Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0870975	04/01/2022
Name of Provider or Supplier	**Street Address, City, State**	
Feitz Foot Clinic Pa	2424 Frankford Ave, Panama City, FL	

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
D0000	A recertification survey was conducted on March 8, 2022 and continued through April 1, 2022 for collection of additional documentation with no email or phone response from the laboratory. Feitz Foot Clinic, clinical laboratory was not in compliance with 42 CFR 493, Requirements for Laboratories. The following Conditions were cited: D5300 - Preanalytic Systems D5400 - Analytic Systems 493.1250 D6000 - Moderate Complexity Laboratory Director 493.1403 D6033 - Technical Consultant-Moderate Complexity 493.1409 D6056 - Clinical Consultant 493.1415 D6063 - Laboratory Testing Personnel 493.1421
D3001	FACILITIES CFR(s): 493.1101(a)(1) The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process. This STANDARD is not met as evidenced by: Based on the laboratory tour and interview with the office manager, the laboratory failed to supply adequate space for all phases of Dermatophyte Test Medium (DTM) testing in the laboratory. Findings include: During the laboratory tour on March 8, 2022 at 10:00 a.m., the laboratory area consisted of: 1. No bench space for test performance. 2. Along the left wall was shelving next to a file cabinet with a basket and several boxes of patient cultures on top, and a large black garbage bag on the floor. 3. Along the back wall was a small sink with a box in it, a biohazard bag in a plastic garbage can with patient specimens inside, a refrigerator, microwave, and toaster oven stacked on each other. 4. An unclean patient chair was along the right wall. An interview with the laboratory office manager on March 8, 2022 at 11:00 a.m., confirmed there was not adequate space for all phases of the DTM testing process.
D3003	FACILITIES CFR(s): 493.1101(a)(2)

	The laboratory must be constructed, arranged, and maintained to ensure contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized. This STANDARD is not met as evidenced by: Based on laboratory tour and interview with the office manager, the laboratory failed to ensure that the laboratory maintained minimal risk of Dermatophyte Test Medium (DTM) patient specimen contamination. Findings include: During the laboratory tour on March 8, 2022 at 10:00 a.m., the laboratory area consisted of: 1. A drink tumbler was on a shelf right next to 3 boxes and a basket full of patient DTM culture specimens on top of a file cabinet. 2. A biohazard bag of patient DTM culture specimens sat approximately 8 inches from the stack of the refrigerator, microwave, and toaster oven. 3. The laboratory employee placed a partially covered piece of pizza onto the unclean patient chair, directly next to patient DTM culture samples while the surveyor was inspecting them. An interview with the office manager on March 8, 2022 at 10:00 a.m., confirmed the laboratory failed to ensure that the laboratory maintained minimal risk of DTM patient specimen contamination.
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on the laboratory tour, direct observation, and interview with the office manager, the laboratory failed to keep food and drink materials separate from the Dermatophyte Test Medium (DTM) testing environment. Findings include: During the tour of the laboratory at 10:00 a.m. on March 8, 2022, it was discovered that a drink cup was on a shelf next to a basket and boxes that contained patient DTM culture tubes. While the surveyor was reviewing labels on patient DTM specimens on March 8, 2022 at approximately 10:15 a.m., the testing person placed a partially wrapped piece of pizza on the patient chair next to the box of patient DTM culture specimens. On March 8, 2022, at approximately 11:00 a.m., it was confirmed by the office manager that food and drink were in the laboratory.
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 the office manager, the laboratory failed to verify the accuracy of Dermatophyte Test Medium (DTM) testing twice a year for 2 of 2 (2020-2021) years reviewed in the subspecialty of Mycology. Findings include: Record review on March 8, 2022 at 11:00 a.m., revealed the laboratory was unable to provide documentation of verification of accuracy for DTM testing for the years 2020

	and 2021. Interview with the office manager on March 8, 2022 at 11:00 a.m., confirmed the laboratory did not have documentation of verification of accuracy for DTM testing.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on record review and interview with the office manager, the laboratory failed to establish and follow written policies and procedures for a quality assessment (QA) program to monitor, assess, and correct problems identified in the laboratory for 2 of 2 (2020-2021) years reviewed. Findings include: Record review on March 8, 2022 at 11: 00 a.m. revealed the laboratory did not have a written QA policy. Interview with the office manager on March 8, 2022 at 11:00 a.m., confirmed that the laboratory did not have a QA policy that they followed.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, 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 overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the laboratory's policy and procedure manual, the laboratory failed to meet the requirements of preanalytic systems. The laboratory failed follow their own written policy for specimen labeling, include a rejection policy for DTM test, and follow manufacturer's instructions for reading cultures within 14 days. Refer to D5311.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on record review, observation, and interview with the office manager, the

