Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2181407	08/14/2023
Name of Provider or Supplier	**Street Address, City, State**	
World Wide Labz	5575 Conner Street, 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
D0000	The purpose of this unannounced survey was for complaint #MI00138493. The Department of Licensing and Regulatory Affairs has evaluated this facility and determined that it is not in compliance with CLIA regulations (42 CFR Part 93, effective April 24, 2003) and has identified Immediate Jeopardy for the following Conditions: 493.1100 Condition: Facility administration (D3000) 493.1250 Condition: Analytic systems (D5400) 493.1441 Condition: Laboratories performing high complexity testing; laboratory director (D6076)
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: . Based on observations and interviews, the laboratory failed to have separate areas for specimen preparation and reagent preparation for its laboratory-developed open molecular amplification SARS-CoV-2 test system (refer to D3005 A) and failed to ensure its laboratory-developed open molecular amplification SARS-CoV-2 test system utilized a unidirectional workflow (refer to D3005 B).
D3005	FACILITIES CFR(s): 493.1101(a)(3)

	Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation. This STANDARD is not met as evidenced by: . A. Based on observation and interview with Testing Personnel #2, the laboratory failed to have separate areas for specimen preparation and reagent preparation for its laboratory-developed open SARS-CoV-2 test system for 6 (March 2023 to August 2023) of 6 months the laboratory has been using this test system. Findings include: 1. The surveyor observed Testing Personnel #2 perform a walkthrough of the laboratory's SARS-CoV-2 testing process using their laboratory-developed, open test system on 8/14/23 at 2:46 pm which revealed the laboratory uses the same biosafety cabinet for specimen preparation and reagent preparation. 2. An interview on 8/14/23 at 2:46 pm with Testing Personnel #2 confirmed the laboratory uses the same biosafety cabinet for specimen preparation and reagent preparation. B. Based on observation and interview with Testing Personnel #2, the laboratory failed to ensure its laboratory-developed open molecular amplification SARS-CoV-2 test system utilized a unidirectional workflow for 6 (March 2023 to August 2023) of 6 months the laboratory has been using this test system. Findings include: 1. The surveyor observed Testing Personnel #2 perform a walkthrough of the laboratory's SARS-CoV-2 testing process using their laboratory-developed, open test system on 8/14/23 at 2:46 pm and revealed testing personnel takes off the post-amplification plate from the QuantStudio 5 analyzer at the same time it loads the pre-amplification test plate on the analyzer. 2. An interview on 8/14/23 at 2:46 pm with Testing Personnel #2 confirmed the laboratory takes off the post-amplification plate from the QuantStudio 5 analyzer at the same time it loads the pre-amplification test plate on the analyzer.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: . Based on record review and interviews, the laboratory failed to have test requests from an authorized provider (refer to D5301) and failed to follow its specimen acceptability and rejection policies and procedures (refer to D5311).
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by:

	. Based on record review and interview with the General Supervisor, the laboratory failed to have test requests from an authorized provider for 8 (Patients 230005083, 230004091, 230004093, 230009114, 230006123, 230005123, 230002128, and 230024159) of 15 test requests reviewed. Findings include: 1. A review of 15 patient test requests revealed the following did not include an authorized provider and had been collected at the laboratory: a. Patient 230005083 had SARS-CoV-2 testing reported on 3/25/23. b. Patient 230004091 had SARS-CoV-2 testing reported on 4/3 /23. c. Patient 230004093 had SARS-CoV-2 testing reported on 4/3/23. d. Patient 230009114 had SARS-CoV-2 testing reported on 4/24/23. e. Patient 230006123 had SARS-CoV-2 testing reported on 5/3/23. f. Patient 230005123 had SARS-CoV-2 testing reported on 5/3/23. g. Patient 230002128 had SARS-CoV-2 testing reported on 5/8/23. h. Patient 230024159 had SARS-CoV-2 testing reported on 6/9/23. 2. The surveyor requested additional information, or a standing order policy used by the laboratory on 8/14/23 at 2:19 pm and it was not made available. 3. An interview on 8 /14/23 at 4:00 pm with the General Supervisor confirmed the laboratory had no standing order policy and the test requests listed above did not have an authorized provider requesting testing.
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: . Based on record review and interview with the General Supervisor, the laboratory failed to ensure test requests included the date and time of specimen collection for 9 (Patients) of 15 patient test records reviewed. Findings include: 1. A review of patient test requisitions revealed the following patients had not had either the date or time of specimen collection indicated: a. Patient 230004091 has SARS-CoV-2 testing reported on 4/3/23 and the test request did not include both the date and time of collection. b. Patient 230002168 had SARS-CoV-2 testing reported on 6/17/23 and the test request did not include the time of collection. c. Patient 230002168 had SARS-CoV-2 testing reported on 6/17/23 and the test request did not include the time of collection. d. Patient 230004191 had SARS-CoV-2 testing reported on 7/10/23 and the test request did not include the time of collection. e. Patient 230004191 had SARS-CoV-2 testing reported on 7/10/23 and the test request did not include the time of collection. f. Patient 230042200 had SARS-CoV-2 testing reported on 7/19/23 and the test request did not include the time of collection. g. Patient 230023200 had SARS CoV-2 testing reported on 7/19/23 and the test request did not include the time of collection. h. Patient 230042200 had SARS-CoV-2 testing reported on 7/19/23 and

