| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 15D0980525 | 07/12/2023 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Christopher Obeime Md | 3330 Founders Road, Suite 100, Indianapolis, IN | |

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 |
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| **D0000** | A recertification survey was completed on 7/12/2023. It was determined that the following condition-level deficiencies existed: 42 C.F.R. 493.1203 Condition: Mycology |
| **D5006** | MYCOLOGY<br>CFR(s): 493.1203<br><br>If the laboratory provides services in the subspecialty of Mycology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1263, and 493.1281 through 493.1299.<br><br>This CONDITION is not met as evidenced by:<br>Based on observation, document review and interview, the laboratory failed to: 1) perform twice annual verification of accuracy in the subspecialty of Mycology (KOH-Potassium Hydroxide and Dermatophyte Testing) (refer to D5217); 2) include the following policies: step-by-step performance, control procedures, limitations of the test methodology, or the system for reporting patient results in their procedure manual (refer to D5403); 3) remove expired reagents (KOH-Potassium Hydroxide) used for testing performed in 2021 (Refer to 5417); 4) check each lot number and shipment of Dermatophyte Test Medium (DTM) for positive and negative reactivity (Refer to D5471). |
| **D5217** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(c)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by: |

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| | Repeat Deficiency Based on observation, document review and interview, the laboratory failed to perform twice annual verification of accuracy in the subspecialty of Mycology (KOH-Potassium Hydroxide and Dermatophyte Testing -DT) for KOH testing in 2021 and four (PT#6-PT#9) of four patients with DT reviewed in 2023. Findings include: 1) During a tour of the laboratory area on 7/12/2023 at 9:45 am the following was observed: a) One bottle of "KOH 10% Potassium Hydroxide" Reorder # KOH/10/2. b) Three bottles of "Delasco Alcohol". c) Four bottles with Dermatophyte Test Medium (DTM) with patient specimens were being processed. d) There were no additional vials of Dermatophyte Test Medium in the laboratory. 2.) In interview on 7/12/2023 at 10:23 am, SP-1 (Medical Assistant) indicated the Dermatophyte Test Medium is stored in the refrigerator but there is none left. They must have used that last of it with the current four patients. Upon request for a log for Dermatophyte testing, SP-1 indicated a log is not kept, documentation is stored in the medical record. 3) Review of the "Indiana State Department of Health CLIA Certification Program Enclosure I Test Methodology and Annual Test Volume Log" signed by the laboratory director on 7/12/2023 indicated the laboratory performed approximately 10 KOH test annually, with a note "Stopped January 1, 2022", and 10 DTM. 4) Review of patient charts for the four patient's specimens processed in DTM during the tour indicated the following: PT#=patient number PT# Date Chart Note: PT#6 6/26/23 DTM Obtained PT#7 6/29/23 DTM Obtained PT#8 6/28/23 DTM Obtained PT#9 6/9/23 DTM Obtained There was no documentation in the chart of any of the DTM being read or final determination. 5) Review of the document "ACU-DTM (Dermatophyte Test Medium) Directions for Use" no date, indicated the following: "ACU-DTM" is available in boxes containing 24 vials each. 6) Review of the "CLIA Program" binder indicated there was no twice annual verification for KOH in 2021. There were two letters dated November 16, 2021, and January 1, 2023, stating the laboratory director and another physician agreed "to exchange mycology (KOH- potassium hydroxide slides for CLIA proficiency testing peer review ..." There was no documentation of peer review for KOH. There was no policy for twice annual verification of Dermatophyte testing and no documentation of verification being performed. 7) Upon request for KOH testing performed in 2021, on 7/12/2023 at 12: 15 pm SP#2 (laboratory director) indicated they do not have a log for KOH testing. The results are documented in the chart but there is no way to find a specific patient who had KOH testing. 8) Upon request a log of testing or documentation of twice annual verification for Dermatophyte Testing on 7/12/2023 at 12:03 pm, SP-1 (Medical Assistant) indicated there was no twice annual verification performed for dermatophyte testing and no log is kept. 9) In interview on 7/12/23 at 12:40 pm, SP-2 (laboratory director) confirmed there was no twice annual verification of accuracy performed in 2021 for KOH nor in 2023 for dermatophyte testing. 10) Annual testing volume for KOH in 2021 is approximately 10 and annual test volume for DTM is 10. |
| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>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) The reportable range for test results for the test system as established or verified in |