laboratory failed to label patient samples with at least two patient identifiers, include specimen rejection instructions for Dermatophyte Test Medium (DTM) samples in the procedure manual, and failed to read DTM test results at the 14 day mark. Findings include: Review of the laboratory procedure manual on March 8, 2022 at 11:00 a.m. revealed: 1. - "The DTM tube is labeled with the patients Name, date of culture taken, chart number and/or D.O.B. (The D.O.B. is required for distinction of same name patients)." 2. no policy for specimen rejection 3. -"The Manufacturer suggests 14 days incubation for DTM testing, we allow up to 4 weeks for slow growing fungal specimens." Review of Remel DTM package insert states: 1. -"Incubate in ambient air at 25-30 degrees Celsius for up to 14 days." 2. -""Disregard color changes after the fourteenth day of incubation because they may be caused by contaminating fungi." Review of the patient log on March 8, 2022 at 11:00 a.m. revealed all results were documented as positive for fungus, except where noted, for 178 patient test results read past the 14 day mark: Patients results read on 2/19/2020: A1 collected 3/12/19 days elapsed to read date 344 days A2-collected 3/12/19 days elapsed to read date 344 days A3-collected 3/26/19 days elapsed to read date 330 days A4-collected 4/2/19 days elapsed to read date 323 days A5-collected 2/12/19 days elapsed to read date 372 days A6-collected 2/1/19 days elapsed to read date 383 days A7-collected 3/12/19 days elapsed to read date 344 days A8-collected 2/12/19 days elapsed to read date 372 days A9-collected 1/9/19 days elapsed to read date 406 days A10-collected 3/26/19 days elapsed to read date 330 days A11-collected 4/23/19 days elapsed to read date 302 days A12-collected 3/19/19 days elapsed to read date 337 days A13-collected 4/9 /19 days elapsed to read date 316 days A14-collected 2/12/19 days elapsed to read date 372 days A15-collected 3/23/19 days elapsed to read date 333 days A16-collected 1/30/19 days elapsed to read date 385 days A17-collected 1/22/19 days elapsed to read date 393 days A18-collected 3/12/19 days elapsed to read date 344 days A19-collected 4/15/19 days elapsed to read date 310 days A20-collected 3/8/19 days elapsed to read date 349 days A21-collected 3/12/19 days elapsed to read date 344 days A22-collected 3/19/19 days elapsed to read date 338 days A23-collected 2/1 /19 days elapsed to read date 384 days A24- collected 1/25/19 days elapsed to read date 391 days A25- collected 1/15/19 days elapsed to read date 401 days A26-collected 8/27/19 days elapsed to read date 177 days A27- collected 8/23/19 days elapsed to read date 181 days A28- collected 8/27/19 - days elapsed to read date 177 days A29- collected 10/15/19 - days elapsed to read date 128 days A30- collected 10 /29/19 - days elapsed to read date 114 days A31- collected 8/27/19 - days elapsed to read date 177 days A32- collected 8/27/19 - days elapsed to read date 177 days A33-collected 8/27/19 - days elapsed to read date 177 days A34- collected 10/18/19 - days elapsed to read date 125 days A35- collected 8/27/19 - days elapsed to read date 177 days A36- collected 9/23/19 - days elapsed to read date 150 days A37- collected 10/22 /19 - days elapsed to read date 121 days A38- collected 8/27/19 - days elapsed to read date 177 days A39- collected 6/25/19 - days elapsed to read date 240 days A40-collected 10/22/19 - days elapsed to read date 121 days A41- collected 10/22/19 - days elapsed to read date 121 days A42- collected 10/3/19 - days elapsed to read date 140 days A43- collected 10/15/19 - days elapsed to read date 128 days A44- collected 10/29/19- days elapsed to read date 114 days A45- collected 10/22/19 - days elapsed to read date 121 days A46- collected 10/22/19 - days elapsed to read date 121 days A47- collected 10/15/19 - days elapsed to read date 128 days A48- collected 10/18/19 - days elapsed to read date 125 days A49- collected 10/15/19 - days elapsed to read date 128 days A50- collected 10/18/19 - days elapsed to read date 125 days A51-collected 10/15/19 - days elapsed to read date 128 days A52- collected 10/29/19 - days elapsed to read date 114 days A53- collected 10/15/19 - days elapsed to read date 128 days A54- collected 10/22/19 - days elapsed to read date 121 days A55- collected 10/29/19 - days elapsed to read date 114 days - resulted as negative for fungus A56-

