Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2181407	01/20/2021
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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: . Based on record review, interview, and email correspondence, the laboratory failed to follow its policy when interpreting patient testing results for COVID-19 testing using the PhoenixDx SARS-CoV-2 multiplex qualitative RT-PCR assay for 6 (11/4 /20, 11/18/20, 11/20/20, 11/25/20, 12/4/20, and 12/22/20) of 10 testing dates reviewed. Findings include: 1. A review of the laboratory's "PhoenixDx SARS-CoV-2 Multiplex Qualitative" instructions for use (IFU) and their "PhoenixDx SARS-CoV-2 Multiplex Quality Control and Results Interpretation Procedure" revealed a section titled "Examination and Interpretation of Patient Specimen Results" stating, "A sample result is invalid if the detection of RNase P (HEX/VIC channel) in the sample fails and the sample also fails to show amplification of SARS-CoV-2 targets (N / ORF1ab in the FAM channel) within less than or equal to 35 Ct. Invalid results cannot be interpreted. Check reaction setup and device settings and repeat the RNA extraction if necessary. These samples should be repeated from the extraction step. Note: Failure to amplify the negative human extraction control may indicate inadequate RNA extraction or loss of RNA isolate due to RNAse contamination. Late Ct values for the IC may indicate a low RNA quality / amount in the extract. For a sample to be considered positive for SARS-CoV-2, the SARS-CoV-2 targets (FAM channel) must give a positive Ct value. Amplification of the IC in the HEX/VIC channel is expected around Ct 22-29. The IC may fail to amplify in the presence of high virus titers. Therefore, a sample with positive amplification of SARS-CoV-2 is positive even in the absence of RNase P amplification (IC). For a sample to be

considered negative for SARS-COV-2, the SARS-CoV-2 assays in the FAM. channel must not give a positive Ct value. The IC must give a positive Ct value in the HEX /VIC channel (Ct 22-29) for these samples to ensure that sample material of suitable quality was present." 2. A review of the laboratory's testing records and patient test reports revealed the following patients, their Ct values, and the final test report results that do not meet the criteria listed above for testing performed on 11/5/20 and 11/2/20: a. Patient 912803MJ i. internal control Ct value (VIC) of 25.908054 ii. SARS-CoV-2 viral target Ct (FAM) of 32.506565 iii. Test report result of negative b. Patient 462140HD i. VIC of 24.49584 ii. FAM of 18.4142 iii. Test report result of negative c. Patient 627107RF i. VIC of 26.584219 ii. FAM of 25.739803 iii. Test report result of negative d. Patient 589330ME i. VIC of Undetermined ii. FAM of 24.361181 iii. Test report result of negative e. Patient 251909JB i. VIC of 27.050365 ii. FAM of 34.74326 iii. Test report result of negative f. Patient 132579GD i. VIC of 26.781395 ii. FAM of 33.514103 iii. Test report result of negative g. Patient 713951LE i. VIC of 27.649044 ii. FAM of 38.688583 with the amplification status of "inconclusive" iii. Test report result of negative h. Patient 828238SD i. VIC of 25.821924 ii. FAM of 29.226145 iii. Test report result of negative i. Patient 409555MS i. VIC of 26.977304 ii. FAM of 26.598774 iii. Test report result of negative j. Patient 876718LJ i. VIC of 28.033558 ii. FAM of 28.71747 iii. Test report result of negative k. Patient 789513BD i. VIC of Undetermined ii. FAM of Undetermined iii. Test report result of negative l. Patient 133594RC i. VIC of 26.938522 ii. FAM of 30.515833 iii. Test report result of negative m. Patient 249106HK i. VIC of 23.868858 ii. FAM of 27.466122 iii. Test report result of negative n. Patient 546125EC i. VIC of 25.305733 ii. FAM of 24.28536 iii. Test report result of negative o. Patient 080109DD i. VIC of 29.47441 ii. FAM of 33.01652 iii. Test report result of negative p. Patient 