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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 34D0698872 | (X3) Date Survey Completed 07/01/2019 |
| Name of Provider or Supplier Davie Dermatology, Pa | Street Address, City, State 108 Dornach Way, Advance, NC | |
| 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 |
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| 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 proficiency testing (PT) records, review of the laboratory's PT procedure and quality assessment plan, and interview with staff on 7/1/2019, the laboratory failed to establish policies and procedures for how the laboratory identifies PT discrepancies and what corrective action is taken when results do not agree. Findings: Review of the laboratory's PT records revealed each provider performs split sample testing for Dermatophyte Test Medium (DTM), potassium hydroxide (KOH), Ectoparasites, and Tzanck twice a year. Review of 2018 records revealed 3 of 6 DTM results did not agree for testing personnel (TP)#1, TP#2, and TP#3, and 2 of 4 Tzanck results did not agree for TP#1 and TP#2. There was no documentation of corrective action for the discrepancies. Review of the PT procedure and the quality assessment plan revealed the laboratory did not have a defined process to monitor, assess, and correct problems when PT results do not agree. During interview at approximately 12pm, the medical assistant confirmed there was no corrective action documented for the discrepancies. She stated the providers should review and discuss when the results do not agree.</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</p> |

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 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 review of the laboratory's procedures, review of QC (quality control) records, and interview with staff on 7/1/19 the laboratory failed to ensure that each lot of DTM (Dermatophyte Test Medium) had acceptable sterility and QC checks before the media was put into use. Findings: The laboratory's procedure, "Fungal Culture/ Dermatophyte Test Medium (DTM)" states under QUALITY CONTROL of DTM "Each lot and shipment of DTM must be tested for sterility, selectivity and/or inhibition of nondermatophytes, and the ability to support growth of dermatophytes with the appropriate biochemical response before the media can be used to test patients. Record each shipment of DTM on the DTM QC log. Positive and negative controls are performed with each lot/shipment....Positive QC-HealthLink Quikswab Quality Controls Culture Devices Trichophyton Mentagrophytes. Negative QC-Healthlink Quikswab Escherichia coli." The laboratory's "Quality Control procedure for Dermatophyte Test Medium" states, "Three DTM bottle are used(1)Plain, (2) T. Mentagrophytes, (3) E.coli. Lot number of DTM bottles, date incubated, and type of organism are logged. They are incubated to day 5. They are read at day 5, day 6, and day 7 by Provider and nurse." 1. Review of the DTM QC logs revealed the laboratory received 2 lot numbers of DTM in May 2019. Sterility and QC checks were documented for only one lot number-1907913. Lot number 1904408 did not have sterility and QC checks performed, but was available for use. During interview at approximately 12pm, the medical assistant confirmed she missed the 2nd lot number when the shipment was received. 2. Review of the DTM QC logs also revealed new lots of media were tested with positive and negative controls in January 2018 and August 2018, but the positive control result was recorded as negative at day 5, day 6, and day 7 for the following lot numbers: a. Lot number 1723313, plated 1/19/18 b. Lot number 1819314, plated 8/30/18. During interview at approximately 12pm, the medical assistant confirmed testing personnel #2 read the positive control results as negative at day 5, day 6, and day 7. She confirmed the laboratory director had not reviewed the DTM quality control records to ensure results were acceptable prior to testing patients.

D5785

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(3)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's procedures and review of 2017, 2018 and 2019 temperature logs on 7/1/19, the laboratory failed to document corrective action when the room and refrigerator temperature were outside acceptable limits. Findings: The Laboratory's procedure, "Fungal Culture/Dermatophyte Test Medium (DTM)" states under TEST PROCEDURE and REPORTING to "...Incubate at 22-30 degrees Celsius." The laboratory's "Quality Control procedure for Dermatophyte Test

Medium" states, "... Daily documentation is done for medium storage. Refrigerator temperatures should maintain range 2-8 degrees C. Daily documentation that laboratory incubation area maintains temperature within 22-30 degrees C (68-76 degrees Fahrenheit) is recorded." The laboratory's "General Maintenance" temperature log states "Draw a red circle around any reading outside the acceptable range and record corrective action below." Review of temperature logs revealed the "Nurses station" room temperature (the DTM incubation area) was below the acceptable range of 22-30 degrees Celsius with no corrective action documented for the following: 1. 1 of 20 days in December 2017; 2. 2 of 21 days in July 2018; 3. 7 of 23 days in August 2018; 4. 2 of 20 days in September 2018; 5. 2 of 20 days in November 2018. Review of temperature logs also revealed the refrigerator temperatures were documented outside the acceptable range of 2-8 degrees Celsius with no corrective action for the following: 1. 17 of 22 days in October 2017; 2. 23 of 23 days in August 2018; 3. 9 of 22 days in May 2019. This deficiency was previously cited on 6/3/2015 and 7/12/2017.

D6025

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(7)

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)(7) Ensure that patient test results are reported only when the system is functioning properly.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's procedures, review of QC (Quality Control) records, review of temperature logs, and interview with staff on 7/1/19, the laboratory director failed to ensure acceptable QC and proper storage for the Dermatophyte Test Medium prior to use for patient testing. (See D5477, D5785).