

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D1063292	(X3) Date Survey Completed 10/10/2019
Name of Provider or Supplier Trinity Health Iha Medical Group Dermatology	Street Address, City, State 4990 W Clark Road Suite 200, Ypsilanti, MI	
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	D0000 A recertification survey was completed on October 10, 2019. During the survey writing process, it was determined that Immediate Jeopardy (IJ) existed for the following condition-level deficiencies: Immunology - 42 CFR 493.1208
D5014	<p>GENERAL IMMUNOLOGY CFR(s): 493.1208</p> <p>If the laboratory provides services in the subspecialty of General immunology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: . Based on document review and interview, the laboratory failed to meet Immunology requirements as specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. Findings include: 1. The laboratory was using the Novodiax ihcDirect Cytokeratin 5 kit immunohistochemical staining kit that exceeded the manufacturer's expiration date. Refer to D5417. 2. The laboratory failed to establish performance specifications for the ihcDirect Cytokeratin 5 test kit. Refer 5423. 3. The laboratory failed to check the immunohistochemical stains for positive and negative reactivity each time of use. Refer D5475.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:</p>

. Based on observation, review of the manufacturer's package insert, and interview with the Laboratory Director (LD), the office manager (OM), and the laboratory liaison, the laboratory was using the NovodiAx ihcDirect Cytokeratin 5 immunohistochemical staining kit that exceeded the manufacturer's expiration date for 4 (date of testing: 4/03/19, 4/25/19, 4/25/19, and 5/23/19) of 4 patient's stained. Findings include: 1. During a tour of the laboratory on 10/10/2019 at 1:00 pm, the surveyor observed the ihcDirect Cytokeratin 5 kit in the refrigerator with an expiration date of 2/07/2019. 2. A review of the manufacturer's package insert stated, "This kit is suitable for use until expiry date when stored at 2-8 degree C." 3. A review of the "IHA - Dermatologic Surgery Consultant IHC Cases Log" revealed four patients were tested on 4/03/19, 4/25/19, 4/25/19, and 5/23/19 using the expired ihcDirect Cytokeratin 5 test kit. 4. During the interview on 10/10/2019 at 1:00 pm, the LD, OM and the office liaison acknowledged the laboratory used an expired kit.

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 document review, procedure review, and interview with the Laboratory Director (LD), the office manager (OM), and the laboratory liaison, the laboratory failed to establish performance specifications for the ihcDirect Cytokeratin 5 test kit for 3 (4/03/19, 4/25/19, and 5/23/19) of 3 testing dates for 4 patients. Findings include: 1. Document review of the "IHA - Dermatologic Surgery Consultants IHC Cases Log" revealed a new immunohistochemical staining kit was put into use on 4/03/19. 2. A review of the "IHA Mohs' Laboratory Standard Operating Procedure Manual" signed on 7/02/19 under section 8 "Reagents in Mohs' lab, Staining process, and coverslipping process, IHC Protocol" states Immunohistochemistry (IHC) stains is a "detector of aggressive cutaneous neoplasma." 3. The surveyor checked in the "FDA" CLIA database to determine the specialty and the complexity of the ihcDirect Cytokeratin 5 test kit and found no evidence that the test had been categorized by the FDA. 4. There was no documentation to show the kit had performance specifications prior to reporting 4 patient results on the following days: a. 4/03/19 - 1 patient tested b. 4/25/19 - 2 patients tested c. 5/23/19 - 1 patient tested 5. On 10/10/19 at approximately 3:00 pm, the LD stated "the stain was being used to rule out melanoma." 6. During the phone interview on 10/15/19 at approximately 9:22 am, the OM acknowledged the laboratory did not perform and document the performance specifications.

