Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0504523	11/15/2018
Name of Provider or Supplier	**Street Address, City, State**	
Dell Seton Medical Center At The University	1500 Red River Street Laboratory-L5012, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on the lack of laboratory records and interviews it was determined that Facility B (CLIA #45D0504523) failed to enroll in an approved cytology proficiency testing (PT) program for gynecologic examination. The cumulative effect of this systemic problem resulted in the laboratory's failure to meet certification requirements to accurately and reliably evaluate patients' gynecologic cytology specimen slides for 2016, 2017 and to the date of the survey in 2018.
D2001	ENROLLMENT CFR(s): 493.801(a)(1)(2)(i) The laboratory must-- (1) Notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart. (2)(i) Designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by CMS;

	This STANDARD is not met as evidenced by: Based on the lack of cytology PT enrollment records and interviews it was determined that Facility B (CLIA #45D0504523) failed to enroll in an approved cytology PT program for 2016, 2017 and to the date of the survey in 2018. Findings include: 1. The Survey Team requested and the Facility B (CLIA #45D0504523) failed to provide records of enrollment in an approved cytology PT program for 2016, 2017 and to the date of the survey in 2018. 2. During an interview on November 13, 2018 at 4:09 PM, the Anatomic Pathology Manager stated that Facility B (CLIA #45D0504523) was not enrolled in an approved cytology PT program for 2016, 2017 and to the date of the survey in 2018. The Anatomic Pathology Manager further stated that Facility B (CLIA #45D0504523) Technical Supervisors participated in the PT program at Facility E (CLIA #45D0505003). 3. During an interview on November 14, 2018 at 3:00 PM, the Laboratory Director/Technical Supervisor confirmed these findings.
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 B (CLIA #45D0504523) failed to establish written policies and procedures for the collection of Becton Dickinson (BD) SurePath and Hologic ThinPrep gynecologic specimens (refer to D5311); failed to establish written procedures for two laboratory processes (refer to D5403); failed to ensure that 16 written procedures were approved, signed, and dated by the Laboratory Director prior to the start of the survey on November 13, 2018 (refer to D5407); failed to follow written policies and procedures for the evaluation and comparison of six of six laboratory statistics, and failed to document six of six required annual statistics for 2016 and 2017 (refer to D5629); failed to follow written policies and procedures to ensure that unsatisfactory gynecologic cytology slide preparations were identified and reported as unsatisfactory and failed to identify and report one gynecologic cytology case from January 2018 as being "Unsatisfactory for Evaluation" (refer to D5655); and failed to establish written policies and procedures to ensure that corrected reports indicated the basis for the correction on the report (refer to D5659). 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.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

	This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interviews it was determined that Facility B (CLIA #45D0504523) failed to establish written policies and procedures for the collection of BD SurePath and Hologic ThinPrep gynecologic specimens. Findings include: 1. The Survey Team requested and Facility B (CLIA #45D0504523) failed to provide written policies and procedures for the collection of BD SurePath gynecologic specimens. 2. The Survey Team requested and Facility B (CLIA #45D0504523) failed to provide written policies and procedures for the collection of Hologic ThinPrep gynecologic specimens. 3. During an interview on November 14, 2018 at 2:15 PM, the Anatomic Pathology Manager stated that there were no policies and procedures to describe how clinicians were to collect BD SurePath and Hologic ThinPrep gynecologic specimens. 4. During an interview on November 14, 2018 at 3:00 PM, the Laboratory Director/Technical Supervisor confirmed these findings.
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 23 laboratory policies and procedures and interviews it was determined that Facility B (CLIA #45D0504523) failed to establish written procedures for two laboratory processes. Findings include: 1. The Survey Team requested and Facility B (CLIA #45D0504523) failed to provide written policies and procedures to describe how many slides and tissue cassettes were to be prepared during nongynecologic specimen accessioning. a. During an interview on November 15, 2018 at 9:40 AM, Staff A explained the following: -Facility B (CLIA #45D0504523) labeled the slides and tissue cassettes to be used during nongynecologic specimen processing. -Facility A (CLIA #45D1062976) processed the nongynecologic specimens for Facility B (CLIA #45D0504523). 2. The Survey Team requested and Facility B (CLIA #45D0504523) failed to provide written policies and procedures to describe how the Technical Supervisors reported results into the laboratory information system (LIS). 3. During an interview on November 13, 2018 at 3:15 PM, the Anatomic Pathology Manager confirmed there were no policies

