| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 36D2214359 | 10/20/2021 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Cwru Advanced Diagnostic Lab | 2103 Cornell Rd, Wolstein Research Building, Cleveland, OH | |

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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| **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 an interview with the Laboratory Director, the laboratory failed to define humidity criteria consistent with the manufacturer's instrument instructions, monitor and document humidity conditions for reliable Advanta Dx SARS-CoV-2 RT-PCR (saliva) testing procedures. All Advanta Dx SARS-CoV-2 RT-PCR (saliva) testing procedures performed in this laboratory from 07/12/2021 to 10/20/2021 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the "BioMark HD System Overview" operating instructions, provided on the date of the inspection, found the following information: "Humidity (relative) 20-80%, non-condensing" 2. Review of the "Juno System Site Requirements Guide", provided on the date of the inspection, found the following information: "Humidity (relative) 20-80%, non-condensing" 3. Review of the laboratory's policies and procedures provided on the date of the inspection, did not find any instructions to monitor and document humidity conditions. 4. The Inspector requested the laboratory's humidity documentation from 07/12/2021 to 10/20/2021 from the Laboratory Director. The Laboratory Director confirmed the laboratory did not establish a policy and procedure to monitor and document humidity conditions consistent with the manufacturer's instructions for Advanta Dx SARS-CoV-2 RT-PCR |

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| | (saliva) testing procedures, did not monitor and document humidity conditions from 07 /12/2021 to 10/20/2021 and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 10/20/2021 at 2:10 PM. %; percent |
| **D6168** | TESTING PERSONNEL<br>CFR(s): 493.1487<br><br>The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of the laboratory's Form CMS-209 and education documentation, the laboratory failed to ensure Testing Personnel (TP) #3 met the qualification requirements of 493.1489 for high complexity testing procedures. Findings Include: 1. The laboratory failed to ensure Testing Personnel (TP) #3 met the high complexity TP qualification requirements. (Refer to D6171) |
| **D6171** | TESTING PERSONNEL QUALIFICATIONS<br>CFR(s): 493.1489(b)<br><br>(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2) (ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b) (4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for |

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| | proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's Form CMS-209 and education documentation, the laboratory failed to ensure Testing Personnel (TP) #3 met the high complexity TP qualification requirements. Findings Include: 1. Review of the laboratory's Form CMS-209, approved and signed by the Laboratory Director on 10/14/2021, found five individuals listed and certified by the Laboratory Director to perform high complexity Advanta Dx SARS-CoV-2 RT-PCR (saliva) testing procedures. 2. Review of education documentation provided for the onsite inspection revealed TP#3 possessed a Master's in Chemical Engineering diploma which is not a recognized laboratory medicine degree and does not meet the minimum TP qualifications for high complexity laboratory testing. 3. The Laboratory Director confirmed via electronic mail on 11/09/2021 at 10:18 AM that the laboratory did not have adequate documentation to show that TP#3 met the high complexity testing personnel requirements. |