

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D0095280	(X3) Date Survey Completed 06/07/2022
Name of Provider or Supplier Integrated Dermatology Of Groton, Llc	Street Address, City, State 481 Gold Star Hwy, Ste 201, Groton, CT	
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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to establish an approved written procedure for scabies preparation and dermatophyte test medium (DTM) testing prior to patient testing in the subspecialties of mycology and parasitology. Findings include: 1. Record review on 06/06/2022 of the 'Laboratory Management Manual Index' binder revealed lack of documentation for the following: a. Approved written procedure for scabies preparation. b. Approved written procedure for DTM testing. 2. Staff interview on 06/06/2022 at 12:10 PM with the laboratory histotechnician confirmed the above findings. 3. The laboratory performs 29 tests in the subspecialty of mycology, and 18 tests in the subspecialty of parasitology.</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6)</p>

The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on record review, surveyor observation and staff interview, the laboratory failed to follow its written H&E procedure to ensure proper specimen staining of tissue specimens in the subspecialty of histopathology. Findings include: 1. Surveyor observation on 06/06/2022 at 10:50 AM of the slide staining station revealed a posted staining protocol on the front facing fume hood. 2. Record review of the 'Laboratory Management Manual Index' binder Hematoxylin and Eosin Stain approved procedure as compared to the posted staining protocol in #1 above revealed the following: a. 10 of 12 reagent steps did not match the written procedure. b. 12 of 12 reagent timing steps for the number of 'dips' did not match the written procedure. 3. Staff interview on 06/06/2022 at 10:55 AM with the laboratory histotechnician confirmed the above findings and commented when staining, the posted staining protocol is what is followed versus the approved procedure. 4. The laboratory performs 36 MOHS procedures annually utilizing the H&E stain in the subspecialty of histopathology.

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 surveyor observation, record review and staff interview, the laboratory failed to discontinue the use of expired reagents prior to patient testing in the subspecialty of histopathology and the subspecialty of mycology. Findings include: 1. Surveyor observation on 06/06/2022 at 12:45 PM of the laboratory work bench revealed the use of the following expired reagents: a. Potassium Hydroxide (KOH) 10% in DMSO with an expiration date of 01/2022. b. OpticMount T, Toluene with an expiration date of 06/2019. c. SubXero Freezing Medium with an expiration date of 09/2021. 2. Record review on 06/06/2022 of the patient testing log for KOH and scabies revealed 3 KOH preparations were performed using the expired reagent. 3. Record review on 06/06/2022 of the 'MOHS Accession Log' revealed from October 2021 until June 6, 2022, the laboratory performed 35 MOHS procedures utilizing the OpticMount T, Toluene and SubXero Freezing expired reagents. 4. Staff interview on 06/06/2022 at 12:45 AM with the laboratory histotechnician (HT) confirmed the above findings. HT commented that she was unaware that the OpticMount T, Toluene and SubXero Freezing had expired.

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 staff interview, the laboratory failed to perform quality control for each prepared commercially dermatophyte test medium (DTM) lot and shipment for its ability to support growth, select or inhibit specific organisms or produce a biochemical response in the subspecialty of mycology. Findings include: 1. Record review on 06/06/2022 of the 'Laboratory Management Manual Index' binder revealed lack of documentation for the following: a. Approved written individualized quality control plan. b. Approved written procedure for DTM testing. 2. Record review on 06/06/2022 of the monthly DTM log from December 2021 through June 2022 revealed the following: a. ACU-DTM box with a lot number of D-1428-0721, receive date of 12/21/2022 and an expiration date of 07/20/2023. b. Monthly documentation of the physical characteristics and deterioration of the media. 3. Staff interview on 06/06/2022 at 12:10 PM with the laboratory histotechnician (HT) confirmed the above finding. The HT further commented the lab is no longer required to perform quality control according to the manufacturer. 4. The laboratory performs 29 DTM tests in the subspecialty of mycology annually.

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 staff interview, the laboratory failed to assess testing personnel for the years of 2020 and 2021 for the subspecialties of mycology and parasitology. Findings include: 1. Record review on 06/06/2022 of the 2021 patient log testing revealed the following: a. Potassium hydroxide (KOH) testing was performed on 38 of 50 testing days. b. Scabies testing was performed on 3 of 50 testing days. c. Dermatophyte Test Medium (DTM) testing was performed on 15 of 50 testing days. 2. Record review on 06/06/2022 of the 'Laboratory Management Manual Index' binder revealed the following: a. "Competency Evaluations: Yearly evaluations will be conducted on all laboratory personnel. These evaluations will be maintained in the Laboratory Manual". b. Lack of documentation of annual competency assessments for 3 of 3 testing personnel in 2020 and 2021 for KOH, scabies, and (DTM) testing. 3. Staff interview on 06/06/2022 at 12:55 PM with the laboratory director confirmed the above findings. 4. The laboratory performs 29 tests in the subspecialty of mycology, and 18 tests in the subspecialty of parasitology.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory director failed to ensure the laboratory written quality assurance policy for the review and revision of procedure manuals and for the competency assessment of moderate complexity testing personnel was being followed. Findings include: 1. Record review on 06/06/2022 of the laboratory's 'Quality Assurance' policy revealed the following: a. Section 3: "Review and Revision of Procedure Manual: The procedure manuals will be reviewed every year. If any revisions are to be made all employees will be given a revision. The Laboratory Director will review and sign the procedure manual on a yearly basis". b. Section 8: "Competency Evaluations: Yearly evaluations will be conducted on all laboratory personnel. These evaluations will be maintained in the Laboratory Manual". 2. Record review on 06/06/2022 of the 'Laboratory Management Manual Index' binder revealed the lack of documentation for the following: a. Active review of the procedure manual by the Laboratory Director for the year of 2021. b. Staff competency assessment for 3 of 3 moderate complexity testing personnel for the years of 2020 and 2021. 3. Staff interview on 06/06/2022 at 10:30 AM with the laboratory histotechnician confirmed the above findings. 4. The laboratory performs 36 MOHS procedures in the subspecialty of histopathology, 29 tests in the subspecialty of mycology, and 18 tests in the subspecialty of parasitology annually.