

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0651428	(X3) Date Survey Completed 01/25/2023
Name of Provider or Supplier M Health Fairview	Street Address, City, State 909 Fulton St Se Room 3384 Mail Code 2121ch, Minneapolis, MN	
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
D5519	<p>MYCOLOGY CFR(s): 493.1263(b)(c)</p> <p>(b)For antifungal susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antifungal agent(s) before, or concurrent with, initial use, using an appropriate control organism(s). (b)(1) The laboratory must establish limits for acceptable control results. (b)(2) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(3) The results for the control organism(s) must be within established limits before reporting patient results. (c) The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory staff, the laboratory failed to retain lot number and expiration date records for two of two stains used for moderate complexity microscopic examinations. Findings include: 1. The laboratory performed moderate complexity microscopic examinations for fungus and parasites under the specialty of Microbiology as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 1:05 p.m. on 01/19/23. 2. Chlorazol Black and PMS fungal stains were observed as present and available for use during the tour of the fungus and parasite testing area at 3:20 p.m. 3. Laboratory policies and procedures did not include instruction to record and retain stain lot numbers and expiration dates for fungus and parasite microscopic examinations. 4. Documentation of Chlorazol Black and PMS fungal stain lot numbers and expiration dates was not found during review of laboratory records from January 2021 through January 2023. The laboratory was unable to provide the required documentation upon request. 5. The laboratory performed 79 microscopic examinations in 2021 and 71 microscopic examinations in 2022 as indicated in laboratory patient testing logs found in the KOH Log Book. 6. In an interview at 3:25 p.m. on 01/19/23, TP1 confirmed the above finding. .</p>

D5787

TEST RECORDS

CFR(s): 493.1283(a)

The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:

. Based on document review and interview with laboratory personnel, the laboratory failed to maintain a complete and accurate patient testing log for moderate complexity microscopic examinations in 2021 and 2022. Findings are as follows: 1. The laboratory performed moderate complexity microscopic examinations for fungus and parasites under the specialty of Microbiology as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 1:05 p.m. on 01/19/23. 2. The KOH and Ectoparasite procedures provided by the laboratory indicated results were recorded in the KOH Log Book along with patient identification information. 3. The patient testing log for fungus and parasite microscopic examinations, found in the KOH Log Book, did not include patient identification information for 2 of 79 patients tested in 2021 and 5 of 71 patients tested in 2022. See below. 2021 accession numbers without patient identification 21-037 21-044 2022 accession numbers without patient identification 21-105 21-135 21-137 21-145 21-155 4. The patient testing log did not consistently include the type of test performed (fungus or parasite) in 2021 and 2022. 5. In an interview at 3:15 p.m. on 01/19/23, TP1 confirmed the above finding. .

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

. Based on document review and interview with laboratory personnel, the Technical Consultant failed to ensure initial training for one of one new testing personnel (provider) was performed and documented in 2022 and annual competency assessments for thirteen of thirteen tenured providers were performed and documented in 2021 and 2022 for one of two moderate complexity microscopic examinations performed by the laboratory. Findings are as follows: 1. The laboratory performed moderate complexity microscopic examinations for fungus and parasites under the specialty of Microbiology as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 1:05 p.m. on 01/19/23. 2. Competency evaluation was required after training and semi-annually for new providers and annually for all providers as established in the KOH and Ectoparasite procedures provided by the laboratory. 3. Initial parasite training documentation was not found for the single provider hired in 2022 during review of 2022 MTS training and competency reports provided by the laboratory. In an interview at 3:55 p.m. on 01/19/23, this provider confirmed parasites were not included in training completed in December 2022. 4. Annual parasite competency assessments were not found for thirteen of thirteen providers during

review of 2021 and 2022 MTS training and competency reports provided by the laboratory. 5. Additional information regarding MTS training and competency content was requested within five days. 6. In an interview at 4:00 p.m. on 01/19/23, TP1 confirmed the above finding. 7. In an email received at 12:19 p.m. on 01/25/23, TP1 indicated parasite testing competency had not been performed. In addition, review of the the MTS courses for Basic Microscopy and Skin KOH provided by the laboratory found parasites were not included in the MTS training and competency program. .