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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 32D0694243 | (X3) Date Survey Completed 08/06/2020 |
| Name of Provider or Supplier Michael R Pincus Dpm Llc | Street Address, City, State 2207 A Golf Course Rd Se, Rio Rancho, NM | |
| 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 |
|---------------------------|---|
| D0000 | The following deficiencies were cited during a recertification survey completed on 08/06/2020 for the federal requirements of 42 CFR Part 493 for Laboratories. 43577 |
| D1001 | <p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on observation and review of manufacturer's instructions, the laboratory failed to follow manufacturer instructions and store reagents at the correct temperature and discard when expired. The laboratory used the expired control for 12 (P3-P14) of 15 (P3-P17) patients tested 07/27/2019-08/06/2020. Findings are: The laboratory failed to store the glucometer control at room temperature and discard the expired control.</p> <p>A. During an inspection of laboratory supplies and reagents on 08/06/2020 at 01:15 pm, an expired bottle or vial of glucometer control solution was observed in the laboratory refrigerator. 1. The label indicated the vial must be discarded 3 months after opening. The laboratory indicated on the label "Discard date 7/26/19." One Touch Ultra Control Solution Lot 9A2BP80 2. Review of patient test records (P3-P14) revealed the following patients were tested using the expired control: P3 tested 08/07/2019 P4 tested 09/20/2019 P5 tested 10/11/2019 P6 tested 11/15/2019 P7 tested 12/20/2019 P8 tested 01/31/2020 P9 tested 02/13/2020 P10 tested 02/24/2020 P11 tested 03/06/2020 P12 tested 03/20/2020 P13 tested 05/27/2020 P14 tested 06/16/2020 B. Review of the manufacturer's instructions for the One Touch Ultra Control Solution indicated "Close the vial tightly immediately after use and store at room temperature below 86 (degrees) Fahrenheit. Do not refrigerate." C. During interview on 08/06</p> |

/2020 at 02:20 pm, the medical assistant confirmed this was the control solution used by the laboratory for quality control testing. She also stated the control solution was used for each patient. 43577

D5411

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(a)

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:

Based on review and observation of patient test vials of Dermatophyte Test Media (DTM), and the review of manufacturer instructions and patient records, the laboratory failed to follow the manufacturer's instructions for incubation time of the DTM. A total of 77 DTM cultures were performed 06/01/2020 - 08/06/2020. Of the 77 patients, 24 test records were reviewed. For 3(DTM #1, DTM #21 and DTM #23) of 24 patients reviewed, the DTM cultures were read beyond 14 days. Findings are: A. Review of the manufacturer's instructions for the Remel DTM media indicated "Incubate in ambient air 15-30 C for up to 14 days." B. Observation of 12 patient tests (DTM) in progress on 08/06/2020 at 01:15 pm revealed 1 patient vial (DTM#1) inoculated or set up on 07/23/2020, 15 days ago, that had not been read and reported by the laboratory. C. Review of 23 of 77 patients test reports from June 2020 - July 2020 revealed 2 additional patients (DTM #21 & DTM#23) read beyond 14 days. DTM #21, collected on 06/25/2020. The culture test report indicated a read date of 07/16/2020, 21 days after inoculation. DTM #23, collected on 06/30/2020. The culture test report indicated a read date of 07/20/2020, 20 days after inoculation.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

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.

This STANDARD is not met as evidenced by:

43577 Based on review of a letter from the laboratory, observation and staff interview, the lab failed to discard all expired tubes from existing lab collection supplies/tray. Findings are: A. During observation on 08/06/2020 at 2:10 pm, the following collection supplies were found to be expired: Eight (8), 4 mL (milliliter), Serum Clot Activator tubes Lot B17103K8 expired on 02-09-2019, found on collection supply tray Twenty-two (22) Red top tubes, same lot and expiration date, were found as part of a 50 piece package located in their cabinet. B. During interview on 08/06/2020 at 2:10 pm, the Medical Assistant was asked if they had more red top tubes in house. She stated that they no longer used the Red top tubes for drawing patient samples. The Medical Assistant further stated no expired tubes were used for collecting patient samples. C. Review of a letter from the laboratory faxed on 08/12/2020 at 11:47 am indicated the laboratory stopped using the Red top tubes more than 2 years ago.

D5477

CONTROL PROCEDURES

CFR(s): 493.1256(e)(4)(g)

(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 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 the review of 2018-2020 quality control records and interview with the Laboratory Director, the laboratory failed to document the physical characteristics and acceptability for the DTM (Dermatophyte Test Medium) for each new shipment or lot received. Findings are: A. Review of the 2018-2020 quality control logs and Certificates of Quality revealed no indication of the received date or of the visual inspection or check of the physical characteristics and acceptability of the DTM media. B. During interview on 08/06/2020 at 2:10 pm, the Laboratory Director verified that he had not been recording his visual inspection of the media anywhere. When asked "Where do you document or record any problems with the media?," he stated he did not know he had to do that. 43577

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(a) 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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

43577 Based on the review of manufacturer's instructions, patient test records, 2018-2020 quality control records, and interviews with laboratory staff, the laboratory failed to establish and follow a written policy for Quality Assessment of DTM (Dermatophyte Test Medium) storage and handling of laboratory supplies. Findings are: A. The laboratory failed to follow the manufacturer's instructions for incubation time of the DTM. A total of 77 DTM cultures were performed 06/01/2020 - 08/06/2020. Of the 77 patients, 24 test records were reviewed. For 3(DTM #1, DTM #21 and DTM #23) of 24 patients reviewed, the DTM cultures were read beyond 14 days. See D5411 1. The laboratory failed to have the manufacturer instructions/package insert for Remel Media that was placed in use on 10/01/2019 (Lot#862592). 2. During interview on 08/06/2020 at 2:20 pm, both the Laboratory Director and Office Manager stated that they did not know the manufacturer of the DTM had changed and obtained a copy of the current instructions from the website. B. The laboratory failed to document the physical characteristics and acceptability for the DTM for each new shipment or lot received. See D5477 C. The lab failed to discard all expired tubes from existing lab collection supplies/tray. See D5417