

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0966774	(X3) Date Survey Completed 03/02/2021
Name of Provider or Supplier Westchester Dermatology	Street Address, City, State 8930 S Sepulveda Blvd Ste 104, Los Angeles, 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
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>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 general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on review of ten (10) random patient histopathology slide and report sampling from 03/1/2019 to 11/04/2020, review of quality control documents, written laboratory policies and procedures and an interview with the laboratory director, it was determined that the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the general laboratory systems. The finding included: 1. On 03/02/2020 (survey date) no documentation could be retrieved to show that the laboratory had a written policy for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified. This correction process must involve identification and resolution of the problem, and development of policies that will prevent recurrence. Policies for preventing problems that have been identified must be written as well as communicated to the laboratory personnel, other staff, and clients, When (preanalytic, analytic and postanalytic) issues were found the laboratory relied only on verbal communication and no documentation could be retrieved to show ongoing mechanism, assessment and corrective actions being monitored and resolved. 2. The laboratory director confirmed on 03/02/2021 at 11:30 a. m. that the laboratory did in have a written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the general laboratory systems. 3. The annual testing declaration 03/02/2021 estimated 300 histopathology biopsies and 20 DTM (Dermatophyte Test Medium) test results reported. .</p>

D5479

CONTROL PROCEDURES

CFR(s): 493.1256(e)(5)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the ACU-DTM (Dermatophyte Test Medium) manufacturer's product insert, lack of quality control records, patients reports, and interview with the laboratory director, it was determined that for the period reviewed from 03/18/2019 to 11/04/2020 for ten (10) randomly selected patients, the laboratory failed to follow the manufacturer's instructions and perform external quality control each new lot received. The findings included: 1. The ACU-DTM manufacturer's insert, under QUALITY CONTROL, stated, "CLIA requires the end user to perform a minimum of a positive and negative control on each new lot or batch purchased. Maintain a log of the QC labels with lot numbers in each box. Retain log for inspection purposes." The laboratory could not retrieve documentation (03/02/2021) to show that the laboratory had performed external controls per manufacturer's guideline for the period cited. 2. On 03/02/2021, 11:30 a. m. (survey date), the laboratory director affirmed that the laboratory had not been following manufacturer's guidelines. 3. Based on the laboratory testing declaration submitted on 03/02/2021 twenty (20) patients' DTM tests were result and reported annually.