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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 34D0243280 | (X3) Date Survey Completed 09/06/2018 |
| Name of Provider or Supplier Pinnacle Dermatology Dbq Qualderm Partners | Street Address, City, State 10512 Park Road, Suite 113, Charlotte, 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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| 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 2018 Temperature Monitor Log records review on 9/6/18 and staff interview, the laboratory failed to monitor the laboratory's refrigerator temperature readings to ensure that it maintained the acceptable temperature range for the storage of Dermatophyte Test Media (DTM). Findings: 1. The ACU-DTM (Dermatophyte Test Medium) Package Insert (PI) list the storage conditions as, "...For maximum shelf life, Acu-DTM should be stored at 2 Degrees to 8 Degrees C (Celsius) (36 Degree F - 46 Degrees F). DO NOT FREEZE...". 2. The laboratory refrigerator Temperature Monitor Log lists the acceptable temperature ranges as 2 Degrees to 8 Degrees C. 3. The review of the laboratory's Temperature Monitor Log during the months of May 2018 to September 2018 revealed: a. May 2018, there were 6 of 9 temperature readings were above 8 Degrees C. They are: i. 5/14/18 (9 Degrees C); ii. 5/17/18 (9 Degrees C); iii. 5/21/18 (9 Degrees C); iv. 5/22/18 (9 Degrees C); v. 5/24/18 (9 Degrees C); and vi. 5/31/18 (10 Degrees C). b. June 2018, there were 5 of 8 temperature readings were above 8 Degrees C. They are: i. 6/4/18 (10 Degrees C); ii. 6/7/18 (10 Degrees C); iii. 6/18/18 (10 Degrees C); iv. 6/20/18 (10 Degrees C); and, v. 6/25/18 (9 Degrees). c. July 2018, there were 7 of 8 temperature readings were above 8 Degrees C. They are: i. 7/2/18 (10 Degrees C); ii. 7/9/18 (10 Degrees C); iii. 7/12/18 (10 Degrees C); iv. 7/16/18 (10 Degrees C); v. 7/19/18 (9 Degrees C); vi. 7/23/18 (9</p> |

Degrees C); and, vii. 7/26/18 (9 Degrees C). d. August 2018, there were 8 of 9 temperature readings were above 8 Degrees C. They are: i. 8/2/18 (10 Degrees C); ii. 8/6/18 (10 Degrees C); iii. 8/9/18 (10 Degrees C); iv. 8/16/18 (9 Degrees C); v. 8/20/18 (9 Degrees C); vi. 8/23/18 (9 Degrees C); vii. 8/27/18 (10 Degrees C); and, viii. 8/30/18 (10 Degrees C). e. September 2018, 1 of 1 temperature reading was above 8 Degrees C. It is: i. 9/6/18 (10 Degrees C). 4. Interview with the testing personnel and office manager at 11:45 a.m. revealed that they were aware of the acceptable refrigerator temperature range for the proper storage of ACU-DTM, but they did not know what to do if the temperature readings were not within that range.