Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2181407	08/26/2020
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 #MI00111924. 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).
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 Laboratory Manager, the laboratory failed to ensure the test requisition listed the tests to be performed for 8 (patients W3-W10) of 10 patient testing records audited. Findings include: 1. An audit of patient testing records revealed the following patients had test requisitions without the tests to be performed indicated on the requisition: a. Patient W3 b. Patient W4 c. Patient W5

	d. Patient W6 e. Patient W7 f. Patient W8 g. Patient W9 h. Patient W10 2. An interview with the Laboratory Manager on 8/26/2020 at 4:00 pm confirmed the laboratory did not ensure the test requisitions indicated the test to be performed.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Manager, the laboratory failed to maintain a record system that included the identity of the testing personnel performing COVID-19 IgM/IgG testing for 10 (patients W1-W10) of 10 patient testing records audited. Findings include: 1. An audit of patient testing records revealed the laboratory did not have a record system in place that included the identity of the testing personnel who performed and documented the COVID-19 IgM and IgG testing results for the patients listed below: a. Patient W1 b. Patient W2 c. Patient W3 d. Patient W4 e. Patient W5 f. Patient W6 g. Patient W7 h. Patient W8 i. Patient W9 j. Patient W10 2. An interview with the Laboratory Manager on 8/26/2020 at 4:00 pm confirmed the laboratory did not have a record system in place to document the identity of the testing personnel performing patient testing.
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: . A. Based on record review and interview with the Laboratory Manager, the laboratory failed to include the test report date on 10 (Patients W1- W10) of 10 patient testing records audited. Findings include: 1. An audit of the laboratory's patient testing records revealed a lack of documentation of the test report date on the test reports for the following patients: a. Patient W1 b. Patient W2 c. Patient W3 d. Patient W4 e. Patient W5 f. Patient W6 g. Patient W7 h. Patient W8 i. Patient W9 j. Patient W10 2. An interview with the Laboratory Manager on 8/26/2020 at 4:00 pm confirmed the laboratory did not include the test report date on patient test reports. B. Based on record review and interview with the Laboratory Manager, the laboratory failed to indicate the test performed on the test report for 8 (Patients W3-W10) of 10 patient testing records audited. Findings include: 1. An audit of the laboratory's patient testing

	records revealed a lack of documentation of the test performed on the test report for the following patients: a. Patient W3 b. Patient W4 c. Patient W5 d. Patient W6 e. Patient W7 f. Patient W8 g. Patient W9 h. Patient W10 2. An interview with the Laboratory Manager on 8/26/2020 at 4:00 pm confirmed the laboratory did not have a system in place to ensure the test performed was indicated on patient test reports. C. Based on record review and interview with the Laboratory Manager, the laboratory failed to provide patients receiving testing with the Healgen COVID-19 IgM/IgG Rapid Test Cassette test with the Fact Sheet for recipients required for interpretation of results for 4 (April 2020 to August 2020) of 4 months. Findings include: 1. A record review of the laboratory's patient test records revealed the earliest test report was signed by the patient on 4/17/2020. 2. A review of the Fact Sheet given to patients with their COVID-19 IgM/IgG results revealed it was not the Fact Sheet authorized by the Food and Drug Administration (FDA) Emergency Use Authorization (EUA). 3. A record review of the "Healgen COVID-19 IgM/IgM Rapid Test Cassette" manufacturer's package insert revealed a section stating, "Authorized laboratories using your product will include with result reports of your product, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media. Authorized laboratories using your product will use your product as outlined in the Instructions for Use. Deviations from the authorized procedures, including the authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted." 4. A record review of the EUA letter from the FDA for the Healgen COVID-19 IgM/IgG Rapid Test Cassette revealed a section titled "Authorized Laboratories" stating, "Authorized laboratories using your product will include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media. Authorized laboratories will use your product as outlined in the Instructions for Use. Deviations from the authorized procedures, including the authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted." 5. An interview with the Laboratory Manager on 8/26/2020 at 4:00 pm confirmed the laboratory had not been distributing the authorized Fact Sheets to patients according to the manufacturer's instructions.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: . Based on record review and interviews with the Laboratory Manager, the Laboratory Director failed to provide overall management and direction in accordance with 493.1407 of this subpart. Findings include: 1. The Laboratory Director failed to ensure the Healgen COVID-19 IgM/IgG Rapid Test Cassette could provide quality results prior to testing patient specimens. Refer to D6012. 2. The Laboratory Director failed to ensure a quality control program was implemented and followed for the Healgen COVID-19 IgM/IgG Rapid Test Cassette test system. Refer to D6020. 3. The