collected 10/19/19- days elapsed to read date 123 days A57- collected 10/22/19- days elapsed to read date 121 days A58- collected 11/22/19- days elapsed to read date 89 days A59- collected 11/5/19- days elapsed to read date 106 days A60- collected 11/26 /19- days elapsed to read date 85 days A61- collected 11/1/19- days elapsed to read date 110 days A62- collected 11/8/19- days elapsed to read date 103 days A63- collected 11/26/19 - days elapsed to read date 85 days A64- collected 11/26/19- days elapsed to read date 85 days A65- collected 11/5/19- days elapsed to read date 106 days A66- collected 11/26/19- days elapsed to read date 85 days A67- collected 11/23 /19- days elapsed to read date 88 days A68- collected 11/26/19- days elapsed to read date 85 days A69- collected 11/5/19- days elapsed to read date 106 days A70- collected 11/5/19- days elapsed to read date 106 days A71- collected 11/26/19- days elapsed to read date 85 days A72- collected 11/5/19- days elapsed to read date 106 days A73- collected 11/22/19- days elapsed to read date 89 days A74- collected 11/23 /19- days elapsed to read date 88 days A75- collected 12/13/19- days elapsed to read date 68 days A76- collected 12/17/19- days elapsed to read date 64 days A77- collected 12/6/19- days elapsed to read date 75 days A78- collected 12/22/19- days elapsed to read date 59 days A79- collected 12/13/19- days elapsed to read date 68 days A80- collected 12/20/19- days elapsed to read date 61 days A81- collected 12/3 /19- days elapsed to read date 78 days A82- collected 12/6/19- days elapsed to read date 75 days A83- collected 12/19/18- days elapsed to read date 427 days A84- collected 12/17/19- days elapsed to read date 64 days A85- collected 12/3/19- days elapsed to read date 78 days A86- collected 12/6/19- days elapsed to read date 75 days A87- collected 12/3/19- days elapsed to read date 78 days A88- collected 11/22/19- days elapsed to read date 89 days A89- collected 12/3/19- days elapsed to read date 78 days A90- collected 12/17/19- days elapsed to read date 64 days A91- collected 12/22 /19- days elapsed to read date 59 days A92- collected 12/27/19- days elapsed to read date 54 days A93- collected 12/17/19- days elapsed to read date 64 days A94- collected 11/5/19- days elapsed to read date 106 days Patients results read on 10/19 /2020: B1- collected 2/20/20 - days elapsed to read date 243 days B2- collected 2/20 /20- days elapsed to read date 243 days B3- collected 2/20/20 - days elapsed to read date 243 days B4- collected 2/18/20 - days elapsed to read date 245 days B5- collected 2/24/20 - days elapsed to read date 239 days B6- collected 2/11/20 - days elapsed to read date 252 days B7- collected 1/24/20 - days elapsed to read date 270 days B8- collected 1/28/20 - days elapsed to read date 266 days B9- collected 1/3/20 - days elapsed to read date 291 days B10- collected 1/14/20 - days elapsed to read date 280 days B11- collected 2/11/20 - days elapsed to read date 252 days B12- collected 2 /11/20 - days elapsed to read date 252 days B13- collected 2/11/20 - days elapsed to read date 252 days B14- collected 1/21/20 - days elapsed to read date 273 days B15- collected 1/21/20 - days elapsed to read date 273 days B16- collected 1/21/20 - days elapsed to read date 273 days B17- collected 1/21/20 - days elapsed to read date 273 days B18- collected 2/4/20 - days elapsed to read date 259 days B19- collected 1/14 /20 - days elapsed to read date 279 days B20- collected 4/4/20 - days elapsed to read date 198 days B21- collected 1/7/20 - days elapsed to read date 286 days B22- collected 1/31/20 - days elapsed to read date 263 days B23- collected 2/28/20 - days elapsed to read date 235 days B24- collected 2/11/20 - days elapsed to read date 252 days B25- collected 8/27/20 - days elapsed to read date 54 days B26- collected 1/28 /20 - days elapsed to read date 266 days B27- collected 1/21/20 - days elapsed to read date 273 days B28- collected 1/28/20 - days elapsed to read date 266 days B29- collected 2/11/20 - days elapsed to read date 252 days B30- collected 1/7/20 - days elapsed to read date 287 days B31- collected 1/3/20 - days elapsed to read date 291 days B32- collected 1/21/20 - days elapsed to read date 273 days B33- collected 2/11 /20 - days elapsed to read date 252 days B34- collected 1/24/20 - days elapsed to read date 270 days B35- collected 1/28/20 - days elapsed to read date 266 days B36-

