

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2005333	(X3) Date Survey Completed 03/24/2022
Name of Provider or Supplier Huntington Dermatology & Cosmetic Associate Pc	Street Address, City, State 200 W Carver Street Suite 2, Huntington, 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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on lack of calibration records for both the room temperature and humidity thermometers, the laboratory failed to maintain the certification for the thermometers. The technical consultant confirmed on an interview on 3/24/2022 about 10:45am.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the reagents stored in the laboratory and interview with the technical consultant, the laboratory failed to review reagent, control & calibration materials for expired dates. Findings: 1.The laboratory was observed to contained 7</p>

expired reagent vials. a. One bottle of CytoSeal 60 Lot#500174 Exp Date July 2021 b. Six bottles of Tissue-Teck O.C.T Compound Lot#9377-00 Exp Date 03/21/2021 2. Confirmed in interview with technical consultant on 3/24/2022 at 10:30am

D6021

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on lack of certification of calibration of thermometer used for room temperature /humidity and expired reagents, it was determined that the laboratory director failed to implement and maintain the laboratory's quality assessment program. Refer D5413 and D5417