| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 23D0701648 | 01/31/2023 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Wsu Infectious Disease Laboratory | 275 E Hancock Street Room 039, Detroit, 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** |
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| **D2015** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(5)(6)<br><br>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.<br><br>This STANDARD is not met as evidenced by:<br>. Based on record review and interview with the Testing Personnel, the laboratory failed to have the attestation statement provided by the proficiency testing program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens for 2 (2022 3rd Event and 2021 2nd Event) of 4 proficiency testing events reviewed. Findings include: 1. A review of the laboratory's "Proficiency Testing Procedure" revealed a section stating, "The attestation statement must be signed the testing personnel and the director. The director must sign the attestation statement agreeing the PT samples were tested just like samples from patients. The attestation statement must be retained with the original paperwork." 2. A review of the laboratory's College of American Pathologists' (CAP) proficiency testing records revealed a lack of attestation statement for the 2022 3rd and 2021 2nd proficiency testing events. 3. An interview on 1/31/23 at 12:13 pm with the Testing Personnel confirmed the attestation statements listed above were not present. |
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| **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, record review, and interviews, the laboratory failed to document temperature monitoring for its freezer, refrigerator, and incubators used in mycology testing (Refer to D5413), ensure culture media was labeled with the expiration dates (Refer to D5415), and perform control procedures according to the manufacturer's specifications for its API 20 C AUX Yeast Identification System (Refer to D5479). |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.<br><br>This STANDARD is not met as evidenced by:<br>. Based on record review and interview with the Testing Personnel, the laboratory failed to document temperature monitoring for its freezer, refrigerator, and incubators used in mycology testing for 7 (10/2/21, 2/8/22, 5/10/22, 6/21/22, 8/12/22, 9/2/22, and 12/2/22) of 12 testing dates reviewed. Findings include: 1. A review of the laboratory's patient test records revealed the following patients had mycology testing reported without temperature monitoring for its incubators, freezer, or refrigerator recorded: a. Patient 768-21 performed on 10/2/21 b. Patient 68-22 performed on 2/8 /22 c. Patient 265-22 performed on 5/10/22 d. Patient 378-22 performed on 6/21/22 e. Patient 495-22 performed on 8/12/22 f. Patient 565-22 performed on 9/2/22 g. Patient 733-22 performed on 12/2/22 2. A review of the laboratory's policies revealed a lack of policy for the frequency of temperature monitoring. 3. An interview on 1/31/23 at 11:20 am with the Testing Personnel revealed temperature was to be documented each date the laboratory was open and confirmed the testing dates listed above did not have temperature monitoring recorded. |
| **D5415** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(c)<br><br>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. |

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| | This STANDARD is not met as evidenced by:<br>. Based on observation and interview with the Testing Personnel, the laboratory failed to ensure culture media was labeled with the expiration dates for 2 (Sabouraud Dextrose Agar and Chlamydospore agar) of 2 media types observed. Findings include: 1. The surveyor observed the Sabouraud Dextrose and Chlamydospore mycology culture media in the laboratory's refrigerator on 1/31/23 at 9:18 am without expiration dates listed on the media plates. 2. An interview on 1/31/23 at 9:24 am with the Testing Personnel confirmed the laboratory makes its own media and had not indicated the expiration dates on the culture media. |
| **D5433** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(b)(1)<br><br>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.<br><br>This STANDARD is not met as evidenced by:<br>. Based on observation, record review, and interview with the Testing Personnel, the laboratory failed to follow its established procedure for the performance of microscope maintenance for 19 months (June 2021 to January 2023) since the laboratory indicated maintenance was due. Findings include: 1. The surveyor observed the laboratory's Leitz Laborlux microscope in the laboratory on 1/31/22 at 9: 18 am with a sticker indicating the last service was performed on 6/12/20 and the next service was due 7/12/21. 2. A review of the laboratory's "Quality Control Policies and Procedures WSU Infectious Disease Mycology Laboratory" policy revealed a section titled, "Equipment Maintenance" stating, "In addition to research-only equipment, microscopes and laminar flow hoods used for processing clinical specimens will be serviced/inspected/certified on a yearly basis, records of which will be kept in the laboratory." 3. A review of the laboratory's "Equipment maintenance" log revealed the last service for the microscope was performed on 6/12/20 and that it was due on 7/12 /21. 4. An interview on 1/31/23 at 9:28 am with the Testing Personnel confirmed the laboratory had not had the microscope serviced according to its established policy. |
| **D5479** | CONTROL PROCEDURES<br>CFR(s): 493.1256(e)(5)(g)<br><br>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>. Based on record review and interview with the Testing Personnel, the laboratory failed to perform control procedures according to the manufacturer's specifications for its API 20 C AUX Yeast Identification System for 2 (January 2021 to January 2023) |