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| | 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.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation, document review and interview, the laboratory failed to include the following in their procedure manual: step-by-step performance, control procedures, limitations of the test methodology, or the system for reporting patient results for Dermatophyte Tests performed on four (PT#6-PT#9) of four patients in 2023. Findings include: 1) During a tour of the laboratory area on 7/12/2023 at 9:45 am, four bottles with Dermatophyte Test Medium (DTM) with patient specimens were being processed. 2) Review of the "Indiana State Department of Health CLIA Certification Program Enclosure I Test Methodology and Annual Test Volume Log" signed by the laboratory director on 7/12/2023 indicated the laboratory performed approximately 10 DTM. 3) Review of patient charts for the four patient's specimens processed in DTM during the tour indicated the following PT#=patient number PT# Date Chart Note: PT#6 6/26/23 DTM Obtained PT#7 6/29/23 DTM Obtained PT#8 6 /28/23 DTM Obtained PT#9 6/9/23 DTM Obtained There was no documentation in the chart of any of the DTM being read or final determination. 4) Review of the "CLIA Program" binder indicated it contained the "Official Policy and Procedure Manual" reviewed by the laboratory director in February 2021. The binder did not contain any policies or procedures for DTM including: a. step-by-step performance, b. control procedures, c. limitations of the test methodology, or d. the system for reporting patient results 5) Review of the document "ACU-DTM (Dermatophyte Test Medium) Directions for Use" no date, indicated the following: a. The end user must perform a minimum of positive and negative control on each new lot or batch purchased. b. A log of the quality control (QC) with lot numbers must be maintained. c. The directions for use did not include step by step instructions for collecting the specimen and reporting the test results. 7) In interview on 7/12/23 at 11:30 am, SP-2 (laboratory director) confirmed there were no policies for DTM, and there were no instructions on how to complete the testing. If it changes colors, it is positive. 8) In interview on 7/12/2023 at 12:15 pm, SP-1 (Medical Assistant) indicated the DTM is read every 30 days, and the check is done on Friday. 8) Annual testing volume for DTM is 10. |
| **D5417** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(d)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation, document review and interview, the laboratory failed to ensure reagents for KOH-Potassium Hydroxide testing performed in 2021 had not expired. Findings include: 1) During a tour of the laboratory area on 7/12/2023 at 9:45 am the |

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| | following was observed: a) One bottle of "KOH 10% Potassium Hydroxide" Reorder # KOH/10/2 had expired on May 2018. b) Three bottles of "Delasco Alcohol" item ALA had expired on 8/27/2020. 2) Review of the "Indiana State Department of Health CLIA Certification Program Enclosure I Test Methodology and Annual Test Volume Log" signed by the laboratory director on 7/12/2023 indicated the laboratory performed approximately 10 KOH test annually, with a note "Stopped January 1, 2022". 3) Review of the "CLIA Program" binder indicated it contained the "Official Policy and Procedure Manual" reviewed by the laboratory director in February 2021. Under "Quality Control... 2. Reagents" the policy read, "b) The reagents are discarded after the expiration date." 4) Upon request for KOH testing performed in 2021, on 7/12 /2023 at 12:15 pm SP#2 (laboratory director) indicated they do not have a log for KOH testing. The results are documented in the chart but there is no way to find a specific patient who had KOH testing. 5) Annual testing volume for KOH in 2021 is approximately 10. |
| **D5471** | CONTROL PROCEDURES<br>CFR(s): 493.1256(e)(1)(g)<br><br>(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation, document review and interview, the laboratory failed to check each lot number and shipment of Dermatophyte Test Medium (DTM) for positive and negative reactivity including four (PT#6-PT#9) of four patients with Dermatophyte testing in 2023. Findings include: 1) During a tour of the laboratory area on 7/12/2023 at 9:45 am, four bottles of Dermatophyte Test Medium (DTM) with patient specimens were being processed. 2) Review of the "Indiana State Department of Health CLIA Certification Program Enclosure I Test Methodology and Annual Test Volume Log" signed by the laboratory director on 7/12/2023 indicated the laboratory performed approximately 10 DTM. 3) Review of patient charts for the four dermatophyte testing patients observed during the tour indicated the following: PT#=patient number PT# Date Chart Note: PT#6 6/26/23 DTM Obtained PT#7 6/29/23 DTM Obtained PT#8 6 /28/23 DTM Obtained PT#9 6/9/23 DTM Obtained There was no documentation in the chart of any of controls for DTM. 4) Review of the "CLIA Program" binder indicated it contained the "Official Policy and Procedure Manual" reviewed by the laboratory director in February 2021. The binder did not contain any policies or procedures for DTM including quality control procedures. 5) Review of the document "ACU-DTM (Dermatophyte Test Medium) Directions for Use" no date, indicated the following: a. The end user must perform a minimum of positive and negative control on each new lot or batch purchased. b. A log of the quality control (QC) with lot numbers must be maintained. c. QC labels are enclosed in each box. 6) In interview on 7/12/23 at 11:30 am, SP-2 (laboratory director) confirmed quality control had not been completed for the DTM testing performed. 7) Annual testing volume for DTM is 10. |
| **D6084** | LABORATORY DIRECTOR RESPONSIBILITIES |