	the test request did not include the time of collection. i. Patient 230023200 had SARS-CoV-2 testing reported on 7/19/23 and the test request did not include the time of collection. 2. An interview on 8/14/23 at 4:00 pm with the General Supervisor confirmed the laboratory had not ensured the date and time of collection had been indicated on the test requests for the patients listed above.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: . Based on record review and interview with the General Supervisor, the laboratory failed to follow its specimen acceptability and rejection policies and procedures for 4 (Patients 1230001060, 1230012094, 1230003097, and 1230025103) of 4 patients having Complete Blood Count (CBC) testing reviewed. Findings include: 1. A review of the laboratory's "CBC with differential on ABX Micros 60" procedure revealed a section titled "Specimen Requirements" stating, "Specimens should be transported at room temperature 18-26 degrees Celsius and can be store in the refrigerator of 2-8 degrees C up to 6 hours." 2. A review of the laboratory's "ABX Micros 60" user manual revealed a section titled "4.2.2 Sample Stability" stating, "Fresh Whole Blood specimens are recommended. The ICSH (International Committee for Standardization in Hematology) defines a Fresh blood specimen as one processed within 4 hours after collection. Well mixed Whole Blood specimens, collected in EDTA anti-coagulant and run eight hours after collection, provide the most accurate results for all parameters. The white cell size distribution may shift when specimens are assayed between 5 and 20 minutes after collection and more than 8 hours after collection." 3. A review of patient test reports revealed the following patients with CBC testing performed more than six hours after collection: a. Patient 1230001060 collected 3/1 /23 at 9:15 am and was performed and reported on 3/2/23 at 10:35 pm. b. Patient 1230012094 collected 4/4/23 at 10:33 am and was performed and reported on 4/4/23 at 7:24 pm. c. Patient 1230003097 collected 4/7/23 at 9:37 am and was performed and reported on 4/7/23 at 9:28 pm. d. Patient 1230025103 collected 4/13/23 at 2:25 pm and was performed and reported on 4/13/23 at 10:39 pm. 4. An interview on 8/14/23 at 4:00 pm with the General Supervisor confirmed the laboratory had not followed its policy for specimen rejection for the patients listed above.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

	This CONDITION is not met as evidenced by: . Based on record review, observation, and interviews, the laboratory failed to establish accuracy performance specifications for its laboratory-developed SARS-CoV-2 test system (refer to D5423 A), failed to establish performance specifications for its laboratory-developed SARS-CoV-2 test system to include the extraction method, the amplification method, the software used to analyze amplification data, the specimen type, and the specimen collection device (refer to D5423 B), and failed to perform corrective actions for patient SARS-CoV-2 testing when the results of internal controls were unacceptable (refer to D5783).
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: . A. Based on record review and interviews, the laboratory failed to establish accuracy performance specifications for its laboratory-developed SARS-CoV-2 test system for 6 (March 2023 to August 2023) of 6 months since the test system has been in use. Findings include: 1. A review of the laboratory's "DNA Software PCR Assay Validation" establishment of performance specification documentation revealed a section titled "Accuracy" revealing 4 of 5 patient samples that were positive had concordance with the reference method, 0 of 5 patient samples spiked with synthetic variants had concordance with the reference method, and the accuracy study did not assess the test system's ability to generate negative results in concordance with the reference method. There was a lack of acceptability criteria. 2. An interview on 8/14 /23 at 12:46 pm with Testing Personnel #2 revealed the laboratory did not establish accuracy performance specifications and acceptability criteria for its laboratory-developed SARS-CoV-2 test system. B. Based on record review, observation, and interviews, the laboratory failed to establish performance specifications for its laboratory-developed SARS-CoV-2 test system to include the extraction method, the amplification method, the software used to analyze amplification data, the specimen type, and the specimen collection device for 6 (March 2023 to August 2023) of 6 months since the test system has been in use. Findings include: 1. A review of the laboratory's "PCRassays.com" SARS-CoV-2 assay instructions for use revealed a section stating, "This kit is for research use only and should not be used for diagnostic procedures" indicating the laboratory was using this test as a laboratory-developed test. 2. A review of the laboratory's "DNA Software PCR Assay Validation" establishment of performance specification documentation revealed a section titled "Equipment/Instruments" that indicated the automated "Nucleic Acid Purification System" in use was the "Allsheng" and a lack of information for amplification instrumentation. 3. The surveyor observed the laboratory's equipment on 8/14/23 at 10:

	48 am revealed the laboratory's automated extraction method utilizes the Phoenix Pure 96-well plate extraction system, not the Allseng, and the QuantStudio 5 amplification system. 4. A review of the laboratory's "DNA Software PCR Assay Validation" establishment of performance specification documentation revealed a lack of documentation indicating the specimen type and the specimen collection device. 5. An interview on 8/14/23 at 12:36 pm with the General Supervisor revealed the laboratory uses UTM Copan Viral Transport Media and anterior nare swabs for its specimen collection. 6. A review of 13 test reports for its patient testing completed using this test system listed the specimen type to be nasopharyngeal swabs, not anterior nares. 7. A review of the laboratory's "DNA Software PCR Assay Validation" establishment of performance specification documentation revealed a lack of documentation indicating the software used to analyze amplification data and the 20X Primer/Probe reagents were produced by "DNA Software." 8. A review of the data from three patient test runs on 3/28/23, 4/24/23, and 5/3/23 from the QuantStudio 5 analyzer software revealed under "Chemistry" the reagents indicated were "TaqMan Reagents", not the reagents produced by DNA Software. 9. The surveyor requested the laboratory's study for the software system used to analyze data produced during the amplification process on 8/14/23 at 12:46 pm and it was not made available.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #2, the laboratory failed to perform corrective actions for patient SARS-CoV-2 testing when the results of internal controls were unacceptable for 52 of 84 patients reviewed. Findings include: 1. An interview on 8/14/23 at 3:09 pm with Testing Personnel #2 revealed the laboratory's internal control, indicated on its testing runs as the "RPP30" control, does not always show amplification and the laboratory reports the SARS-CoV-2 patient test results when the internal control does not show amplification. 2. A review of the laboratory's "DNA Software PCR" SARS-CoV-2 test procedure revealed a section titled "Quality Control" stating, "If any of the quality control failed, the patient results must not be interpreted and released. Corrective actions of failed quality control must be documented." 3. A review of the laboratory's "DNA Software PCR" SARS-CoV-2 test procedure revealed a section titled "Result Interpretation" indicating if no amplification is seen in the Omicron FAM and the RPP30 HEX channels, the recommended interpretation would be "The PCR reaction failed. Please repeat the experiment." 4. A review of three patient test runs revealed the following patients had no amplification in the Omicron FAM and the RPP30 HEX channels and were reported: a. Patient test run 03282823WO619 tested a total of 74 patients on 3/28/23, 48 had failed internal controls. i. Patients 230015087, 230018087, 230020087, 230021086, 230025087, 230027087, 230030087, 230032087, 230034087, 230036087, 230037087, 230038087, 230039087, 230040087, 230041087, 230042087, 230044087, 230046087, 230047087, 230048087, 230049087,

