

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D2074005	<b>(X3) Date Survey Completed</b> 07/19/2018
<b>Name of Provider or Supplier</b> Resolute Hospital Company, Llc DbA Resolute	<b>Street Address, City, State</b> 555 Creekside Crossing, New Braunfels, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5032</b>	<p>CYTOLOGY CFR(s): 493.1221</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on record review and surveyor interviews the laboratory failed to establish written procedures to document and evaluate one of three annual statistics for non-gynecologic cases (refer to D5629); failed to establish written procedures for workload limits, reassessing workload limits, not exceeding workload limits, prorating workload limits and maintaining workload hours and slide numbers (refer to D5633, D5637, D5639, D5641, D5645). 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.</p>
<b>D5629</b>	<p>CYTOLOGY CFR(s): 493.1274(c)(5)</p> <p>(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</p>

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, lack of laboratory records, and interview it was determined that the laboratory failed to establish a written policy or procedure for an annual statistical evaluation of the number of non-gynecologic cytology cases reported by diagnosis in 2016, 2017 and to the date of the survey in 2018. Findings include: 1. The Survey Team requested, and the laboratory failed to provide, a written policy or procedure for an annual statistical laboratory evaluation of the number of non-gynecologic cytology cases reported by diagnosis, to include unsatisfactory. 2. The Survey Team requested, and the laboratory failed to provide, documentation for the number of non-gynecologic cytology cases reported by diagnosis in 2016, 2017 and to the date of the survey in 2018. 3. During an interview on 07/17/2018 at 10:30 AM, the Laboratory Director/Technical Supervisor #1 confirmed these findings.

**D5633**

CYTOLOGY

CFR(s): 493.1274(d)(1)

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1) The technical supervisor establishes a maximum workload limit for each individual who performs primary screening.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, lack of laboratory records, and interview it was determined that the laboratory failed to establish written policies and procedures to ensure that a maximum workload limit was established for three of three Technical Supervisors when performing primary evaluation of cytology specimen slide preparations in 2016, 2017 and to the date of the survey in 2018. Findings include: 1. The Survey Team requested, and the laboratory failed to provide, written policies and procedures to ensure that a maximum workload limit was established by the Laboratory Director/Technical Supervisor #1 for the three of three Technical Supervisors. 2. The Survey Team requested, and the laboratory failed to provide, documentation of an established workload limit for three of three Technical Supervisors for 2016, 2017 and to the date of the survey in 2018. Technical Supervisors include: Laboratory Director/Technical Supervisor #1 Technical Supervisor #2 Technical Supervisor #3 3. During an interview on 07/17/2018 at 10:30 AM, the Laboratory Director/Technical Supervisor #1 confirmed these findings.

**D5637**

CYTOLOGY

CFR(s): 493.1274(d)(1)(ii)

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1)(ii) Each individual's workload limit is reassessed at least every 6 months and adjusted when necessary.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, lack of laboratory records and interview it was determined that the laboratory failed to establish written policies and

procedures to ensure that the workload limits of three of three Technical Supervisors were reassessed at least every six months and adjusted when necessary in 2016, 2017 and to the date of the survey in 2018. Findings include: 1. The Survey Team requested, and the laboratory failed to provide, written policies and procedures to ensure that a workload limit for three of three Technical Supervisors would be reassessed at least every 6 months and adjusted when necessary. 2. The Survey Team requested, and the laboratory failed to provide, documentation of reassessed workload limits for the three of three Technical Supervisors for 2016, 2017 and to the date of the survey in 2018. Technical Supervisors include: Laboratory Director/Technical Supervisor #1 Technical Supervisor #2 Technical Supervisor #3 3. During an interview on 07/17/2018 at 10:30 AM, the Laboratory Director/Technical Supervisor #1 confirmed these findings.