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| | of 2 years reviewed. Findings include: 1. A review of the laboratory's "Quality Control of Speciation Tests" revealed a section titled "API 20C AUX" stating, "A known ATCC yeast sample is tested on each API lot and results recorded. Our laboratory uses API strips manufactured by BIOMERIEUX. Their recommendation for Quality Control strains is to use C. guilliermondii, C. laurentii and C glabrata. These three strains should be tested to demonstrate positive and negative reactivity for most of the API 20 C AUX tests. ATCC strains of Candida guilliermondii (9390), Candida glabrata (90030) and Cryptococcus laurentii have been chosen to perform quality control of API strips in our lab." 2. A review of the laboratory's "API 20 C AUX Yeast Identification System" manufacturer's instructions revealed a section titled "Quality Control" stating, "As there are no substrates that are consistently sensitive to degradation during shipping conditions, streamlined quality control may be conducted by testing two strains: Cryptococcus laurentii ATCC 18803 that is mostly positive and Candida glabrata ATCC 15126, which is mostly negative for reactions on the API 20 C AUX System. For those users who are required to perform comprehensive quality control testing with the strip, the following three strains should be tested to demonstrate positive and negative reactivity for the most of the API 20 C AUX system tests: a. Cryptococcus laurentii b. Candida glabrata c. Candida guilliermondii 3. A review of the laboratory's "Quality Control of API 20 C AUX Yeast" log revealed the laboratory had only used one organism in its quality control testing: a. Quality Control testing on 3/4/20 for lot 100790230 expiring on 3/3/21 was tested with C. guilliermondii. b. Quality Control testing on 2/1/21 for lot 109187163 expiring on 7/2/22 was tested with C. guilliermondii. c. Quality Control testing on 1/26 /22 for lot 1008840910 expiring on 9/23/22 was tested with C. glabrata. d. Quality Control testing on 8/17/22 for lot 1008840870 expiring on 1/4/23 was tested with C. guilliermondii. 4. A review of the laboratory's patient logs from January 2021 to January 2023 revealed a total of 53 patients had testing using the API 20 C AUX Yeast Identification Test strips when control procedures had not been followed. 5. An interview on 1/31/23 at with the Testing Personnel revealed the laboratory performed quality control testing with each new lot or shipment with one organism. |
| **D6076** | LABORATORY DIRECTOR<br>CFR(s): 493.1441<br><br>The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.<br><br>This CONDITION is not met as evidenced by:<br>. Based on observations, review of records, and interviews, the Laboratory Director failed to ensure the corrective action plan established for unacceptable proficiency testing results was followed (Refer to D6092), ensure the established quality control program for mycology testing was maintained (Refer to D6093), and ensure the quality assessment program was maintained according to its established policy (Refer to D6094). |
| **D6092** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(4)(iv)<br><br>The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. |

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| | This STANDARD is not met as evidenced by:<br>. Based on record review and interview with the Testing Personnel, the Laboratory Director failed to ensure the corrective action plan established for unacceptable proficiency testing results was followed for 1 (2021 3rd Event) of 4 proficiency testing events reviewed. Findings include: 1. A review of the laboratory's "Proficiency Testing Procedure" revealed a section stating, "If there are any unacceptable results, there must be documentation regarding each unacceptable result. The use of the Proficiency Testing Corrective Action form may be required. The director must sign and date any corrective action that is used." 2. A review of the laboratory's College of American Pathologists' (CAP) proficiency testing records revealed 2021 3rd Event specimen F1-15 had an unacceptable result for yeast identification and no documentation of corrective action performed. 3. An interview on 1/31/23 at 12:15 pm with the Testing Personnel confirmed documentation of corrective action for the proficiency testing event listed above was not present. |
| **D6093** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5)<br><br>The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.<br><br>This STANDARD is not met as evidenced by:<br>. Based on record review and interview with the Testing Personnel, the Laboratory Director failed to ensure the established quality control program for mycology testing was maintained. Refer to D5479. |
| **D6094** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>. Based on record review and interview with the Testing Personnel, the Laboratory Director failed to ensure the quality assessment program was maintained according to its established policy for 2 (2021 and 2022) of 2 years reviewed. Findings include: 1. A review of the laboratory's "Quality Assessment Policy" revealed a section stating, "The Quality Systems (QA) for Wayne State University Infectious Diseases Laboratory will be reviewed on an on-going basis annually to monitor, assess and when indicated, corrected problems identified in the laboratory's quality systems." 2. A review of the laboratory's quality assessment records revealed a lack of quality assessments completed between 6/14/19 and 1/10/23. 3. An interview on 1/31/23 at 11:51 am with the Testing Personnel confirmed quality assessment documentation between 6/14/19 and 1/10/23 was not present. |