	230050087, 230051087, 230053087, 230054087, 230055087, 230056087, 230057087, 230059087, 230060087, 230061087, 230062087, 230063087, 230064087, 230065087, 230066087, 230067087, 230068087, 230070087, 230072087, 230073087, 230075087, 230078087, 230079087, 230080087, 230081087, 230082087, and 230084087. b. Patient test run 04242023WO631 tested a total of five patients on 4/24/23, two had failed internal controls: i. Patients 230066111 and 230067111. c. Patient test run 050320223WO633 tested a total of three patients on 5/3/23, two had failed internal controls: i. Patients 230005123 and 230006123. 5. The surveyor requested corrective action documentation for the patient test runs listed above with failed internal controls on 8/14/23 at 3:10 pm and it was not made available.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #2, the laboratory failed to include the address of the laboratory location where testing was performed for 2 (Patients 230008223 and 1230008223) of 2 patient test reports reviewed that had included testing at a reference laboratory. Findings include: 1. A review of two test reports issued using results from a reference laboratory revealed a lack of address of the laboratory performing the testing for patients 230008223 and 1230008223, both performed on 8/12/23. 2. An interview on 8/14/23 at 2:31 pm with Testing Personnel #2 confirmed the test reports did not include the address of the laboratory where testing was performed for the patients listed above.
D5817	TEST REPORT CFR(s): 493.1291(i) If a laboratory refers patient specimens for testing-- (i)(1) The referring laboratory must not revise results or information directly related to the interpretation of results provided by the testing laboratory; (i)(2) The referring laboratory may permit each testing laboratory to send the test result directly to the authorized person who initially requested the test. The referring laboratory must retain or be able to produce an exact duplicate of each testing laboratory's report; and (i)(3) The authorized person who orders a test must be notified by the referring laboratory of the name and address of each laboratory location where the test was performed. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #2, the laboratory revised the reference ranges used in interpretation of results for 1 (Patient 230008223 /59126) of 2 patient test reports transcribed from reference laboratory results

	reviewed. Findings include: 1. A review of the reference laboratory's test report for patient 230008223/59126 performed on 8/12/23 revealed the reference range for Thyroid Stimulating Hormone (TSH) was 0.5 to 5.0 uIU/mL. 2. A review of the laboratory's test report issued to patient 230008223/59126's ordering provider revealed the TSH reference range to be 0.465 to 4.68 uIU/mL. 3. An interview on 8/14 /23 at 2:31 pm with Testing Personnel #2 revealed the laboratory manually transcribes the information from the reference laboratory test report into a new test report with the laboratory's information and the ordering provider only gets the transcribed copy of the test report.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 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. This CONDITION is not met as evidenced by: . Based on record review, observations, and interviews, the Laboratory Director failed to provide overall management and direction, failed to have separate areas for specimen preparation and reagent preparation for its laboratory-developed open molecular amplification SARS-CoV-2 test system (refer to D6083 A), failed to ensure its laboratory-developed open molecular amplification test system for SARS-CoV-2 utilized a unidirectional workflow (refer to D6083 B), failed to ensure accuracy performance specifications for its laboratory-developed SARS-CoV-2 test system were established (refer to D6085 A), failed to ensure established performance specifications for its laboratory-developed SARS-CoV-2 test system included the extraction method, the amplification method, the software used to analyze amplification data, the specimen type, and the specimen collection device (refer to D6085 B), failed to ensure laboratory personnel followed its specimen acceptability and rejection policies and procedures (refer to D6087), and failed to ensure corrective actions were performed for patient SARS-CoV-2 testing when the results of internal controls were unacceptable (refer D6097).
D6083	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) The laboratory director must ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed. This STANDARD is not met as evidenced by: . A. Based on observation and interviews, the Laboratory Director failed to have separate areas for specimen preparation and reagent preparation for its laboratory-developed open molecular amplification SARS-CoV-2 test system. Refer to D3005 A. B. Based on observation and interviews, the Laboratory Director failed to ensure its laboratory-developed open molecular amplification test system for SARS-CoV-2 utilized a unidirectional workflow. Refer to D3005 B.
D6085	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)

	The laboratory director must ensure that the test methodologies selected have the capability of providing the quality of results required for patient care. This STANDARD is not met as evidenced by: . A. Based on record review, observation, and interviews, the Laboratory Director failed to ensure accuracy performance specifications for its laboratory-developed SARS-CoV-2 test system were established. Refer to D5423 A. B. Based on record review, observation, and interviews, the Laboratory Director failed to ensure established performance specifications for its laboratory-developed SARS-CoV-2 test system included the extraction method, the amplification method, the software used to analyze amplification data, the specimen type, and the specimen collection device. Refer to D5423 B.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: . Based on record review and interviews, the Laboratory Director failed to ensure laboratory personnel followed its specimen acceptability and rejection policies and procedures. Refer to D5311.
D6097	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that patient test results are reported only when the system is functioning properly. This STANDARD is not met as evidenced by: . Based on record review and interviews, the Laboratory Director failed to ensure corrective actions were performed for patient SARS-CoV-2 testing when the results of internal controls were unacceptable. Refer to D5783.