

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0139386	(X3) Date Survey Completed 11/26/2018
Name of Provider or Supplier Jack I Hershman Md	Street Address, City, State 777 N Broadway Suite 309, Sleepy Hollow, NY	
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
D5629	<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 negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms.</p> <p>This STANDARD is not met as evidenced by: Based on a lack of cytology procedures and confirmed by the laboratory director in an interview on November 26, 2018, at approximately 10:40 am, the laboratory failed to establish policies and procedures for a program to evaluate and compare the laboratory statistics annually to detect errors in the performance of cytological examinations and reporting results. The procedure must include: 1. Cytology cases examined; 2. Specimens processed by specimen type; 3. Patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation); THIS IS A RECITATION FROM THE SURVEY OF NOVEMBER 10, 2016</p>
D5633	<p>CYTOLOGY CFR(s): 493.1274(d)(1)</p>

(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 a lack of urine cytology procedures and confirmed by the laboratory director in an interview on November 26, 2018, at approximately 10:40 am, the laboratory failed to establish written policies and procedures to ensure that a maximum workload limit was set for the person who performed primary screening for non-gynecologic specimens. THIS IS A RECITATION FROM THE SURVEY OF NOVEMBER 10, 2016

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 a lack of urine cytology procedures and confirmed by the laboratory director in an interview on November 26, 2018, at approximately 10:40 am, the laboratory failed to establish and follow written policies and procedures to ensure that the workload limit for the individual who performs primary screening is reassessed at least every six months and adjusted when necessary. THIS IS A RECITATION FROM THE SURVEY OF NOVEMBER 10, 2016

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 a lack of urine cytology procedures and confirmed by the director in an interview on November 26, 2018, at approximately 10:40 am, the laboratory failed to have written policies and procedures to ensure that the maximum number of slides examined by an individual in 24-hours does not exceed 100 slides. THIS IS A RECITATION FROM THE SURVEY OF NOVEMBER 10, 2016

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 a lack of urine cytology procedures and confirmed by the laboratory director in an interview on November 26, 2018, at approximately 10:40 am, the laboratory failed to establish written policies and procedures for workload limits for the individual examining slides in less than an 8-hour workday. THIS IS A RECITATION FROM THE SURVEY OF NOVEMBER 10, 2016

D5647

CYTOLOGY
CFR(s): 493.1274(d)(4)

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(4) Records are available to document the workload limit for each individual.

This STANDARD is not met as evidenced by:
Based on a lack of urine cytology procedure and confirmed by the laboratory director in an interview on November 26, 2018, at approximately 10:40 am, the laboratory failed to establish written policies and procedures to ensure that records are maintained and available to document the workload for the individual who performs primary screening of non-gynecologic cytology slides. THIS IS A RECITATION FROM THE SURVEY OF NOVEMBER 10, 2016

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 a lack of urine cytology procedures and confirmed by the laboratory director in an interview on November 26, 2018, at approximately 10:40 am, the laboratory failed to establish and follow written policies and procedures to ensure that unsatisfactory specimens or slide preparations are identified and reported as unsatisfactory. THIS IS A RECITATION FROM THE SURVEY OF NOVEMBER 10, 2016

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 a surveyors review of the laboratory's records and interview with the laboratory director, the laboratory director failed to fulfill his/her responsibilities and provide overall management of the laboratory and assure compliance with all CLIA regulations and standards. Refer to D6094

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 surveyor's review of the quality assessment (QA) program and an interview with the laboratory director/testing person, the laboratory director failed to ensure that the laboratory's QA program was maintained as part of the laboratory's overall quality systems program. Refer to: D5629, D5633, D5637, D5639, D5641, D5647, and D5655 THIS IS A RECITATION FROM THE SURVEY OF NOVEMBER 10, 2016