collected 2/11/20 - days elapsed to read date 252 days B37- collected 2/18/20 - days elapsed to read date 245 days B38- collected 1/28/20 - days elapsed to read date 266 days B39- collected 2/4/20 - days elapsed to read date 259 days B40- collected 2/18 /20 - days elapsed to read date 245 days B41- collected 2/4/20 - days elapsed to read date 259 days B42- collected 2/4/20 - days elapsed to read date 259 days B43- collected 8/18/20 - days elapsed to read date 63 days B44- collected 8/11/20 - days elapsed to read date 70 days B45- collected 8/11/20 - days elapsed to read date 70 days B46- collected 8/11/20 - days elapsed to read date 70 days B47- collected 8/25 /20 - days elapsed to read date 56 days B48- collected 8/4/20 - days elapsed to read date 77 days B49- collected 8/7/20 - days elapsed to read date 74 days B50- collected 8/7/20 - days elapsed to read date 74 days B51- collected 8/7/20 - days elapsed to read date 74 days B52- collected 8/4/20 - days elapsed to read date 77 days B53- collected 8/18/20 - days elapsed to read date 63 days B54- collected 2/21/20 - days elapsed to read date 242 days B55- collected 2/25/20 - days elapsed to read date 238 days B56- collected 2/28/20 - days elapsed to read date 235 days B57- collected 2/21/20 - days elapsed to read date 242 days B58- collected 2/25/20 - days elapsed to read date 238 days B59- collected 2/21/20 - days elapsed to read date 242 days B60- collected 2/25 /20 - days elapsed to read date 238 days B61- collected 2/25/20 - days elapsed to read date 238 days B62- collected 2/25/20 - days elapsed to read date 238 days B63- collected 2/21/20 - days elapsed to read date 242 days B64- collected 2/21/20 - days elapsed to read date 242 days B65- collected 2/25/20 - days elapsed to read date 238 days B66- collected 2/25/20 - days elapsed to read date 238 days B67- collected 2/25 /20 - days elapsed to read date 238 days B68- collected 2/28/20 - days elapsed to read date 245 days B69- collected 2/25/20 - days elapsed to read date 238 days Patients results read on 5/4/2021: C1- collected 10/13/20 - days elapsed to read date 204 days C2- collected 10/13/20 - days elapsed to read date 204 days C3- collected 11/24/20 - days elapsed to read date 162 days - resulted as negative for fungus C4- collected 11 /10/20 - days elapsed to read date 176 days C5- collected 11/24/20 - days elapsed to read date 162 days C6- collected 11/12/20 - days elapsed to read date 174 days C7- collected 11/10/20 - days elapsed to read date 176 days C8- collected 11/3/20 - days elapsed to read date 183 days C9- collected 9/25/20 - days elapsed to read date 222 days C10- collected 9/22/20 - days elapsed to read date 225 days C11- collected 9/22 /20 - days elapsed to read date 225 days C12- collected 9/29/20 - days elapsed to read date 218 days C13- collected 9/11/20 - days elapsed to read date 236 days C14- collected 9/29/20 - days elapsed to read date 218 days C15- collected 9/29/20 - days elapsed to read date 218 days C16- collected 9/22/20 - days elapsed to read date 225 days C17- collected 9/15/20 - days elapsed to read date 232 days C18- collected 9/29 /20 - days elapsed to read date 218 days C19- collected 9/22/20 - days elapsed to read date 225 days C20- collected 9/29/20 - days elapsed to read date 218 days C21- collected 9/8/20 - days elapsed to read date 239 days C22- collected 9/8/20 - days elapsed to read date 239 days C23- collected 10/6/20 - days elapsed to read date 211 days C24- collected 10/27/20 - days elapsed to read date 190 days C25- collected 10 /27/20 - days elapsed to read date 190 days C26- collected 10/16/20 - days elapsed to read date 201 days C27- collected 10/2/20 - days elapsed to read date 215 days C28- collected 10/6/20 - days elapsed to read date 211 days C29- collected 10/6/20 - days elapsed to read date 211 days C30- collected 10/27/20 - days elapsed to read date 190 days C31- collected 10/13/20 - days elapsed to read date 204 days C32- collected 10 /16/20 - days elapsed to read date 201 days C33- collected 10/6/20 - days elapsed to read date 211 days C34- collected 10/16/20 - days elapsed to read date 201 days C35- collected 10/27/20 - days elapsed to read date 190 days C36- collected 11/10/20 - days elapsed to read date 176 days C37- collected 11/24/20 - days elapsed to read date 162 days C38- collected 10/30/20 - days elapsed to read date 187 days C39- collected 11 /24/20 - days elapsed to read date 162 days C40- collected 11/10/20 - days elapsed to

