

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 02D0931068	(X3) Date Survey Completed 06/08/2021
Name of Provider or Supplier Fortson Dermatology & Skin Care Center	Street Address, City, State 2401 E 42nd Avenue, Suite 301, Anchorage, AK	
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 review of refrigerator temperature logs and interview with the medical assistant, the laboratory failed to document corrective actions when the front refrigerator temperature was out of the acceptable range for Dermatophyte Test Medium (DTM) storage for sixty two days in February 2020 through April 2020. Findings include: 1. The DTM package insert indicates that the media should be stored at 36 F to 46 F, and not be frozen. 2. The temperature was below 36 F for 62 days and below 32 F (below freezing) for forty eight days during February through April 2020. 3. Ten patients were tested using the DTM media during February through April 2020. 4. The medical assistant confirmed these findings on 6/8/2021 at 2:15 pm.</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>

This STANDARD is not met as evidenced by:
Based on surveyor observation of potassium hydroxide (KOH) reagent vials and interview with the medical assistant, the laboratory failed to ensure testing personnel did not use expired reagents in four of four KOH reagents. Findings include: 1. Observation on 6/8/2021 at 2 pm, showed four KOH reagents in use: a. 1 vial lot number: 1629916, expired 10/25/2017 b. 2 vials lot number: 1634718, expired 12/12/2017 c. 1 vial lot number: 1811506, expired 4/25/2019 2. The laboratory performs approximately 105 KOH preparations annually. 3. The medical assistant confirmed these findings on 6/8/2021 at 2:15 pm.

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 lack of documentation and interview with the laboratory director, the laboratory failed to check each lot or shipment of Dermatophyte Test Medium (DTM) for selectivity, inhibition, and the ability to support the growth of dermatophytes and other microorganisms. Findings include: 1. No quality control documentation was found during the survey. 2. The laboratory was using ACU-DTM, lot # D1382-0920 expiration date 9/23/2022. 3. The laboratory performs approximately 50 fungal cultures using DTM annually. 4. The laboratory director confirmed these findings 6/8/2021 at 2:00 pm.