

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0948745	(X3) Date Survey Completed 06/22/2022
Name of Provider or Supplier West Michigan Dermatology	Street Address, City, State 3290 N Wellness Drive Bldg D Suite #240, Holland, 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
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 Medical Assistant Manager, the laboratory failed to establish policies to assess competency for its technical consultants and technical supervisors for 2 (Technical Consultant #1/Technical Supervisor and Technical Consultant #2) of 2 technical consultants and technical supervisors listed on Form CMS-209. Findings include: 1. A review of the laboratory's competency assessments on 6/22/22 revealed a lack of competency assessments for personnel filling the technical consultant and technical supervisor roles: a. Technical Consultant #1, also serving as the Technical Supervisor. b. Technical Consultant #2. 2. The surveyor requested the competency assessment documentation for Technical Supervisor and Technical Consultant #2 on 6/22/22 at 12:40 pm and it was not made available. 3. An interview on 6/22/22 at 12:40 pm with the Medical Assistant Manager confirmed the Technical Consultant and Technical Supervisor competency assessment documentation was not available.</p>
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the</p>

overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:

. Based on record review and interviews, the laboratory failed to meet applicable analytic system requirements and correct identified problems. Findings include: 1. The laboratory failed to establish procedures for its histopathology testing. Refer to D5401. 2. The laboratory failed to perform media control procedures for its Dermatophyte Test Media (DTM). Refer to D5477.

D5401

PROCEDURE MANUAL

CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Medical Assistant Manager and Practice Administrator, the laboratory failed to establish procedures for its histopathology testing for 14 (April 2021 to June 2022) of 14 months reviewed. Findings include: 1. A review of the laboratory's procedure manual on 6/22/22 revealed a section titled "Procedure Manual" stating "Written procedures for the performance of all analytical methods used by the laboratory shall be maintained in a test procedure manual(s). Written procedures shall be available to testing personnel during the performance of their duties to act as a reference for the tests they perform." 2. The surveyor requested the laboratory's histopathology procedure on 6/22/22 at 12:55 pm and it was not made available. 3. An interview on 6/22/22 at 1:55 pm with the Medical Assistant Manager and the Practice Administrator confirmed the laboratory did not have a histopathology testing procedure available.

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:

. Based on observation, record review, and interview with the Medical Assistant Manager, the laboratory failed to ensure the tissue marking dyes used in histopathology testing had not exceed their expiration dates for 2 (red and yellow) of 3 tissue marking dyes in use. Findings include: 1. The surveyor observed the laboratory's tissue marking dyes on the laboratory counter on 6/22/22 at 11:59 am. Two of the dyes had the following expiration dates: a. Cancer Diagnostics Inc, Yellow, Lot number 9199, expiration date 7/31/21. b. Cancer Diagnostics Inc, Red, Lot number 9203, expiration date 7/31/21. 2. A review of the laboratory's procedure manual revealed a section titled "Test Systems, Equipment, Instruments, Reagents, Materials, and Supplies" stating, "Reagents, solutions, culture media, control

materials, calibration materials and other supplies shall not be used when they have exceeded their expiration date, have deteriorated or are found to be of sub-standard quality." 3. An interview on 6/22/22 at 11:59 am with the Medical Assistant Manager confirmed the tissue marking dyes in use had exceeded the expiration dates.

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 record review and interviews, the laboratory failed to perform media control procedures for its Dermatophyte Test Media (DTM) for 2 (D1425-0621 and D1338-0819) of 2 lots of media reviewed. Findings include: 1. A review of the laboratory's "MOHS LABORATORY TEST REQUISITIONS AND REPORT LOG-SUPPLY LIST" revealed two lots of DTM had been in use by the laboratory: a. Four boxes of DTM lot number D133-0819 with the expiration date of 8/2021 were received in the laboratory on 10/15/19. b. DTM lot number D1425-0621 with the expiration date of 6/29/23 was received on 8/13/21. 2. A review of the laboratory's photocopied "Laboratory Tests Log for DTM, Parasites, KOH or Tzanck" on 6/22/22 revealed a lack of a documentation for sterility control, positive dermatophyte growth control, positive yeast growth control, and an inhibition of growth control for lot number D1425-0621. It revealed a lack of sterility control and positive yeast growth control documentation for lot number D133-0819. 3. An interview on 6/22/22 at 1:22 pm with the Medical Assistant Manager revealed the "Laboratory Tests Log for DTM, Parasites, KOH or Tzanck" photocopied log noting the positive and inhibition of growth control results for lot number D133-0819 came from a separate laboratory. The laboratory received media and documentation of the media control procedures from a separate laboratory and had not performed media control procedures. 4. A review of the laboratory's procedure manual revealed a section titled, "Control Procedures" on 6/22/22 stating, "Before or concurrent with initial use the laboratory must: (a) check each batch of media for sterility if sterility is required for testing; (b) 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 (c) document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer." 5. A review of the laboratory's "Laboratory Test Log for DTM, Parasites, KOH or Tzanck" on 6/22/22 revealed 44 patients had received testing with DTM from the lot number D133-0819 from 3/12/20 to 9/7/21 and 30 patients had received testing from the lot number D1425-0621 from 8/31/21 to 6/21/22. 6. An interview on 6/22/22 at 1:55 pm with the Medical Assistant Manager and the Practice Administrator confirmed the laboratory had not performed media control procedures for the DTM lots listed above prior to testing patients.