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| | CFR(s): 493.1445(e)(2)<br><br>The laboratory director must ensure that the physical plant and environmental conditions provide a safe environment in which employees are protected from physical, chemical, and biological hazards.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation, document review, and interview, the laboratory director failed to ensure 1) proper chemical storage for one of four chemicals observed (Delasco Alcohol); and 2) eye wash station was not available for first aid of staff. Findings included: 1. During a tour of the laboratory area on 7/12/2023 at 9:45 am the following was observed: a) One bottle of "KOH 10% Potassium Hydroxide" b) One bottle of "Delasco Alcohol "sitting on top of the Ritter autoclave. The bottle was marked flammable on label. "Danger! Hazards: Highly flammable liquid and vapor.. Precautionary: Keep away from heat/sparks/open flames/hot surfaces.." c) Two additional bottle of "Delasco Alcohol" were stored in the cabinet below the Ritter autoclave. d) Four bottles with Dermatophyte Test Medium with patient specimens were being processed, were stored on a shelf above eye level. e) One container of" Maxiwipe Germicidal Cloths" were used for disinfection. f) There was no eye wash observed. 2. In interview on 7/12/2023 at 11 am, SP-1 (Medical Assistant) confirmed there was no eye wash in the laboratory. They had an eye wash in the old laboratory, but they had an address change on February 1, 2023 and did not remember to bring it with them. 3. Review of Safety Data Sheets (SDS) indicated the following: a. SDS for "KOH 10% Potassium Hydroxide" read: "Section 4. First-aid Measures... Eye contact... Immediately flush eyes with plenty of water for at least 15 minutes, occasionally lifting the upper and lower eyelids..." b. SDS for "Delasco Alcohol" read: "Highly flammable liquid and vapor... 4. First-aid measures: After eye contact: Hold eyelids apart and flush eyes with plenty of water for at least 15 minutes... 7. Handling and storage... Store in cool dry conditions... Protect from heat and direct sunlight." c. SDS for Dermatophyte Test Medium read: "4. First aid measures... After eye contact Rinse open eye for 15 minutes under running water..." d. SDS for "Maxiwipe Germicidal Cloths" read "4. First Aid Measures... Eye contact If in eyes, hold eye open and rinse slowly and gently with water for 15-20 minutes...Symptoms may include stinging, tearing, redness, swelling and blurred vision." 4. Annual testing volume for KOH in 2021 is approximately 10 and annual test volume for DTM is 10. |
| **D6095** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(6)<br><br>The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation, document review and interview, the laboratory director failed ensure maintenance of the OMAX microscope used for histology testing was completed per policy in 2022 or 2023 for four (PT#2-PT#5) of five patients reviewed with histology testing performed. Findings include: 1) During a tour of the laboratory area on 7/12/2023 at 9:45 am the OMAX microscope was observed to be available for histopathology slide reading. 2) Review of the "Indiana State Department of Health CLIA Certification Program Enclosure I Test Methodology and Annual Test Volume Log" signed by the laboratory director on 7/12/2023 indicated the laboratory |

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| | performed approximately 1200 histology tests annually, using (Hematoxylin and Eosin -H&E-stained slides). 3) Review of patient records indicated the following patients had slides read in 2022 and 2023 using the OMAX Microscope: PT#=patient number PT# Date Number of Slides: PT#2 3/10/23 3 slides PT#3 2/27/22 2 slides PT#4 6/19/23 2 slides PT#5 9/28/22 2 slides 4) Review of the "CLIA Program" binder indicated it contained the "Official Policy and Procedure Manual" reviewed by the laboratory director in February 2021. Under "Quality Control... 1. Microscope" the policy required the microscope to be cleaned on an annual basis professionally and general cleaning performed monthly. A copy of the receipt of purchase for the OMAX microscope indicated it was purchased on February 18, 2021. There was no documentation of professional cleaning in 2022, or 2023. There was no documentation of monthly cleaning. 5) In interview on 7/12/23 at 12:40 pm, SP-2 (laboratory director) confirmed there was no documentation of maintenance for the new microscope. 8) Annual testing volume for histology testing is 1200. |