

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0671449	(X3) Date Survey Completed 04/13/2022
Name of Provider or Supplier David Lieu Md DbA Fine Needle	Street Address, City, State 320 S Garfield Ave Ste 278, Alhambra, CA	
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
D5032	<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 review of laboratory policies and procedures, laboratory records and interviews it was determined that the laboratory failed to establish written policies and procedures to assess the competency of the Laboratory Director/Technical Supervisor (refer to D5209); failed to establish written policies and procedures for the evaluation and comparison of three of three annual nongynecologic statistics (refer to D5629); failed to establish written policies and procedures for the establishment and reassessment of individual workload limits (refer to D5633 and D5637); failed to establish written policies and procedures to document the workload limit (refer to D5647); and failed to establish written policies and procedures to maintain records of the total number of slides examined and the total number of hours spent examining slides (refer to D5645).</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of laboratory records and</p>

interview it was determined that the laboratory failed to establish written policies and procedures to assess the competency of the Laboratory Director/Technical Supervisor. The laboratory failed to assess the competency of the Laboratory Director/Technical Supervisor in 2020, 2021 and to the date of the survey in 2022. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to assess the competency of the Laboratory Director/Technical Supervisor. 2. The Survey Team requested and the laboratory failed to provide documentation of competency assessments for the Laboratory Director/Technical Supervisor in 2020, 2021 and to the date of the survey in 2022. 3. During an interview on April 11, 2022 at 10:30 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor.

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, lack of laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures for the evaluation and comparison of three of three nongynecologic statistics. The laboratory failed to document three of three required annual nongynecologic statistics for 2020 and 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for the evaluation and comparison of three of three nongynecologic statistics. Statistics include: -Number of cytology cases examined -Number of specimens processed by specimen type -Number of patient cases reported by diagnosis, including the number reported as unsatisfactory 2. The Survey Team requested and the laboratory failed to provide records of the three required annual nongynecologic statistics for 2020 and 2021. 3. During an interview on April 11, 2022 at 10:30 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor.

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 and interview it was determined that the laboratory failed to establish written policies and procedures to ensure individual maximum workload limits were established for the Laboratory Director/Technical Supervisor. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure the Laboratory Director/Technical Supervisor established individual maximum workload limits for the Laboratory Director/Technical Supervisor who performed primary nongynecologic slides examinations. 2. During an interview on April 11, 2022 at 10:30 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor.

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 and interview it was determined that the laboratory failed to establish written policies and procedures to ensure workload limits were reassessed and adjusted, when necessary, at least every six months for the Laboratory Director/Technical Supervisor. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail how the Laboratory Director/Technical Supervisor's workload limits would be reassessed at least every six months and adjusted when necessary. 2. During an interview on April 11, 2022 at 10:30 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor.

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 laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures to ensure that the workload limits for the Laboratory Director/Technical Supervisor would be prorated when examining slides in less than eight hours. The laboratory failed to ensure that the number of slides examined by the Laboratory Director/Technical Supervisor was prorated in 2020, 2021 and to the date of the survey in 2022. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to prorate the workload limits for the Laboratory Director/Technical Supervisor when examining slides in less than an eight-hour day. 2. The Survey Team requested and the laboratory failed to provide records

of prorated workload limits for the Laboratory Director/Technical Supervisor who performed nongynecologic slide examinations in 2020, 2021 and to the date of the survey in 2022. 3. During an interview on April 11, 2022 at 10:30 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor.

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 and interview it was determined that the laboratory failed to establish written policies and procedures to ensure that the laboratory maintained records of the total number of nongynecologic slides examined and the total number of hours the Laboratory Director/Technical Supervisor spent examining nongynecologic slides per 24-hour period. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that the laboratory maintained records of the total number of slides examined and total number of hours the Laboratory Director/Technical Supervisor spent examining slides per 24-hour period. 2. During an interview on April 11, 2022 at 10:30 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor.

