Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D1003519	09/22/2021
Name of Provider or Supplier	**Street Address, City, State**	
Bayside Urgent Care & Family Medical	39 Birch St Ste A, Redwood City, CA	

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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on the surveyor's review of laboratory testing operations and an interview with the laboratory Testing Personnel (TP) on 9/22/2021 between 10 a.m. and 11:30 a.m., it was determined that there were electrical wires connected to a surge protector in the sink immediately adjacent to the Optigen testing device. The associated cords and hoses in the area presented an employee safety issue. Findings include: 1. On 9/22/21, an inspection was conducted between the hours of 10 a.m. and 11:30 a.m. 2. The Optigen device is in a small room, and there is a sink immediately adjacent to the device. 3. Next to the sink, there was a radiology-related device with multiple water hoses. 4. There was also a surge protector with multiple cords in the sink next to the hoses linked to the radiology device. 5. The TP recognized the safety issues.
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 the surveyor's review of the laboratory's records for quality control and an interview with the laboratory Testing Personnel (TP) on 9/22/2021 between 10 a.m. and 11:30 a.m., it was determined the documentation to support control procedures was not present. The Optigen device is used for testing 56 different allergens. The laboratory must monitor and evaluate the overall quality of the analytics systems for each specialty of testing performed. Findings include: 1. On 9/22/22, an inspection was conducted between the hours of 10 a.m. and 11:30 a.m. 2. Refer to citations 5401 and 5445 regarding quality control documentation and procedures.
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 the surveyor's review of the laboratory's records for quality control and an interview with the laboratory Testing Personnel (TP) on 9/22/2021 between 10 a.m. and 11:30 a.m., it was determined that there was not documentation to define the allergen values in the control material used for the Hitachi Optigen. The Optigen device is used for testing 56 different allergens. Findings include: 1. On 9/22/21, an inspection was conducted between the hours of 10 a.m. and 11:30 a.m. 2. During a review of the laboratory quality control materials and quality control records, it was noted that the Cliniqa Immunoassy Control Tri-level reagent was used control purposes. 3. The specification sheet for the Cliniqa reagent did not specify any of the 56 allergens that were being used for patient reporting. 4. The lack of allergen control material in the control reagent could not support verification of patient testing levels. 5. The TP confirmed that there were not allergens listed on the Cliniqa reagent content worksheet
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's records for quality control and an interview with the laboratory Testing Personnel (TP) on 9/22/2021 between 10 a.m. and 11:30 a.m., it was determined that there was not documentation to support daily control procedures. The Optigen device is used for testing 56 different allergens. Findings include: 1. On 9/22/21, an inspection was conducted between the hours of 10

	a.m. and 11:30 a.m. 2. During a review of the laboratory quality control documentation records, the following items were identified or not present: - The Positive Control Serum QC log for 2021 only had entries for one day per month - The 2021 log sheet did not have any entries beyond April of 2021, and the inspection was on 9/22/21. - There was not a log sheet for daily QC results to indicate that the controls had been run- CLIA regulations stipulate that controls should be run each day if the frequency is not specified by the manufacturer 3. The TP confirmed that the log entries were as indicated
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 the surveyor's review of the laboratory's records for quality control and an interview with the laboratory Testing Personnel (TP) on 9/22/2021 between 10 a.m. and 11:30 a.m., it was determined that there were electrical wires connected to a surge protector in the sink immediately adjacent to the Optigen testing device. The associated cords and hoses in the area present an employee safety issue. 1. On 9/22 /21, an inspection was conducted between the hours of 10 a.m. and 11:30 a.m. 2. Refer to citation 3011 regarding laboratory safety.