

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 02D0931068	(X3) Date Survey Completed 08/29/2025
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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on record review and an interview with the Medical Assistant (MA2), the laboratory failed to enroll in proficiency testing (PT) in the subspecialty of mycology after the implementation of the new CLIA Proficiency Testing Final Rule (42 CFR Part 493 493.2 and 493.801 through 493.959) on January 1, 2025 requiring PT enrollment when testing for the presence or absence of fungi in culture. Findings include: 1. A request was made to review proficiency testing records for mycology testing using the Dermatophyte Test Media and no records could be provided. 2. An interview with MA2 8/29/25 at 12:00 PM confirmed that the laboratory was not enrolled in an approved PT program in 2025. 3. The laboratory reports performing approximately 100 fungal cultures annually.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p>

This STANDARD is not met as evidenced by:
 Based on a review of the Dermatophyte and KOH Proficiency Protocol, record review, and an interview with the Medical Assistant (MA2), the laboratory failed to verify the accuracy of fungal cultures in 2024, Potassium Hydroxide (KOH) preparations and dermatopathology slides at least twice annually in 2024 and 2025. Findings include: 1. A review of the Dermatology and KOH Proficiency Protocol states the laboratory uses peer review to monitor the accuracy of KOH skin scrapings, and Dermatophyte fungal culture testing twice a year and is documented in the office "green log book". 2. A request was made to review the documentation of the peer reviews for KOH preparations, fungal cultures, and dermatopathology slides, but documentation could not be provided. 3. An interview with MA2 on 8/29/25 at 12:00 PM confirmed these findings. 4. The laboratory reports 50 KOH skin scrapings, 100 fungal cultures, and 275 dermatopathology slides performed annually.

D5417

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

(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:
 Based on observations, record review, manufacturer's package insert, and an interview with the Medical Assistant (MA1), the laboratory failed to ensure the Hardy Dermatophyte Test Media (DTM) agar slants used for patient fungal cultures were inoculated before the manufacturer's expiration date listed on the vial in four of five patient cultures observed. Findings include: 1. Observation on 8/29/25 at 11:00 AM of patient DTM cultures in progress revealed that four of the five samples were inoculated after DTM lot # 650643 expired on 8/4/2025; patient samples were set up on 8/6, 8/7, and 8/8/2025. 2. A review of the Hardy Instructions for Use for DTM revealed the "product may be used and tested up to the expiration date on the product label". 3. An interview with MA2 on 8/29/25 at 12:00 PM confirmed these findings. 4. The laboratory reports performing approximately 100 fungal cultures annually.

D5477

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

(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.

This STANDARD is not met as evidenced by:
 Based on review of procedure manuals, quality control (QC) records, and an interview with the Medical Assistant (MA2), the laboratory failed to check each lot number of DTM agar slants for its ability to support dermatophyte growth, inhibit normal flora and skin contaminants, and produce the media color change to indicate the presence /absence of dermatophytes, and to document these findings for each lot number of

commercially prepared DTM in one (1) of seven (7) lots of DTM received in 2024-2025. Findings include: 1. A review of the procedure for DTM Fungal Cultures states "Quality Control is performed for each new lot number of DTM media". 2. A review of DTM QC logs for 2024 and 2025 revealed that lot number DTM 65064, in use at the time of the survey, did not have QC documented. 3. An interview with MA2 on 8/29/25 at 12:00 PM confirmed the findings. 4. The laboratory reports performing approximately 100 fungal cultures annually.

D5481

CONTROL PROCEDURES
CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of the Dermatophyte Test Media (DTM) Quality Control (QC) procedure, QC records, and an interview with the Medical Assistant (MA2), the laboratory failed to document observations of the control microorganisms including the growth and color characteristics of the QC microorganisms, and the color changes of the DTM agar slant for 21 of 24 QC observations for DTM lots received in 2024 and 2025. Findings include: 1. A review of the laboratory Instructions for DTM QC Kit revealed the expected results include documentation of growth/no growth, a description of the growth, and media color changes to indicate the presence/absence of dermatophytes. 2. A review of seven (7) DTM QC logs from 2024 and 2025 showed that the description of QC microorganism growth and media color changes were not recorded for 21 of 24 control microorganisms. 3. An interview with MA2 on 8/29/25 at 12:00 PM confirmed these findings. 4. The laboratory reports performing approximately 100 fungal cultures annually.