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 review of laboratory policies and procedures, laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures to ensure records were available to document the workload limits for the Laboratory Director/Technical Supervisor who performed primary nongynecologic slide examinations. The laboratory also failed to provide records of individual workload limits for the Laboratory Director/Technical Supervisor, who provided primary examinations of nongynecologic slides in 2020, 2021 and to the date of the survey in 2022. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure records were available to document the workload limits for the Laboratory Director/Technical Supervisor who performed primary nongynecologic slides examinations. 2. The Survey Team requested and the laboratory failed to provide records of individual workload limits for the Laboratory Director/Technical Supervisor who performed primary nongynecologic slides examinations in 2020, 2021 and to the date of the survey in 2022. 3. During an interview on April 11, 2022 at 10:30 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor.

<p>D5659</p>	<p>CYTOLOGY CFR(s): 493.1274(e)(6)</p> <p>(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.</p> <p>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 corrected test reports indicated the basis for the correction on the test report. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure corrected test reports indicated the basis for the correction on the test report. 2. During an interview on April 11, 2022 at 10:30 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor.</p>
<p>D6130</p>	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES 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 review of written policies and procedures, lack of laboratory records and interview it was determined that the Laboratory Director/Technical Supervisor failed to establish individual workload limits and failed to reassess workload limits at least every six months for the Laboratory Director/Technical Supervisor who performed primary nongynecologic slide examinations in 2020, 2021 and to the date of the survey in 2022. Cross refer to D5633 and D5637. Findings include: 1. The Survey Team requested and the Laboratory Director/Technical Supervisor failed to provide documentation that the Laboratory Director/Technical Supervisor established maximum workload limits for the Laboratory Director/Technical Supervisor who performed primary nongynecologic slide examinations. 2. The Survey Team requested and the Laboratory Director/Technical Supervisor failed to provide documentation that the Laboratory Director/Technical Supervisor reassessed workload limits at least every six months for the Laboratory Director/Technical Supervisor who performed primary nongynecologic slide examinations. 3. During an interview on April 11, 2022 at 10:30 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor.</p>
<p>D6133</p>	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES 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 cytology slides screened in 24 hours and the number of hours devoted during each 24-hour period to screening cytology slides.</p>

This STANDARD is not met as evidenced by:

A. Based on review of laboratory policies and procedure, laboratory records and interview it was determined that the Laboratory Director/Technical Supervisor performing primary nongynecologic slide examinations failed to document the number of slides examined during each 24-hour period in 2020, 2021 and for January and February in 2022. Cross refer to D5645. Findings include: 1. The Survey Team requested and the Laboratory Director/Technical Supervisor failed to provide records of the total number of nongynecologic slides examined during each 24-hour period in 2020, 2021 and January and February in 2022. 2. During an interview on April 11, 2022 at 10:30 AM, the Laboratory Director/Technical Supervisor provided a record titled CYTOLOGY SLIDES 2022 which included workload records for the Laboratory Director/Technical Supervisor for March and April 2022. When asked if there were additional records to provide the number of slides examined on each nongynecologic case for 2020, 2021 and January and February in 2022, the Laboratory Director/Technical Supervisor replied, "no."

B. Based on review of laboratory policies and procedure, laboratory records and interview it was determined that the Laboratory Director/Technical Supervisor performing primary nongynecologic slide examinations failed to document the number of hours devoted to examining slides during each 24-hour period in 2020, 2021 and to the date of the survey in 2022. Findings include: 1. The Survey Team requested and the Laboratory Director/Technical Supervisor failed to provide records of the total number of hours the Laboratory Director/Technical Supervisor spent examining nongynecologic slides during each 24-hour period in 2020, 2021 and to the date of the survey in 2022. 2. During an interview on April 11, 2022 at 10:30 AM, when asked if there were records to provide the time spent examining the nongynecologic slides for 2020, 2021 and to the date of the survey in 2022, the Laboratory Director/Technical Supervisor replied, "no."

D9999

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