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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 29D1052695 | (X3) Date Survey Completed 02/09/2026 |
| Name of Provider or Supplier Thomas Dermatology | Street Address, City, State 9097 W Post Rd Ste 100, Las Vegas, NV | |
| 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 | This Statement of Deficiencies was created as a result of an on-site CLIA recertification survey conducted at your facility on February 9, 2026. The findings and conclusions of any investigation by the Nevada Health Authority-Division of Healthcare Purchasing and Compliance shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws. |
| D2007 | <p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory patient test log for the Dermatophyte Test Media (DTM) testing between the dates of June 25, 2024 and December 11, 2025, a review of the 2024 and 2025 American Proficiency Institute (API) Proficiency Testing (PT) records, a review of the complete, submitted CMS-209 form, and an interview with laboratory personnel, the laboratory failed to ensure that performance of proficiency testing was rotated among seven of seven testing personnel that perform the DTM patient tests. Findings include: 1. A review of the laboratory patient log revealed that DTM patient testing was performed by a total of seven testing personnel. 2. A review of the API PT 2024 and 2025 attestations revealed the DTM testing was not rotated between all of the staff who performed the patient testing. The API PT testing was not performed by five of the seven personnel who performed the test that were listed on the CMS-209 form. 3. Laboratory personnel confirmed the findings during an interview conducted on February 9, 2026 at approximately 4:00 PM. According to the provided CMS-116 form, the laboratory performs 70 mycology tests annually.</p> |
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D3009

FACILITIES

CFR(s): 493.1101(c)

The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.

This STANDARD is not met as evidenced by:

Based on the Nevada Health Authority Division of Health Care Purchasing and Compliance (The Division) laboratory licensure records, a review of the Nevada Administrative Code (NAC), a review of the Dermatophyte Test Media (DTM) patient test logs, a review of the complete, submitted CMS-209 form, and an interview with the laboratory personnel, the laboratory failed to ensure that the appropriate State of Nevada laboratory licensure was procured for based on the laboratory personnel qualifications of five of seven for the testing performed. Findings include: 1. A review of the Nevada Health Authority Division of Health Care Purchasing and Compliance licensure records revealed that the laboratory possessed an active State of Nevada Exempt Laboratory License. 2. The Nevada Administrative Code, NAC 652.175(2)(d)(1) does not permit a laboratory that possesses an Exempt Laboratory License to perform non-waived testing by personnel other than a physician making the readings on his or her own patients. 3. A review of the CMS-209 form, and a review of the DTM laboratory patient logs revealed that five of the seven personnel who performed patient DTM tests were not licensed by the State of Nevada as a physician. One of the five not licensed as a physician was licensed by the State of Nevada Board of Nursing as an Advanced Registered Nurse Practitioner (APRN). Four of the five not licensed as a physician were licensed by the State of Nevada Board of Medical Examiners as Physician Assistants (PAs). 4. The findings were confirmed during an interview with the laboratory personnel conducted on February 9, 2026 at approximately 4:00 PM. According to the provided CMS-116 form, the laboratory performs 70 mycology tests annually.

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES

CFR(s): 493.1235

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.

This STANDARD is not met as evidenced by:

Based on the lack of training and competency records for five of seven testing personnel who performed the Dermatophyte Test Media (DTM) patient testing, a review of the director approved laboratory procedures, and email correspondence with the office manager, the laboratory failed to establish and follow a written policy and procedure for the assessment of the testing personnel competency to ensure that accurate and reliable patient results would be produced. Findings include: 1. There were no initial, semi-annual or annual records of training and competency assessment for five of seven testing personnel who performed the DTM patient testing. 2. A review of the laboratory procedures revealed that there was no established director approved procedure to assess the competency of the personnel who performed the DTM testing. 3. The findings were confirmed via email correspondence received from the office manager on February 18, 2026 at 4:32 PM. According to the provided CMS-116 form, the laboratory performs 70 mycology tests annually.

D5477

CONTROL PROCEDURES

CFR(s): 493.1256(e)(4)(g)

