Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2105931	02/09/2022
Name of Provider or Supplier	**Street Address, City, State**	
Quality Metrics Laboratories, Llc	1860 Crown Dr Suite 1408, Dallas, TX	

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	The laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCY: D6168 - 42 C.F.R. 493.1487 Condition: Testing Personnel Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representative was given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was determined the laboratory failed to have documentation of performing competency assessments on the clinical consultant. The findings include: 1. A review of the laboratory's submitted Form CMS 209 revealed the laboratory identified 1 clinical consultant. 2. The laboratory was asked to provide documentation of a competency assessment being performed on the clinical consultant. No documentation was provided. 3. A review of the laboratory's

	policies revealed the facility did not identify the need for or frequency for competency assessments for the clinical consultant. 4. An interview with the compliance administrator on 02/07/2022 at 1045 hours in the break room confirmed the findings.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on review of the laboratory's test menu, review of the laboratory's proficiency testing records, and staff interview, it was revealed the laboratory failed to have documentation of performing twice annual accuracy assessments for toxicology analytes reported quantitatively in 2020 and 2021. The findings include: 1. Review of the CMS-116 form submitted at survey revealed the following non-regulated urine toxicology analytes were reported out quantitatively by the laboratory: 2-Hydroxyethylflurazepam; 6-MAM (monoacetylmorphine); 7-Aminoclonazepam; 9-Hydroxyrisperidone; Alpha-hydroxyalprazolam; Alprazolam; Amitriphtyline; Benzolyecgonine; Zolpidem COOH; Citalopram; Codeine; Cotinine; Cyclobenzaprine; Desipramine; Diazepam; Dihydrocodeine; Doxepin; EDDP (2-Ethylidene-1, 5-Dimethyl-3, 3-Diphenylpyrrolidine); Fentanyl; Gabapenin; Hydrocodone; Hydromorphone; Imipramine; Ketamine; Lorazepam; mCPP; MDA (3,4 - methylenedioxymethamphetamine); MDEA (Methyldiethanolamine); MDMA (2,3-methylenedioxymethamphetamine); Meperidine; Meprobamate; Methadone; Methamphetamine; Methylphenidate; Morphine; Naloxone; N-Desmethyltapentadol; N-Desmethylzopicione; Norbuprenorphine; Nordiazepam; Norfentanyl; Norhydrocodone; Nortriptyline; O-Desmethyltramadol; O-Desmethylvenlafaxine; OPC-3373 (metabolite of aripiprazole); Oxazepam; PCP (Phencyclidine); Phentermine; Pregabalin; Propoxyphene; Ritalinic Acid; Sufentanil; Tapentadol; Temazepam; THCA; Tramadol; Venlafaxine; and Zolpidem. 2. Review of laboratory proficiency testing records (2020 and 2021) revealed the laboratory failed to verify the accuracy of quantitative non-regulated urine toxicology twice in 2020 and 2021. The following analytes had quantitative accuracy assessments performed once in 2020 and once in 2021: 9-Hydroxyrisperidone mCPP MDEA (Methyldiethanolamine) O-Desmethylvenlafaxine Sufentanil Norhydrocodone Tapentadol The following analytes had quantitative accuracy assessments performed once in 2021: Ritalinic acid Naloxone The following analytes did not have quantitative accuracy assessments performed in 2020 and 2021 OPC-3373 2-Hydroxyethylflurazepam 6-MAM (monoacetylmorphine) 7-Aminoclonazepam Alpha-hydroxyalprazolam Alprazolam Amitriphtyline Benzolyecgonine Zolpidem COOH Citalopram Codeine Cotinine Cyclobenzaprine Desipramine Diazepam Dihydrocodeine Doxepin EDDP (2-Ethylidene-1, 5-Dimethyl-3, 3-Diphenylpyrrolidine) Fentanyl Gabapenin Hydrocodone Hydromorphone Imipramine Ketamine Lorazepam MDA (3,4 - methylenedioxymethamphetamine) MDMA (2,3-methylenedioxymethamphetamine) Meperidine Meprobamate Methadone Methamphetamine Methylphenidate Morphine Naloxone N-Desmethyltapentadol N-Desmethylzopicione Norbuprenorphine Nordiazepam Norfentanyl Norhydrocodone Nortriptyline O-Desmethyltramadol Oxazepam PCP (Phencyclidine) Phentermine Pregabalin Propoxyphene Tapentadol Temazepam THCA Tramadol Venlafaxine Zolpidem. 3. The laboratory was asked to provide documentation of twice annual quantitative accuracy assessments 2020 and 2021. No documentation was provided. 4. An interview with the Technical Supervisor

	on 02/08/2022 at 1030 hours in the break room - after her review of the records- confirmed the findings. NOTE: This is a repeat deficiency from the survey conducted 02/10/2020
D6055	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's test menu, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of the technical consultant performing competency assessments prior to testing personnel reporting patient results for the new methodology of Urine Microalbumin. The findings include: 1. The laboratory started moderate-complexity urine microalbumin testing in March 2021. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of performing competency assessments on testing personnel prior to patient results being reported. Competency assessments were performed: a) Testing personnel number 2 January 2021 January 2022 b) Testing personnel number 3 June 2020 December 2020 June 2021 c) Testing personnel number 4 February 2020 September 2020 September 2021 3. An interview with the technical supervisor on 02/07/2022 at 1040 hours in the break room revealed the facility did not perform competency assessments when the new assay was introduced. This confirmed the findings.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's test menu, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of training for 4 of 4 testing personnel for the new methodology of Urine Microalbumin. The findings include: 1. The laboratory started moderate-complexity urine microalbumin testing in March 2021. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of training on 4 of 4 testing personnel. They were (as listed on Form CMS 209): Testing personnel number 1 Testing personnel number 2 Testing personnel number 3 Testing personnel number 4 3. The laboratory was asked to provide documentation of training for the new methodology. No documentation was provided. 3. An interview with the technical supervisor on 02/07/2022 at 1040 hours in the break room -after her review of the records- confirmed the findings.
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 review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation to qualify 1 of 4 testing personnel to perform high complexity testing (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 review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation to qualify 1 of 4 testing personnel to perform high complexity testing. The findings include: 1. A review of the laboratory's submitted Form CMS 209 revealed the laboratory identified 4 personnel who performed high complexity testing. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of education which would qualify testing personnel number 4 to perform high complexity testing. The education provided was a medical assistant diploma and a certification as a vocational nurse. 3. The laboratory was asked to provide documentation of education which would qualify testing personnel number 4 to perform high complexity testing. No documentation was provided. 4. An interview with the general supervisor on 02/07/2022 at 1030 - after her review of the records- confirmed the findings.