	and procedures for reporting results into the LIS. 4. During interviews on November 14, 2018 at 3:00 PM and November 15, 2018 at 1:00 PM, the Laboratory Director /Technical Supervisor confirmed these findings.
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 23 written laboratory procedures and interviews it was determined that Facility B (CLIA #45D0504523) failed to ensure that 16 written procedures were approved, signed, and dated by the Laboratory Director prior to the start of the survey on November 13, 2018. Findings include: 1. The Laboratory Director failed to sign and date 16 laboratory procedures. Procedures include: - EXTERNAL PROFICIENCY TESTING FOR GYNECOLOGIC CYTOLOGY - SUBMITTING SPECIMENS TO THE CYTOLOGY LABORATORY - PATIENT IDENTIFICATION PROCEDURE - PROCESSING TEST IN QUESTION AND REJECTING SPECIMENS - ROUTINE HANDLING AND DISPOSAL OF INFECTIOUS MATERIALS - CYTOLOGY RAPID H&E STAIN PROCEDURE - 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 - TRANSPORTING MATERIALS USING MEDSPEED - CYTOLOGY TRAINING AND COMPETENCY ASSESSMENT 2. During an interview on November 13, 2018 at 3: 15 PM, the Anatomic Pathology Manager confirmed that the Laboratory Director did not approve the procedures prior to the start of the survey. 3. During an interview on November 14, 2018 at 3:00 PM, the Laboratory Director/Technical Supervisor confirmed these findings.
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 B (CLIA #45D0504523) failed to follow written policies and procedures for the evaluation and comparison of six of six laboratory statistics, and failed to document six of six required annual statistics for 2016 and 2017. Findings include: 1. Facility B (CLIA #45D0504523) failed to follow the procedure titled CYTOLOGY STATISTICAL REPORTS which stated: Facility A's (CLIA #45D1062976) "cytology department will prepare an annual statistical summary report." "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 Facility B (CLIA #45D0504523) failed to provide the laboratory's six required annual statistics. 3. During an interview on November 13, 2018 at 9:45 AM, the Anatomic Pathology Manager stated that Facility A (CLIA #45D1062976) compiled statistics that combined cases reported at Facility A (CLIA #45D1062976) and Facility B (CLIA #45D0504523). The Anatomic Pathology Manager further stated that there were no annual statistics for cases reported only at Facility B (CLIA #45D0504523). 4. During an interview on November 14, 2018 at 3: 00 PM, the Laboratory Director/Technical Supervisor confirmed there were no annual statistics for cases reported at Facility B (CLIA #45D0504523).
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 and gynecologic cytology slides it was determined that Facility B (CLIA #45D0504523) failed to follow written policies and procedures to ensure that unsatisfactory gynecologic cytology slide preparations were identified and reported as unsatisfactory. Facility B (CLIA #45D0504523) failed to identify and report one gynecologic cytology case from January 2018 as being "Unsatisfactory for Evaluation." Findings include: 1. Facility B (CLIA #45D0504523) failed to follow the procedure titled CRITERIA FOR PAP ADEQUACY AND ENDOCERVICAL COMPONENT which stated: "Set a minimum limit of 5,000 well-visualized/preserved squamous cells for LBP (liquid-based preparation) with the following caveats:" 2. Facility B (CLIA #45D0504523) failed to identify and report one gynecologic cytology case as being "Unsatisfactory for Evaluation." Case includes: - UC17-728 3. These findings were confirmed by the Laboratory Director/Technical Supervisor on November 26, 2018.
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, laboratory records and

	interviews it was determined that Facility B (CLIA #45D0504523) failed to establish written policies and procedures to ensure that corrected reports indicated the basis for the correction on the report. One of one corrected reports from 2018 did not indicate the basis for the correction. Findings include: 1. The Survey Team requested and Facility B (CLIA #45D0504523) 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. The Survey Team reviewed one corrected report. The corrected report failed to state the basis for the correction. Report includes: - UC18-48 3. During an interview on November 13, 2018 at 3:15 PM, the Anatomic Pathology Manager stated that there were no procedures detailing Facility B (CLIA #45D0504523) process for correcting reports. 4. During an interview on November 14, 2018 at 3:00 PM, the Laboratory Director/Technical Supervisor confirmed these findings.
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, laboratory records and interviews it was determined that Facility B (CLIA #45D0504523) 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, D5407, D5629, D5655 and D5659
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 B (CLIA #45D0504523) 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 the laboratory enrolled in an annual gynecologic cytology PT event (refer to D6088); and failed to ensure that quality assessment programs were established (refer to D6094). 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 B (CLIA #45D0504523), to include assuring compliance with the applicable regulations and ensuring that all the duties of the Laboratory Director were performed. Cross refer to D5311, D5403, D5407, D5629, D5655 and D5659
D6088	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4) The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on the lack of cytology PT enrollment records and interviews it was determined that the Laboratory Director failed to ensure that Facility B (CLIA #45D0504523) enrolled in an annual gynecologic cytology PT event for 2016, 2017 and prior to the date of the survey in 2018. Cross refer to D2001
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, review of laboratory records and interviews it was determined that the Laboratory Director failed to ensure that quality assessment programs were established to assure the quality of laboratory services and identify failures in quality as they occur. Cross refer to D5791
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 review of 161 non-negative gynecologic cases/166 slides from November 2017 through November 2018 and confirmation by the Technical Supervisor on November 26, 2018 it was determined that the Technical Supervisor failed to verify the accuracy of three gynecologic tests. 1. UC17-728 1/4/18 SurePath Pap Test (SPPT) LABORATORY DIAGNOSIS: Atypical Glandular Cells of Undetermined Significance SURVEY TEAM DIAGNOSIS: Unsatisfactory for Interpretation - Insufficient Cellularity TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory for Interpretation 2. UC17-631 11/21/17 SPPT LABORATORY DIAGNOSIS: Atypical Glandular Cells of Undetermined Significance SURVEY TEAM DIAGNOSIS: Negative for Intraepithelial Lesion of Malignancy TECHNICAL SUPERVISOR DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy 3. UC18-380 5/16/18 SPPT LABORATORY DIAGNOSIS: Atypical Squamous Cells of Undetermined Significance Rare Atypical Glandular Cells Also Present SURVEY TEAM DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy TECHNICAL SUPERVISOR DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy
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