

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2244741	(X3) Date Survey Completed 02/10/2026
Name of Provider or Supplier Forefront Dermatology, S C	Street Address, City, State 535 S Burdick Street Suite 256, Kalamazoo, MI	
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
D3013	<p>FACILITIES CFR(s): 493.1101(e)</p> <p>Records and, as applicable, slides, blocks, and tissues must be maintained and stored under conditions that ensure proper preservation.</p> <p>This STANDARD is not met as evidenced by: . Based on observation and interview with the laboratory director, the laboratory failed to maintain histopathology tissue slides to ensure proper preservation for five (patients 1, 2, 6, 7, and 8) of nine cases reviewed. Findings include: 1. A review of nine histopathology cases performed between 3/18/24 and 11/3/25 showed five cases with significant bubbling between the tissue and the coverslip on slides from the following patients: a. Patient #1 had testing performed on 1/27/25. b. Patient #2 had testing performed on 3/31/25. c. Patient #6 had testing performed on 3/18/24. d. Patient #7 had testing performed on 6/24/24. e. Patient #8 had testing performed on 10/14/24. 2. An interview on 2/10/26 at 11:38 am with the laboratory director confirmed the presence of bubbles on patient histopathology slides.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the team lead, the laboratory failed to establish a competency assessment policy to assess histopathology testing personnel for two (February 2024 to February 2026) of two years reviewed. Findings include: 1.</p>

A review of the competency assessment records revealed a lack of documentation for testing personnel #1, performing high complexity histopathology testing, between February 2024 and February 2026. 2. A review of the laboratory's procedures revealed the only competency assessment policy was in the "PPM" binder used for the laboratory's mycology and parasitology testing. 3. An interview on 2/10/26 at 10:49 am with the team lead confirmed a competency assessment policy for histopathology testing personnel was not established and revealed the personnel competency assessment policy in the "PPM" binder is only used with the laboratory's mycology and parasitology testing.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(c)(1)

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.

This STANDARD is not met as evidenced by:
. Based on record review and interview with testing personnel #2, the laboratory failed to verify the accuracy of its mycology and parasitology testing for two (February 2024 to February 2026) of two years reviewed. Findings include: 1. A review of the laboratory's "Ectoparasite/Wet Mount Examination" procedure revealed a section titled "Accuracy" stating, "Verification of the accuracy of the ectoparasite prep is completed with each Provider Performed Microscopy (PPM). Each physician and mid-level provider uses clinical correlation, along with collection and reading each test. Initial competency is assessed using an internal pictorial quiz. Twice yearly, quality assurance via peer review will be completed and maintained in Quality Control Logbook [sic]." 2. A review of the laboratory's "KOH Examination and QC" procedure revealed a section titled "Accuracy stating, "Verification of the accuracy of the KOH prep is completed with each Provider Performed in Microscopy (PPM). Each physician and mid-level provider uses clinical correlation, along with collecting and reading each test. Provide shall maintain KOH quality assurance (peer review) done bi-annually. The Proficiency testing will be done bi-annually with CAP, WSLH ACMS or other accredited organization, or split sampling (quiz) done annually." 3. The surveyor requested the laboratory's proficiency testing events for its Potassium Hydroxide (KOH) preparation testing on 2/10/26 at 10:51 am and it was not made available. 4. A review of the laboratory's quality control logbook revealed a lack of documentation supporting peer review performed twice annually in 2024 and 2025. 5. An interview on 2/10/26 at 11:00 am with testing personnel #2 confirmed the verification of accuracy testing was not documented.

D5433

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(b)(1)

(b)(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section.

This STANDARD is not met as evidenced by:
. Based on record review and interview with the team lead, the laboratory failed to perform and document cyrostat monthly maintenance in accordance with its protocol

for two (February 2024 to February 2026) of two years reviewed. Findings include: 1. A review of the laboratory's "Quality Control Policies and Documentation" policy revealed a section titled "M-721-E-ii Cryostat" stating, "Monthly: Interior is cleaned out as done daily and remove all shavings from top chamber. The blade holder, trays and metal side pieces are removed. All pieces wiped with gauze and 100% alcohol and sat on counter to dry 24 hours. All shavings are removed from deeper section of cryostat. All surfaces inside cryostat is wiped with gauze and 100% alcohol." 2. A review of the laboratory's "Cryostat Maintenance & Temperature Log" from February 2024 to February 2026 revealed a lack of documentation of any monthly maintenance performed. 3. An interview on 2/10/26 at 11:45 am with the team lead confirmed the above findings.

D5473

CONTROL PROCEDURES
CFR(s): 493.1256(e)(2)(g)

(e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate.

This STANDARD is not met as evidenced by:
. Based on record review and interview with the team lead, the laboratory failed to test hematoxylin and eosin stains for intended reactivity for one (12/23/2024) of nine histopathology testing dates reviewed. Findings include: 1. A review of the laboratory's hematoxylin and eosin stain quality assessments for nine patient testing dates revealed a lack of documentation for testing performed on 12/23/2024. 2. A review of the laboratory's patient testing log on 12/23/24 revealed a total of seven patients received testing using hematoxylin and eosin stain. 3. An interview on 2/10/26 at 12:04 pm with the team lead confirmed hematoxylin and eosin stain quality was not documented on 12/23/24.