Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 36D2061372	**(X3) Date Survey Completed** 10/07/2020
Name of Provider or Supplier Cmcd (Center For Molecular Cancer Diagnostics)	**Street Address, City, State** 7956 Tyler Blvd, Mentor, 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**
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on record review and interviews with the Clinical Consultant (CC), Laboratory Manager (LM) and Technical Supervisor (TS), the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the TaqPath Quantstudio 12 K COVID-19 RT-PCR testing procedures performed from July 16, 2020 to current. All patients tested for TaqPath Quantstudio 12 K COVID-19 RT-PCR testing procedures had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's policy and procedure manuals, titled "SOP", provided on the date of this survey, revealed the following policies and procedures did not indicate the Laboratory Director's approval via signature and date prior to beginning patient testing on July 16, 2020: Quant Studio 12K Flex OpenArray Genotyping Assay Protocol Covid 19 (SARS-CoV-2) detection on QuantStudio 12K (approved 08/10/2020) DNA Extraction Lab Turbo QC Record SOPM of QIAxcel DNA Protocol Temperature /Humidity Monitoring Hazardous Materials Hazardous Waste Contingency Plan 2. The Surveyor requested the laboratory's approved TaqPath Quantstudio 12 K COVID-19 RT-PCR policies and procedures, via the Laboratory Director's signature and date prior to beginning patient testing as well as the above mentioned policies and procedures, from the CC, the LM and the TS. The CC, the LM and the TS confirmed the Laboratory Director did not approve all of the policies and procedures prior to beginning patient testing and were unable to provide the requested documentation on the date of the complaint investigation. The interviews occurred on 10/07/2020 at 11: 15 AM and 3:45 PM.

D6168	TESTING PERSONNEL CFR(s): 493.1487 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. This CONDITION is not met as evidenced by: Based on record review and interviews with the Clinical Consultant (CC), Laboratory Manager (LM) and Technical Supervisor (TS), the laboratory failed to ensure Testing Personnel (TP) #3 met the qualification requirements of 493.1489 for high complexity testing procedures. All high complexity patient testing performed by TP#3 had the potential to be affected by this deficient practice. Findings Include: 1. The laboratory failed to ensure TP#3 met the minimum qualification requirements of 493.1489 for high complexity testing procedures. (Refer to D6171)
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (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 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. This STANDARD is not met as evidenced by: Based on record review and interviews with the Clinical Consultant (CC), Laboratory Manager (LM) and Technical Supervisor (TS), the laboratory failed to ensure Testing Personnel (TP) #3 met the minimum qualification requirements of 493.1489 for high complexity testing procedures. All high complexity patient testing performed by TP#3 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's Form CMS-209, approved and signed by the Laboratory Director on 10/07/2020, found four individuals listed and certified by the Laboratory Director to perform high complexity testing procedures. 2. Review of education documentation revealed one out of four TP, TP#3, achieved a Bachelor of Science degree in General Psychology which does not meet the minimum qualification requirements for high complexity TP. 3. The Inspector requested any additional education documentation for TP#3 that meets the high complexity TP qualification requirements from the CC, the LM and the TS. The CC, the LM and the TS confirmed no other education documentation was available and were unable to provide the requested documentation on the date of the complaint investigation to prove high complexity TP qualification requirements were met for TP#3. The interviews occurred on 10/07/2020 at 11:15 AM and 3:45 PM.