**D5639**

CYTOLOGY  
CFR(s): 493.1274(d)(2)(i)

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the Following: (d)(2) The maximum number of slides examined by an individual in each 24-hour period does not exceed 100 slides (one patient specimen per slide; gynecologic, nongynecologic, or both) irrespective of the site or laboratory. This limit represents an absolute maximum number of slides and must not be employed as an individual's performance target. In addition-- (d)(2)(i) The maximum number of 100 slides is examined in no less than an 8-hour workday;

This STANDARD is not met as evidenced by:  
Based on review of laboratory policies and procedures, lack of laboratory records, and interview it was determined that the laboratory failed to establish written policies and procedures to ensure the maximum number of slides examined would not exceed 100 slides in each 24-hour period for the three of three Technical Supervisors in 2016, 2017 and to the date of the survey in 2018. Findings include: 1. The Survey Team requested, and the laboratory failed to provide, written policies and procedures to describe the laboratory's process for ensuring that the maximum number of slides to be examined by the three of three Technical Supervisors would not exceed 100 slides in each 24-hour period. Technical Supervisors include: Laboratory Director/Technical Supervisor #1 Technical Supervisor #2 Technical Supervisor #3 2. The Survey Team requested, and the laboratory failed to provide, documentation to ensure the maximum number of slides examined in each 24-hour period was not exceeded for the three of three Technical Supervisors in 2016, 2017 and to the date of the survey in 2018. 3. During an interview on 07/17/2018 at 10:30 AM, the Laboratory Director/Technical Supervisor #1 confirmed these findings.

**D5641**

CYTOLOGY  
CFR(s): 493.1274(d)(2)(ii)

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(2)(ii) For the purposes of establishing workload limits for individuals examining slides in less than an 8-hour workday (includes full-time employees with duties other than slide examination and part-time employees), a period of 8 hours is used to prorate the number of slides that may be examined. The formula-- Number of hours examining slides X 100 / 8 is used to determine maximum slide volume to be examined;

This STANDARD is not met as evidenced by:  
 Based on review of laboratory policies and procedures, lack of documentation, and interview it was determined that the laboratory failed to establish written policies and procedures to ensure that the workload limit for the three of three Technical Supervisors who examined slides during 2016, 2017 and to the date of the survey in 2018, would be prorated using a period of eight hours to determine the number of slides that may be examined. Findings include: 1. The Survey Team requested, and the laboratory failed to provide, written policies and procedures to determine how to prorate the workload limit for the three of three Technical Supervisors, when examining slides in less than an 8-hour workday or on activities other than primary examinations of cytology slides. 2. The Survey Team requested, and the laboratory failed to provide, documentation of prorated workload limits for the three of three Technical Supervisors. Technical Supervisors include: Laboratory Director/Technical Supervisor #1 Technical Supervisor #2 Technical Supervisor #3 3. During an interview on 07/17/2018 at 10:30 AM, the Laboratory Director/Technical Supervisor #1 confirmed these findings.

**D5645**

**CYTOLOGY**  
 CFR(s): 493.1274(d)(3)

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(3) The laboratory must maintain records of the total number of slides examined by each individual during each 24-hour period and the number of hours spent examining slides in the 24-hour period irrespective of the site or laboratory.

This STANDARD is not met as evidenced by:  
 Based on review of laboratory policies and procedures, lack of laboratory records, and interview it was determined that the laboratory failed to establish written policies and procedures for maintenance of workload records. The laboratory failed to maintain records of the number of hours devoted to examining slides for three of three Technical Supervisors in 2016, 2017 and to the date of the survey in 2018. Findings include: 1. The Survey Team requested, and the laboratory failed to provide, written policies and procedures to ensure that the laboratory would maintain records of the total number of slides examined during each 24-hour period and the number of hours devoted to examining slides during each 24-hour period for the three of three Technical Supervisors. 2. The Survey Team requested, and the laboratory failed to provide, documentation of the number of hours devoted to examining slides during each 24 hour period for three of three Technical Supervisors in 2016, 2017 and to the date of the survey in 2018. Technical Supervisors include: Laboratory Director /Technical Supervisor #1 Technical Supervisor #2 Technical Supervisor #3 3. During an interview on 07/17/2018 at 10:30 AM, the Laboratory Director/Technical Supervisor #1 confirmed these findings.