488447JA i. VIC of 27.187027 ii. FAM of 28.438496 iii Test report result of negative q. Patient 201104008778 i. VIC of 31.882978 ii. FAM of 33.999035 iii. Test report result of negative r. Patient 201104008807 i. VIC of 31.360435 ii. FAM of 31.072567 iii. Test report result of negative s. Patient 201104008808 i. VIC of 31.990444 ii. FAM of 33.633293 iii. Test report result of negative t. Patient 201104008796 i. VIC of 31.22648 ii. FAM of 33.20088 iii. Test report result of negative u. Patient 201104008775 i. VIC of 31.123308 ii. FAM of 26.890274 iii. Test report result of negative v. Patient 201104008806 i. VIC of 30.952454 ii. FAM of 32.557846 iii. Test report result of negative w. Patient 201104008806 i. VIC of 30.977468 ii. FAM of 31.541794 iii. Test report result of negative x. Patient 201104008766 i. VIC of 30.75918 ii. FAM of 30.448345 iii. Test report result of negative y. Patient 201104008790 i. VIC of 30.354326 ii. FAM of 19.277208 iii. Test report result of negative z. Patient 201104008790 i. VIC of Undetermined ii. FAM of 24.269781 iii. Test report result of negative aa. Patient 201104008768 i. VIC of 30.150524 ii. FAM of 29.350496 ii. Test report result of negative 3. A review of the laboratory's testing records revealed the following discrepancies for patients' Ct values and the results that do not meet the criteria listed above for testing completed on 11/18/20, 11/25/20, 12/4 /20, and 12/22/20: Testing performed on 11/18/20 a. Patient 420643GD i. VIC of 29.067991 ii. FAM of 21.122551 iii. Results of negative Testing performed on 11/25 /20 a. Patient HFOH1020 i. VIC of 28.855377 ii. FAM of 34.21538 iii. Result of negative b. Patient HFOH1243 i. VIC of 30.694355 ii. FAM of 34.42861 iii. Result of negative c. Patient 051441FY i. VIC of 24.594633 ii. FAM of 34.501133 iii. Result of negative d. Patient 073378SC i. VIC of 24.439243 ii. FAM of 23.478592 iii. Result of negative e. Patient HFOH1061 i. VIC of 28.744646 ii. FAM of 34.598576 iii. Result of negative f. Patient HLX67901527 i. VIC of 26.797724 ii. FAM of 34.040012 iii. Result of negative g. Patient HLX67901540 i. VIC of 27.283403 ii. FAM of 27.031754 iii. Result of negative Testing performed on 12/4/20 a. Patient WS2115 i. VIC of 31.29995 ii. FAM of 21.526726 iii. Result of negative Testing performed on 12

	/22/20 a. Patient HLX67901656 i. VIC of 34.328255 ii. FAM of 28.54934 iii. Result of negative 4. An interview on 1/19/21 with the Laboratory Director revealed the laboratory's process was to review the confidence levels for the specimens. If the confidence levels were not acceptable, the laboratory would interpret the results from the run prior to the software interpretation, then report the patient results. 5. A review of email correspondence sent to the surveyor on 1/20/21 from the laboratory consultant revealed the following criteria used, "Please see below the interpretation of Cq Conf as our techs learned from the onsite training (10/30/2020). The Cq Conf value were included in the raw PCR result table for review. Once the lab encountered a questionable Cq Conf value, the lab used to consult with manufacturer for further review and interpretation. During our in-lab training (10/30/2020) with a technical consultant from Trax team. Our techs were told that Cq Conf should be considered when reviewing results. A Cq Conf value lower than ~0.8 should be considered as false positive, or a rerun should be considered. Starting from December 2020, the laboratory is performing QC review on a daily basis with techs and LD. The lab has been performing interpretation strictly following the IFU and lab procedure. Only Ct values and amplification status were utilized for interpretation and review. If any run returned positive or undetermined results, the lab will immediately perform a rerun." 6. The surveyor requested corrective action for patients with unacceptable confidence values on 1/19/21 at 4:55 pm and it was not made available.