

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0373931	(X3) Date Survey Completed 07/16/2019
Name of Provider or Supplier Pinnacle Dermatology Flint- Hill Rd	Street Address, City, State 2256 West Hill Road, Flint, MI	
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
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with the Quality Assurance Manager, the laboratory failed to establish and follow a maintenance protocol for timers for 2 (July 2017 to July 2019) of 2 years. Findings include: 1. An observation by the surveyor on 7/16/19 at 8:55 am exposed a timer (VWR, SN 90960855) with a calibration expiration date of 6/9/11. 2. A record review of laboratory procedures revealed a lack of documentation of a procedure to calibrate timers. When requested on 7/16/19 at 8:55 am, the Quality Assurance Manager was unable to provide a procedure 3. An interview on 7/16/19 at 8:55 am with the Quality Assurance Manager confirmed a function check procedure had not been established for the timer with an expired calibration date.</p>
D5477	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or</p>

produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Quality Assurance Manager, the laboratory failed to perform and document media checks for the "Acuderm, INC Dermatophyte Test Medium (DTM)" with each new batch, lot, or shipment for the ability to support growth of yeast for 2 (July 2017 to July 2019) of 2 years reviewed. Findings include: 1. A record review of "Protocol for Performing Quality Control on DTM" exposed a section stating, "One new DTM culture will be inoculated with a positive control culture to determine if it supports growth. A second DTM culture will be labeled as above and kept for a negative control. These two cultures will be observed daily for growth for two weeks by the Medical Director." 2. When requested by the surveyor on 7/16/19 at 9:42 am, the Quality Assurance Manager did not provide records of performing yeast controls on DTM. 3. An interview on 7/16/19 at 9:42 am with the Quality Assurance Manager confirmed media checks for the ability to support growth of yeast had not been performed.

D5805

TEST REPORT

CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Quality Assurance Manager, the laboratory failed to include the name and address of the laboratory location where testing was performed for 4 (Patients #2, #14, #15, and #16) of 16 patient charts reviewed. Findings include: 1. A record review of Mohs Map reports revealed a lack of name and address of the laboratory location where testing was performed for the following patients reviewed: a. Patient #2 performed on 2/13/19 b. Patient #14 performed on 1/2/19 c. Patient #15 performed on 10/4/18 d. Patient #16 performed on 4/19/17 2. An interview on 7/16/19 at 10:42 am with the Quality Assurance Manager confirmed the name and address of the laboratory location where testing was performed was missing from the Mohs Maps for the above patients reviewed. This is a repeat deficiency from the 1/14/15 survey.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether

supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

. Based on review of the various job descriptions and interview with the Quality Assurance Manager, the laboratory did not have job descriptions, duties and responsibilities for the Laboratory Director, Clinical Consultant, Technical Consultant, Technical Supervisor, General Supervisor, and Testing Personnel for 2 (July 2017 to July 2019) of 2 years. Findings include 1. When requested on 7/16/19 at approximately 12:00 pm, the Laboratory Director, Clinical Consultant, Technical Consultant, Technical Supervisor, General Supervisor, and Testing Personnel job descriptions were not available. 2. An interview on 7/16/19 at approximately 12:00 pm with the Quality Assurance Manager confirmed the laboratory did not have job descriptions available to the Laboratory Director, Clinical Consultant, Technical Consultant, Technical Supervisor, General Supervisor, and Testing Personnel available.