/14/17 ThinPrep Pap Test (TPPT) LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion; Reactive SURVEY TEAM DIAGNOSIS:c Unsatisfactory for Evaluation: scant cellularity LABORATORY DIRECTOR/TECHNICAL SUPERVISOR A DIAGNOSIS: Unsatisfactory 3. XC18-04 02/19/18 SurePath Pap Test (SPPT) LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion; Reactive SURVEY TEAM DIAGNOSIS: Unsatisfactory for Evaluation: scant cellularity LABORATORY DIRECTOR/TECHNICAL SUPERVISOR A DIAGNOSIS: Unsatisfactory
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