**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, specimen slides and their corresponding test reports, 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 and oversight 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 policies and procedures and laboratory records 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 D6130 and D6133

**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 the review of specimen slides and their corresponding test reports it was determined that the Technical Supervisor failed to verify the accuracy of one non-gynecologic test report (refer to D6115). The cumulative effect of this practice resulted in the Technical Supervisor's inability to provide technical supervision requirements of 493.1451 of this subpart. Based on the review of written policies and procedures, record review, glass slides and corresponding test reports, and surveyor interviews it was determined that the Laboratory Director/Technical Supervisor #1 failed to verify the accuracy of one non-gynecologic test report (refer to D6115); failed to ensure that workload limits were established and reassessed (refer to D6130) and failed to ensure that the time spent examining slides was documented (refer to

	<p>D6133). The cumulative effect of these practices resulted in the Technical Supervisor's inability to provide technical supervision requirements of 493.1451 of this subpart.</p>
<p><b>D6115</b></p>	<p><b>TECHNICAL SUPERVISOR RESPONSIBILITIES</b>  CFR(s): 493.1451(b)(2)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:  Based on the review of 114 negative non-gynecologic cases (563 slides) from 2016, 2017 and 2018 it was determined that the Laboratory Director/Technical Supervisor #1 failed to verify the accuracy of one non-gynecologic test. 1. RC-17-0085 8/28/17 Ascites Fluid LABORATORY DIAGNOSIS: Reactive Mesothelial cells and sparse inflammation. No Malignant Cells Identified. SURVEY TEAM PATHOLOGIST DIAGNOSIS CONFIRMED ON 07/19/2018: Metastatic Lobular Carcinoma Based on the review of 114 negative non-gynecologic cases (563 slides) from 2016, 2017 and 2018 it was determined that the Laboratory Director/Technical Supervisor #1 failed to verify the accuracy of one non-gynecologic test. 1. RC-17-0085 8/28/17 Ascites Fluid LABORATORY DIAGNOSIS: Reactive Mesothelial cells and sparse inflammation. No Malignant Cells Identified. SURVEY TEAM PATHOLOGIST DIAGNOSIS CONFIRMED ON 07/19/2018: Metastatic Lobular Carcinoma Based on the review of 114 negative non-gynecologic cases (563 slides) from 2016, 2017 and 2018 it was determined that the Laboratory Director/Technical Supervisor #1 failed to verify the accuracy of one non-gynecologic test. 1. RC-17-0085 8/28/17 Ascites Fluid LABORATORY DIAGNOSIS: Reactive Mesothelial cells and sparse inflammation. No Malignant Cells Identified. SURVEY TEAM PATHOLOGIST DIAGNOSIS CONFIRMED ON 07/19/2018: Metastatic Lobular Carcinoma</p>
<p><b>D6130</b></p>	<p><b>TECHNICAL SUPERVISOR RESPONSIBILITIES</b>  CFR(s): 493.1451(c)(2)(3)</p> <p>(c) In cytology, the technical supervisor or the individual qualified under 493.1449(k) (2)-- (c)(2) Must establish the workload limit for each individual examining slides and (c)(3) Must reassess the workload limit for each individual examining slides at least every 6 months and adjust as necessary.</p> <p>This STANDARD is not met as evidenced by:  Based on the review of laboratory policies and procedures, laboratory records and interview it was determined that the Laboratory Director/Technical Supervisor #1 failed to establish workload limits and failed to reassess the workload limits at least every six months for three of three Technical Supervisors in 2016, 2017 and to the date of the survey in 2018. Cross Refer to D5633 and D5637</p>
<p><b>D6133</b></p>	<p><b>TECHNICAL SUPERVISOR RESPONSIBILITIES</b>  CFR(s): 493.1451(c)(6)</p> <p>In cytology, the technical supervisor or the individual qualified under 439.1449(k)(2), if responsible for screening cytology slide preparations, must document the number of</p>

cytology slides screened in 24 hours and the number of hours devoted during each 24-hour period to screening cytology slides.

This STANDARD is not met as evidenced by:  
Based on the review of laboratory policies and procedures, laboratory records and interview it was determined that three of three Technical Supervisors failed to document the time spent examining slides in each 24-hour period in 2016, 2017 and to the date of the survey in 2018. Cross refer to D5645

**D9999**

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