	read date 176 days C41- collected 11/10/20 - days elapsed to read date 176 days C42- collected 11/12/20 - days elapsed to read date 174 days C43- collected 11/10/20 - days elapsed to read date 176 days C44- collected 11/24/20 - days elapsed to read date 162 days C45- collected 11/10/20 - days elapsed to read date 176 days C46- collected 11 /10/20 - days elapsed to read date 176 days Patients results read on 8/31/2021: D1- collected 1/26/21 - days elapsed to read date 218 days D2- collected 1/22/21 - days elapsed to read date 222 days D3- collected 1/12/21 - days elapsed to read date 232 days D4- collected 1/19/21 - days elapsed to read date 225 days - resulted as negative for fungus D5- collected 1/26/21 - days elapsed to read date 218 days D6- collected 1 /5/21 - days elapsed to read date 239 days - resulted as negative for fungus D7- collected 1/5/21 - days elapsed to read date 239 days D8- collected 1/5/21 - days elapsed to read date 239 days - resulted as negative for fungus D9- collected 1/8/21 - days elapsed to read date 236 days D10- collected 1/22/21 - days elapsed to read date 222 days - resulted as negative for fungus D11- collected 1/26/21 - days elapsed to read date 218 days D12- collected 1/22/21 - days elapsed to read date 222 days D13- collected 1/19/21 - days elapsed to read date 225 days D14- collected 1/8/21 - days elapsed to read date 236 days D15- collected 1/5/21 - days elapsed to read date 239 days D16- collected 1/15/21 - days elapsed to read date 229 days D17- collected 1/5 /21 - days elapsed to read date 239 days D18- collected 1/5/21 - days elapsed to read date 239 days D19- collected 1/5/21 - days elapsed to read date 239 days D20- collected 1/5/21 - days elapsed to read date 239 days - resulted as negative for fungus D21- collected 1/12/21 - days elapsed to read date 232 days D22- collected 1/12/21 - days elapsed to read date 232 days D23- collected 1/5/21 - days elapsed to read date 239 days D24- collected 1/5/21 - days elapsed to read date 239 days D25- collected 1/5 /21 - days elapsed to read date 239 days D26- collected 1/5/21 - days elapsed to read date 239 days Observation of a sampling of labeled patient DTM culture tubes on March 8, 2022 at 11:00 a.m. revealed: Patient X1 - no chart number, no date of birth Patient X2 - no chart number, no date of birth Patient X3 - no chart number, no date of birth Patient X4 - no chart number, no date of birth Patient X5 - no chart number, no date of birth Patient X6 - no chart number, no date of birth Patient X7 - no chart number, no date of birth Patient X8 - no chart number, no date of birth Patient X9 - no chart number, no date of birth Patient X10 - no collection date, no chart number, no date of birth Patient X11 - no collection date, no chart number, no date of birth Interview on March 8, 2022 at 11:00 a.m. with the office manager confirmed patient samples were not labeled according to their written policy, there was no policy for specimen rejection in the laboratory procedure manual for DTM testing, and test results were read past the Manufacturer's stated instruction of 14 days.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual and patient log, the laboratory failed to implement a quality assessment policy for monitoring, assessing and correcting problems when identified in preanalytic systems. The laboratory failed to follow their own written policy for specimen labeling, include a rejection policy for DTM test, and follow manufacturer's instructions for reading cultures within 14 days. Refer to D5311.

D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 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 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 review of procedure manual and laboratory records, the laboratory failed to meet the requirements of analytic systems, as evidenced by: 1. The laboratory failed to ensure the Dermatophyte Test Medium (DTM) procedure had been reviewed, signed and dated by the laboratory director. Refer to D5407 2. The laboratory failed to monitor and document incubation temperature for DTM culture samples. Refer to D5413 3. The laboratory failed to ensure DTM culture media for patient testing had not exceeded the expiration date. Refer to D5417 4. The laboratory failed to establish performance specifications for DTM cultures. Refer to D5423 5. The laboratory failed to document sterility and perform quality control for DTM culture media. Refer to D5477
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on record review and interview with the office manager, the laboratory failed to ensure the procedure for Dermatophyte Test Medium (DTM) testing had not been reviewed, signed, and dated by the laboratory director. Findings include: Record review on March 8, 2022 at 11:00 a.m., revealed the laboratory director had not signed and dated the procedure for DTM testing. Interview with the office manager on March 8, 2022 at 11:00 a.m., confirmed the laboratory did not have a signed and dated copy of the DTM procedure in the policy and procedure manual.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) 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. This STANDARD is not met as evidenced by: Based on record review, direct observation, and interview with the office manager, the