D5475

CONTROL PROCEDURES
CFR(s): 493.1256(e)(3)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (3) Check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use. (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 Laboratory Director (LD), the office manager (OM), and the laboratory liaison, the laboratory failed to check the immunohistochemical stains for positive and negative reactivity each time of use for 3 (dates of testing: 4/03/19, 4/25/19, and 5/23/19) of 3 dates of patient testing. Findings include: 1. A record review of the "IHA-Dermatologic Surgery Consultants IHC Cases Log" revealed four patient's were tested using the ihcDirect Cytokeratin 5 test kit. The laboratory did not have any documentation to show the immunohistochemical stain was checked for positive and negative reactivity each day of testing as follows: a. 4/03/19 - 1 patient tested b. 4/25/19 - 2 patients tested c. 5/23/19 - 1 patient tested 2. During the interview on 10/10/19 at 1:00 pm, the LD, OM, and the laboratory liaison acknowledge the laboratory did not perform and document positive and negative immunohistochemical stain reactivity each day of testing.

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 record review and interview with the Laboratory Director (LD), the office manager (OM) , and the laboratory liaison, the laboratory failed to maintain a record system that included the specimen receipt time into the laboratory for each tissue specimen for 12 (MS17-1325, MS17-1633, MS18-109, MS18-325, MS18-513, MS18-845, MS18-1122, MS18-1358, MS19-180, MS19-494, MS19-774, and MS19-1103) of 12 Mohs' patient charts audited. Findings include: 1. A record review for 12 of 12 Mohs' cases revealed the laboratory failed to include the specimen receipt time into the laboratory for the processing of each tissue specimen on the final Mohs' map as follows: a. MS17-1325 - no time for level 1 and 2 b. MS17-1633 - no time for levels 1 and 2 c. MS18-109 - no time for level 1 d. MS18-325 - no time for level 1 e. MS18-513 - no time for level 1 f. MS18-845 - no time for level 1 g. MS18-1122 - no time for level 1 and 2 h. MS18-1358 - no time for levels 1-3 i. MS19-180 - no time for level 1 j. MS19-494 - no time for levels 1-3 k. MS19-774 - no time for levels 1-3 l. MS19-1103 - no time for levels 1 and 2 2. During the interview on 10/10/2019 2:20 pm, the LD, OM, and the laboratory liaison acknowledged the final Mohs' map scanned into the patient's chart did not contain the receipt times for each specimen level.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification,

either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Laboratory Director (LD), the office manager (OM), and the laboratory liaison, the laboratory failed to indicate the name and/or address of the laboratory location where testing was performed for 1) 1 (FS18-0001) of 1 frozen section final report and 2) for 12 (MS17-1325, MS17-1633, MS18-109, MS18-325, MS18-513, MS18-845, MS18-1122, MS18-1358, MS19-180, MS19-494, MS19-774, and MS19-1103) of 12 Mohs' cases reviewed. Findings include: 1. A record review for 1 (FS18-0001) of 1 frozen section final reports revealed the address of the testing facility was not included on the final report in the patient's chart. 2. A record review for 12 (MS17-1325, MS17-1633, MS18-109, MS18-325, MS18-513, MS18-845, MS18-1122, MS18-1358, MS19-180, MS19-494, MS19-774, and MS19-1103) of 12 Mohs' cases reviewed revealed the name and address was not included on the final Moths' map scanned into the patient's chart. 3. During the interview on 10/10/19 at 2:07 PM, the LD, OM, and the office liaison acknowledged the name and/or address was not included on the final frozen section report and the Moths' map.

D5821

TEST REPORT
CFR(s): 493.1291(k)

When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Laboratory Director (LD), the office manager (OM), and the laboratory liaison, the laboratory failed to issue corrected patient reports when the case number was changed for 89 (case #857 - 945) of 89 Mohs' cases performed in December 2009. Findings include: 1. On 10/10/2019 at approximately 2:30 pm, record review for December 2009 revealed for 89 (case #857-945) of 89 Mohs' cases written on the "Mohs' Specimen Accession Log" the case numbers were renumbered. The Mohs' map did not show the change in the numbering. 2. During the interview on 10/10/2019 at approximately 2:30 pm, The LD, OM, and the laboratory liaison acknowledged the change in the case numbering was not corrected on the final Mohs' map.