

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1081226	(X3) Date Survey Completed 05/12/2022
Name of Provider or Supplier Palm Harbor Dermatology	Street Address, City, State 4197 Woodlands Pkwy 2nd Fl, Palm Harbor, 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	An announced CLIA recertification survey was conducted at Palm Harbor Dermatology on 05/10/22 - 05/12/22. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Condition was cited: 493.1230 Condition: General Laboratory Systems
D5200	<p>GENERAL LABORATORY SYSTEMS CFR(s): 493.1230</p> <p>Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview with the histotechnologist and Laboratory Director, the laboratory failed to perform competency assessments for two of two Testing Personnel (#E and #F) for two of two years reviewed (2020 - 2022) (See D5209) and failed to evaluate the accuracy of the subspecialty mycology (Fungi) and parasitology (Scabies) testing at least twice a year for 2 of 2 years reviewed (2020-2022) (See D5217). Failure to evaluate the accuracy of Fungi and Scabies testing is a repeat deficiency from the recertification survey conducted on 02/04/20.</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>

This STANDARD is not met as evidenced by:
 Based on record review and interview with the histotechnologist and Laboratory Director, the laboratory failed to have documentation of competency assessments for two of two (#E and #F) Testing Personnel performing moderate complexity testing for the subspecialties of mycology (fungi) and parasitology (scabies) for two of two years reviewed (2020-2022). Findings Included: Review of the CMS 209 signed by the Laboratory Director on 05/10/22 revealed Testing Personnel #E and #F performed moderate complexity testing. Review of Testing Personnel #E and #F personnel files revealed no evidence of competency assessments from 2020-2022. Review of the Provider Performed Microscopy Procedure manual revealed "Competency is the ability of personnel to apply their skill, knowledge, and experience to perform their duties correctly. Competency assessment is used to ensure that the testing personnel are fulfilling their duties as required by applicable federal, state, and local requirements. To make sure testing is consistent and accurate, the laboratory director should periodically check the competency of testing personnel and provide additional training when needed." On 05/10/22 at 11:50 AM, the histotechnologist confirmed the lack of competency assessments for Testing Personnel #E and #F. On 05/12/22 at 04:35 PM, a telephone interview with the Laboratory Director revealed the previous histotechnologist had been gone for 2 years. The Laboratory Director reported that the prior histotechnologist kept track of peer reviews and competency assessments and since this person left, the task was overlooked.

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 histotechnologist and Laboratory Director, the laboratory failed to verify the accuracy of testing twice a year for 2 out of 2 years (2020-2022) reviewed for the subspecialties of Mycology (Fungi), and Parasitology (Scabies). Findings Included: Review of the "PPM (Provider Performed Microscopy) Log Sheet " revealed that QA (Quality Assurance) had not been performed for 39 of 39 Koh (potassium hydroxide used to diagnose fungi) tests performed and 2 of 2 scabies tests performed in 2020, 2021, and 2022. Review of the PPM procedure manual, which contained a procedure titled "PT [Proficiency Testing] Requirements," revealed "...PT is an important tool used to verify the accuracy and reliability of testing... PPM testing sites need to verify the accuracy of their testing at least twice per year..." On 05/10/22 at 11:50 AM, the histotechnologist confirmed the laboratory had not verified the accuracy of testing for fungi and scabies from 2020 - 2022. On 05/12/22 at 04:35 PM, a telephone interview with the Laboratory Director revealed the previous histotechnologist who handled this task has been gone for 2 years, and this has been overlooked. This is a repeat deficiency.

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 and interview with the histotechnologist and Laboratory Director, the laboratory failed to ensure the Potassium Hydroxide and Chlorazol Black E used for the subspecialty mycology (Fungi) and parasitology (Scabies) testing was not expired prior to patient testing. or Fungi and Scabies testing from 02/05/20 (date of last survey) to 05/10/22 (date of survey) was 39 Fungi tests and 2 Scabies.

Findings Included: A tour of the laboratory 05/10/22 on at 10:30 a.m. revealed a bottle of Chlorazol Black E with an expiration date of 10/23/21 and a bottle of Potassium hydroxide with an expiration date of 10/18/19. On 05/10/22 at 11:00 AM, the histotechnologist confirmed that the Chlorazol Black E and Potassium Hydroxide was expired and had been used for patient testing. Review of the "PPM (Provider Performed Microscopy) Log Sheet " revealed that 39 fungi tests and 2 scabies tests had been performed from 2/4/2020 (the last survey date) through 5/10/22. On 05/12 /22 at 4:35 PM, a telephone interview with the Laboratory Director revealed the previous histotechnologist who handled the tracking of reagent expiration dates has been gone for 2 years, and this has been overlooked.