	Laboratory Director failed to ensure all personnel using the Healgen COVID-19 IgM /IgM Rapid Test Cassette test system received training prior to testing patients' specimens. Refer to D6029.
D6012	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) 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: . Based on record review and interview with the Laboratory Manager, the Laboratory Director failed to ensure the Healgen COVID-19 IgM/IgG Rapid Test Cassette could provide quality results prior to testing patient specimens for 4 (April 2020 to August 2020) of 4 months the test system has been in use. Findings include. 1. A record review of the laboratory's patient test records revealed the earliest test report was signed by the patient on 4/17/2020. 2. When requested by the surveyor on 8/24/2020 at 2:26 pm, the laboratory's records of a verification of test performance specifications for the Healgen COVID-19 IgM/IgG Rapid Test Cassette test system were not made available. 3. An interview with the Laboratory Manager on 8/24/2020 at 3:21 pm confirmed the laboratory did not perform verification of test performance specifications for the Healgen COVID-19 IgM/IgG Rapid test Cassette test system.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Manager, the Laboratory Director failed to ensure a quality control program was implemented and followed for the Healgen COVID-19 IgM/IgG Rapid Test Cassette test system for 4 (April 2020 to August 2020) of 4 months the test system has been in use. Findings include: 1. A record review of the laboratory's patient test records revealed the earliest test report was signed by the patient on 4/17/2020. 2. A review of the Healgen COVID-19 IgM /IgG Rapid Test Cassette manufacturer package insert revealed a section titled "Quality Control" stating, "A procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance. Additional controls may be required according to

	guidelines or local, state, and/or federal regulations (such as 42 CFR 493.1256) or accrediting organizations." 3. A review of the Emergency Use Authorization (EUA) letter from the Food and Drug Administration (FDA) revealed a section titled "Authorized Product Details" stating, "Your product requires the following internal control, that is processed along with the specimen on the device cassette. The internal control listed below must generate expected results in order for a test to be considered valid, as outlined in the Instructions for Use. Internal Control - The C line color change from blue to red should appear for every test and checks that flow of reagents is satisfactory. You also recommend use of external positive and negative controls, or other authorized controls, to be run as outlined in the Instructions for Use. Your product also requires the use of additional authorized materials and authorized ancillary reagents that are not included with your product and are described in the Instructions for Use." 4. When the surveyor requested documentation of control performance for the Healgen COVID-19 IgM/IgG Rapid Test Cassette test system on 8/24/2020 at 2:48 pm, the documents were not made available. 5. A review of the laboratory's established "Rapid COVID-19 IgG/IgM Testing" procedure revealed a lack of protocol for documenting control activities. 6. An interview with the Laboratory Manager on 8/24/2020 at 3:52 pm confirmed the laboratory did not have records of the Healgen COVID-19 IgM/IgM Rapid Test Cassette test system control performance.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Manager, the Laboratory Director failed to ensure all personnel using the Healgen COVID-19 IgM/IgM Rapid Test Cassette test system received training prior to testing patients' specimens for 4 (April 2020 to August 2020) of 4 months the test system has been in use. Findings include: 1. A record review of the laboratory's patient test records revealed the earliest test report was signed by the patient on 4/17/2020. 2. The surveyor requested documentation of training for the testing personnel listed on the CMS-209 form performing the Healgen COVID-19 IgM/ IgG Rapid Test Cassette test system on 8/24 /2020 at 2:16 pm and the documents were not made available. 3. An interview with the Laboratory Manager on 8/26/2020 at 4:00 pm confirmed the laboratory did not have documentation of training for testing personnel performing testing using the Healgen COVID-19 IgM/IgG Rapid Test Cassette test system.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in

	accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: . Based on review of records submitted by the Laboratory Manager, the laboratory failed to ensure the Technical Consultant met the qualification requirements at 493.1411. Findings include: 1. The laboratory failed to ensure personnel acting as the Techinical Consultant were qualified. Refer to D6033.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) 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; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: . Based on a review of personnel records provided by the Laboratory Manager and lack of documentation, the laboratory failed to ensure personnel acting as the Techinical Consultant was qualified for 4 (April 2020 to August 2020) of 4 months. Findings include: 1. The surveyor requested qualification documentation for all staff listed on the CMS-209 form showing they were qualified on 8/24/2020 at 1:41 pm. 2. A record review of personnel records submitted to the surveyor from the Laboratory Manager on 9/1/2020 at 7:40 am revealed a lack of documentation of at least 2 years

	of laboratory training or experience or both in non-waved testing in the designated specialties indicated on the laboratory's CMS-116 form. 3. The laboratory was provided 7 days to supply documentation and it was not made available.
D6056	CLINICAL CONSULTANT CFR(s): 493.1415 The laboratory must have a clinical consultant who meets the qualification requirements of 493.1417 of this part and provides clinical consultation in accordance with 493.1419 of this part. This CONDITION is not met as evidenced by: Based on review of records submitted by the Laboratory Manager, the laboratory failed to ensure the Clinical Consultant met the qualification requirements at 493.1419 of this part. Findings include: 1. The laboratory failed to ensure the Clinical Consultant was qualified. Refer to D6057.
D6057	CLINICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1417 The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493. 1405(b)(1), (2), or (3)(i); or (b) Be a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine and possess a license to practice medicine, osteopathy or podiatry in the State in which the laboratory is located. This STANDARD is not met as evidenced by: . Based on a review of personnel records provided by the Laboratory Manager and lack of documentation, the laboratory failed to ensure the Clinical Consultant was qualified for 4 (April 2020 to August 2020) of 4 months. Findings include: 1. The surveyor requested qualification documentation for all staff listed on the CMS-209 form showing they were qualified on 8/24/2020 at 1:41 pm. 2. A record review of personnel records submitted to the surveyor from the Laboratory Manager on 9/1 /2020 at 7:40 am revealed a lack of documentation showing the Clinical Consultant was a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine and possesses a State of Michigan license to practice. 3. The laboratory was provided 7 days to supply documentation and it was not made available.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: . Based on review of records submitted by the Laboratory Manager, the laboratory

	failed to ensure the testing tersonnel met the qualification requirements at 493.1423. Findings include: 1. The laboratory failed to ensure testing personnel was qualified. Refer to D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy 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; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: . Based on a review of records provided by the Laboratory Manager and lack of documentation, the laboratory failed to ensure testing personnel were qualified for 3 (Testing Personnel #2-#4) of 4 testing personnel listed on the laboratory's CMS-209 form. Findings include: 1. The surveyor requested qualification documentation for all staff listed on the CMS-209 form showing they were qualified on 8/24/2020 at 1:41 pm. 2. A record review of personnel records submitted to the surveyor from the Laboratory Manager on 9/1/2020 at 7:40 am revealed a lack of documentation of the necessary qualifications listed at 493.1423 for the following testing personnel listed on the CMS-209 form: a. Testing Personnel #2 b. Testing Personnel #3 c. Testing Personnel #4 3. The laboratory was provided 7 days to supply documentation and it was not made available.