Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0655844	05/15/2019
Name of Provider or Supplier	**Street Address, City, State**	
Ohio Department Of Health Laboratory	8995 East Main Street, Bldg 22, Reynoldsburg, 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
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 review of patient test records and laboratory procedure manual, laboratory personnel failed to follow the written procedure manual and performed patient testing beyond the approved symptom onset date for one of one patient test reports and one of one laboratory procedure manual reviewed. Findings include: 1) Review of the approved laboratory procedure manual titled, "Trioplex real-time RT-PCR Assay (EUA), approval date 12/19/2018, Section 3.5 states, "Specimens collected greater than 7 days after symptom onset will not be tested by PCR but forwarded to CDC for serological testing." 2) Review of the "Ohio Department of Health Microbiology Submission Form," ID # XXXXXXXX14, in Section #3 lists a symptom onset date of 12/31/2018 with a collection date of 01/13/2019, which is greater than 7 days after the onset of symptoms. 3) Review of patient test report ID # XXXXXXXX14 shows the following PCR tests were analyzed and reported on January 15, 2019, which is greater than 7 days from symptom onset: Chikungunya Virus RNA- Not Detected Dengue Virus RNA- Not Detected Zika Virus RNS- Not Detected
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as

	determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of manufacturer testing instructions, patient test records and TP interview, the facility failed to follow the manufacturer's instructions for Neisseria meningitidis serogroup testing for one of one patient test report and one of one manufacturer testing instructions reviewed. Findings include: 1) Review of BD Difco Neisseria menigitidis manufacturer testing instructions state, "Difco-Quality Control-at the time of use, test both negative and positive control culture to check performance of antisera." 2) Review of patient test report XXXXXXXXX4 shows that patient testing was performed for Neisseria menigitidis serotyping using the BD Difoc Neisseria menigitidis test kit on 02/21/2018 with a final patient test report of "Neisseria menigitidis group B." 3) Review of Neisseria meningitidis Serogrouping QC chart shows that there was no entry or documentation on 02/21/2018 to show that the antisera performance was tested with negative and positive control cultures at the time of use for patient test report XXXXXXXXX4. 4) TP #3 stated on 05/13/2019 at 11:15 AM, "We use Difco for Serotyping."