	laboratory failed to monitor and document incubation temperature for Dermatophyte Test Medium (DTM) culture samples for 2 of 2 (2020-2021) years reviewed. Findings include: 1. Record review on March 8, 2022 at 10:00 a.m., revealed there was no temperature log for laboratory room temperature where DTM culture samples were stored. 2. Review of policy and procedure manual on March 8, 2022 at 10:00 a.m., revealed - "The temperature in lab should be 22-27 degrees Celsius for storage of processing cultures." Direct observation during laboratory tour on March 8, 2022 at 10:00 a.m. revealed: 1. The thermometer on the wall read at 20 degrees Celsius. 2. One basket full of patient culture tubes, two boxes full of clear plastic bags containing patient DTM samples labeled "Feb", "March/April", "May", "June", "Sept", "Dec", and other bags that did not have labels on them from 2021 were stored on top of the file cabinet for incubation and had not had results read or resulted yet. Interview with the office manager on March 8, 2022 at 10:00 a.m., confirmed the laboratory room temperature had not been monitored and documented and the laboratory was too cold for incubation of DTM cultures at the time of laboratory tour.
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 direct observation and staff interview, the laboratory failed to ensure culture media for patient testing had not exceeded the expiration date for 9 of 9 patients in December 2020. Findings include: During the laboratory tour at 10:00 a.m. on March 8, 2022, patient culture specimens #X1, #X2, #X3, #X4, #X5, #X6, #X7, #X8, and #X9 were inoculated on DTM culture media, lot number L27-444455, expiration date 2/04/2020. The patient's test results had not been read and recorded at time of survey. An interview at 10:00 a.m. on March 8, 2022, confirmed that the expired DTM culture tubes were used with patient samples. The testing person stated, "I didn't know how long the culture tubes were good for."
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on record review, lack of establishment documentation and interview with the office manager, the laboratory failed to establish performance specifications for

	Dermatophyte Test Medium (DTM) cultures when manufacturer's incubation time and temperature were modified. Findings include: Record review on March 8, 2022 at 11: 00 a.m., Remel DTM manufacturer's instructions stated: "Incubate in ambient air at 25 - 30 degrees Celsius for up to 14 days." Record review on March 8, 2022 at 11:00 a. m., the laboratory policy and procedure manual revealed: 1. -"The Manufacturer suggests 14 days incubation for DTM testing, we allow up to 4 weeks for slow growing fungal specimens." 2. -"The temperature in lab should be 22-27 Celsius for storage of processing cultures." Record review of laboratory documents on March 8, 2022 at 11:00 a.m., revealed no establishment documentation for modified incubation time and temperature for DTM testing. Interview with the office manager on March 8, 2022 at 11:00 a.m. confirmed the laboratory did not establish performance specifications for the modified incubation time and temperature.
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 interview with the office manager, the laboratory failed to document sterility and perform quality control for Dermatophyte Test Medium (DTM) culture media used to test patients for 2 of 2 (2020-2021) years reviewed. Findings include: Record review on March 8, 2022 at 10:00 a.m., revealed no documentation for DTM sterility and no documentation of quality control for the DTM culture media for its ability to support growth or select or inhibit specific organisms. Review of the policy and procedure manual on March 8, 2022 at 10:00 a.m., revealed: 1. - "To ensure the sterility of the DTM Lot, a culture is set to the side for the allotted time of 10 days to 4 weeks, for slow growth, to ensure there is not a false positive result." 2. - "In the event there is not a positive or negative results, the manufacturer would be contacted for a new lot." 3. - "Quality Control - to ensure quality control while processing DTM cultures, two individual personnel document the sterility, using a patient's positive controlled result and a patient's negative controlled result." Review of the DTM package insert on March 8, 2022 at 10:00 a.m., revealed: - "Quality Control - All lot numbers of Dermatophyte Test Medium (DTM) have been tested using the following quality control organisms and have been found to be acceptable. Testing of control organisms should be performed in accordance with established laboratory quality control procedures. If aberrant quality control results are noted, patient results should not be reported." "Candida albicans - good growth Trichophyton mentagrophytes - good growth Aspergillus niger - inhibition (partial to complete) Cryptococcus neoformans - inhibition (partial to complete) Eschericha coli - inhibition (partial to complete) Pseudomonas Aeruginsoa - inhibition (partial to complete) Staphylococcus Aeureus - inhibition (partial to complete)" Interview with the office manager on March 8, 2022 at 10:00 a.m., confirmed sterility had not been documented and quality control of DTM media had not been performed.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT

	CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of procedure manual and laboratory records, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems, as evidenced by: 1. The laboratory failed to ensure the Dermatophyte Test Medium (DTM) procedure had been reviewed, signed and dated by the laboratory director. Refer to D5407 2. The laboratory failed to monitor and document incubation temperature for DTM culture samples. Refer to D5413 3. The laboratory failed to ensure DTM culture media for patient testing had not exceeded the expiration date. Refer to D5417 4. The laboratory failed to establish performance specifications for DTM cultures. Refer to D5423 5. The laboratory failed to document sterility and perform quality control for DTM culture media. Refer to D5477
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview with office manager, the laboratory director failed to provide qualifying documents for position held. See D6003
D6003	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1405 AND 493.1406 The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of moderate complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the Laboratory is located; and (b)(2)(ii) Have had laboratory training or experience consisting of: (b)(2)(ii)(A) At least one year directing or supervising non-waived laboratory testing; or (b)(2)(ii)(B) Beginning September 1, 1993, have at least 20 continuing medical education credit hours in laboratory practice commensurate with the director responsibilities defined in 493.1407; or (b)(2)(ii)(C) Laboratory

training equivalent to paragraph (b)(2)(ii)(B) of this section obtained during medical residency. (For example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution; and (b)(3)(i) Be certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or the American Board of Medical Laboratory Immunology; or (b)(3)(ii) Have had at least one year experience directing or supervising non-waived laboratory testing; (b)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; (b)(4)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing; and (b)(4)(iii) In addition, have at least one year of supervisory laboratory experience in non-waived testing; or (b)(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; (b)(5)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing; and (b)(5)(iii) In addition, have at least 2 years of supervisory laboratory experience in non-waived testing; (b)(6) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under 493.1406; or (b)(7) On or before February 28, 1992, qualified under State law to direct a laboratory in the State in which the laboratory is located. Laboratory director qualifications on or before February 28, 1992 The laboratory director must be qualified to manage and direct the laboratory personnel and test performance. (a) The laboratory director must possess a current license as a laboratory director issued by the State, if such licensing exists; and (b) The laboratory director must: (b)(1) Be a physician certified in anatomical or clinical pathology (or both) by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; (b)(2) Be a physician who: (b)(2)(i) Is certified by the American Board of Pathology or the American Osteopathic Board of Pathology in at least one of the laboratory specialties; or (b)(2)(ii) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board in one of the laboratory specialties; or (b)(2)(iii) Is certified by the American Society of Cytology to practice cytopathology or possesses qualifications that are equivalent to those required for such certification; or (b)(2)(iv) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (b)(3) For the subspecialty of oral pathology only, be certified by the American Board of Oral Pathology, American Board of Pathology or the American Osteopathic Board of Pathology or possesses qualifications that are equivalent to those required for certification; (b)(4) Hold an earned doctoral degree from an accredited institution with a chemical, physical, or biological science as a major subject and (b)(4)(i) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board acceptable to HHS in one of the laboratory specialties; or (b)(4)(ii) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (b)(5) With respect to individuals first qualifying before July 1, 1971, have been responsible for the direction of a laboratory for 12 months between July 1, 1961, and January 1, 1968, and, in addition, either: (b)(5)(i) Was a physician and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (b)(5)(ii) Held a master's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 4 years of pertinent full-

	time laboratory experience; (b)(5)(iii) Held a bachelor's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 6 years of pertinent full-time laboratory experience; or (b)(5)(iv) Achieved a satisfactory grade through an examination conducted by or under the sponsorship of the U.S. Public Health Service on or before July 1, 1970; or (b)(6) Qualify under State law to direct the laboratory in the State in which the laboratory is located. Note: The January 1, 1968 date for meeting the 12 months' laboratory direction requirement in paragraph (b)(5) of this section may be extended 1 year for each year of full-time laboratory experience obtained before January 1, 1958 required by State law for a laboratory director license. An exception to the July 1, 1971 qualifying date in paragraph (b)(5) of this section was made provided that the individual requested qualification approval by October 21, 1975 and had been employed in a laboratory for at least 3 years of the 5 years preceding the date of submission of his qualifications. This STANDARD is not met as evidenced by: Based on record review and interview with office manager, the laboratory failed to provide any qualifying documents for the position of Laboratory Director. Findings include: Review of personnel records on March 8, 2022 at 11:00 a.m., revealed documentation was not available to qualify the Laboratory Director. Interview with the office manager on March 8, 2022 at 11:00 a.m. confirmed the laboratory had no qualifying documents for the position of Laboratory Director.
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (E) The laboratory director must-- (E)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic and analytic phases of testing. Findings include: 1. The laboratory failed to label patient samples with at least two patient identifiers, include specimen rejection instructions for Dermatophyte Test Medium (DTM) samples in the procedure manual, and failed to read DTM test results at the 14 day mark. Refer to D5311 2. The laboratory failed to implement a quality assessment policy for monitoring, assessing and correcting problems when identified in preanalytic systems. Refer to D5391 3. The laboratory failed to ensure the procedure for Dermatophyte Test Medium (DTM) testing had not been reviewed, signed, and dated by the laboratory director. Refer to D5407 4. The laboratory failed to monitor and document incubation temperature for Dermatophyte Test Medium (DTM) culture samples for 2 of 2 (2020-2021) years reviewed. Refer to D5413