(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.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory Media Receipt Log for the Dermatophyte Test Media (DTM), a review of the manufacturer's instructions for the Dermatophyte Test Media, and an interview with the laboratory personnel, the laboratory failed to ensure that sterility checks and known positive and negative quality control (QC) was performed for five of seven lot numbers or shipments since February 21, 2024 of the Dermatophyte Test Media prior to placing it in use for patient testing. Findings include: 1. A review of the log entitled, "Media Receipt Log DTM" revealed that the quality control and condition check of the media was performed for the Remel Dermtube lot number 787714 on February 21, 2024 and was performed for Hardy Diagnostics DTM media on August 29, 2024. 2. A review of the patient log and the Media Receipt Log revealed that there were no records of the quality control and condition check for the following lot numbers of media in use on the following dates: A: Lot Number: D-1502-0623 In Use: June 24, 2024 B: Lot Number: 642797 In Use: December 26, 2024 C: Lot Number: 647801 In Use: June 20, 2025 D: Lot Number: 655615 In Use: September 22, 2025 E: Lot Number: 667536 In Use: January 6, 2026 3. The manufacturer's instructions from Hardy Diagnostics entitled, "Instructions for Use Dermatophyte Test Medium (DTM)" stated, "End users of commercially prepared culture media should perform QC testing in accordance with applicable government regulatory agencies, and in compliance with accreditation requirements. Hardy Diagnostics recommends end users check for signs of contamination and deterioration and, if dictated by laboratory quality control procedures or regulation, perform quality control testing to demonstrate growth or a positive reaction and to demonstrate inhibition or a negative reaction if applicable." 4. The laboratory personnel confirmed the findings during an interview conducted on February 9, 2026 at approximately 3:45 PM. According to the provided CMS-116 form, the laboratory performs 70 mycology tests annually.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(11)

(e)(11) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;

This STANDARD is not met as evidenced by:

Based on a review of the laboratory Dermatophyte Test Media (DTM) patient testing records, the lack of training and competency assessment records for five of seven testing personnel performing the DTM testing, and an interview with the laboratory personnel, the director failed to ensure that initial training and competency assessment

was performed and documented for five of seven personnel who perform the DTM testing on patient specimens. Findings include: 1. A review of the patient logs revealed that DTM patient testing was being performed by a total of seven providers. 2. There was no documentation of initial training and competency assessment for five of the seven providers performing the DTM testing on patient specimens. 3. The findings were confirmed during an interview with the laboratory personnel conducted on February 9, 2026 at approximately 4:00 PM. According to the provided CMS-116 form, the laboratory performs 70 mycology tests annually.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

(b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on a review of the laboratory Dermatophyte Test Media (DTM) patient testing records, the lack of training and competency assessment records for five of seven testing personnel performing the DTM testing, and an interview with the laboratory personnel, the technical consultant failed to ensure that semi-annual competency assessment was performed and documented for five of seven personnel who perform the DTM testing on patient specimens. Findings include: 1. A review of the patient logs revealed that DTM patient testing was being performed by a total of seven providers. 2. There was no documentation of semi-annual competency assessment during the first year of employment for five of the seven providers performing the DTM testing on patient specimens. 3. The findings were confirmed during an interview with the laboratory personnel conducted on February 9, 2026 at approximately 4:00 PM. According to the provided CMS-116 form, the laboratory performs 70 mycology tests annually.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

(b)(9) Thereafter, evaluations must be performed at least annually

This STANDARD is not met as evidenced by:
Based on a review of the laboratory Dermatophyte Test Media (DTM) patient testing records, the lack of training and competency assessment records for five of seven testing personnel performing the DTM testing, and an interview with the laboratory personnel, the technical consultant failed to ensure that annual competency assessment was performed and documented for five of seven personnel who perform the DTM testing on patient specimens. Findings include: 1. A review of the patient logs revealed that DTM patient testing was being performed by a total of seven providers. 2. There was no documentation of annual competency assessment during the first year of employment, and annual competency assessment thereafter for five of the seven providers performing the DTM testing on patient specimens. 3. The findings were confirmed during an interview with the laboratory personnel conducted on February 9, 2026 at approximately 4:00 PM. According to the provided CMS-116 form, the laboratory performs 70 mycology tests annually.

D6064

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(a)

Each individual performing moderate complexity testing must-- (a) possess a current license issued by the State in which the laboratory is located, if such licensing is required; and

This STANDARD is not met as evidenced by:

Based on a review of the laboratory Dermatophyte Test Media (DTM) patient test log, a review of the State of Nevada Division of Health Care Purchasing and Compliance records (the Division), a review of the Nevada Revised Statutes (NRS), and an interview with the laboratory personnel, five of seven testing personnel failed to obtain as an Office Laboratory Assistant as required by the State of Nevada. Findings include: 1. A review of the patient logs revealed that DTM patient testing was being performed by a total of seven providers. 2. A review of the Division of Health Care Purchasing and Compliance records revealed that five of seven personnel had not obtained certification as an Office Laboratory Assistant as required by the State of Nevada. 3. Nevada Revised Statutes NRS 652.210(1) permits physician assistants (PA) and advanced practice registered nurses (APRN) to perform tests classified as a waived test by the Food and Drug Administration (FDA) without obtaining certification from the Division as an Office Laboratory Assistant. The DTM test is classified by the FDA as a moderate complexity test. 4. The findings were confirmed during an interview with the laboratory personnel conducted on February 9, 2026 at approximately 4:00 PM. According to the provided CMS-116 form, the laboratory performs 70 mycology tests annually.