D6011	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(2) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(2) and provide a safe environment in which employees are protected from physical, chemical, and biological hazards. This STANDARD is not met as evidenced by: Based on observation and interview with the office manager, the Laboratory Director failed to provide a safe environment in which employees are protected from physical, chemical, and biological hazards. Findings include: 1. The laboratory failed to supply adequate space for all phases of Dermatophyte Test Medium (DTM) testing in the laboratory. Refer to D3001 2. The laboratory failed to ensure that the laboratory maintained minimal risk of Dermatophyte Test Medium (DTM) patient specimen contamination. Refer to D3003 3. The laboratory failed to keep food and drink materials separate from the Dermatophyte Test Medium (DTM) testing environment. Refer to D3011
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. Findings include: 1. The laboratory failed to establish and follow written policies and procedures for a quality assessment (QA) program to monitor, assess, and correct problems identified in the laboratory for 2 of 2 (2020-2021) years reviewed. Refer to D5291 2. The laboratory failed to ensure culture media for patient testing had not exceeded the expiration date for 9 of 9 patients in December 2020. Refer to D5417 3. The laboratory failed to document sterility and perform quality control for Dermatophyte Test Medium (DTM) culture media used to test patients for 2 of 2 (2020-2021) years reviewed. Refer to D5477 4. The laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems. Refer to D5791
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in

	accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview with office manager, the laboratory failed to provide qualifying documents for the position of Technical Consultant. See D6035
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on record review and interview with office manager, the laboratory failed to provide qualifying documents for the Technical Consultant position held in the laboratory. Findings include: Review of personnel records on March 8, 2022 at 11:00 a.m., revealed documentation was not available to qualify the Technical Consultant. Interview with the office manager on March 8, 2022 at 11:00 a.m. confirmed there were no qualifying documents in the laboratory for the position of Technical Consultant.
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 record review and interview with the office manager, the Laboratory Technical Consultant (TC) failed to establish and follow written policies to assess employee competency for 3 of 3 (#A-#C) testing personnel (TP) for 2 of 2 (2020-2021) years reviewed. Findings include: Review of personnel documents on March 8, 2022 at 11:00 a.m., revealed that the TC did not perform annual competencies for 3 of 3 (#A-#C) TP in the laboratory. Interview with the office manager on March 8, 2022 at 11:00 a.m., confirmed that the TC did not perform the annual competency assessments.
D6056	CLINICAL CONSULTANT CFR(s): 493.1415 The laboratory must have a clinical consultant who meets the qualification requirements of 493.1417 of this part and provides clinical consultation in accordance with 493.1419 of this part. This CONDITION is not met as evidenced by: Based on record review and interview with office manager, the laboratory failed to provide qualifying documentation for the position of Clinical Consultant. See D6057
D6057	CLINICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1417 The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493.1405(b)(1), (2), or (3)(i); or (b) Be a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine and possess a license to practice medicine, osteopathy or podiatry in the State in which the laboratory is located. This STANDARD is not met as evidenced by: Based on record review and interview with office manager, the laboratory failed to provide qualifying documentation for the position of Clinical Consultant. Findings include: Review of personnel records on March 8, 2022 at 11:00 a.m., revealed documentation was not available to qualify the Clinical Consultant. Interview with office manager on March 8, 2022 at 11:00 a.m., confirmed the laboratory had no qualifying documentation in the laboratory for the Clinical Consultant.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.

	1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on record review and interview with office manager, the laboratory failed to provide qualifying documentation for the three positions of Testing Personnel in the laboratory. See D6065
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on record review and interview with office manager, the laboratory failed to provide qualifying documents for three of three Testing Personnel on the CMS-209. Findings include: Review of personnel records on March 8, 2022 at 11:00 a.m., revealed documentation was not available to qualify the three testing personnel. Interview with the office manager on March 8, 2022 at 11:00 a.m. confirmed there was no qualifying documentation for the three Testing Personnel listed on the CMS-209.