Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D0623515	08/06/2020
Name of Provider or Supplier	**Street Address, City, State**	
Portland Clinic, The	800 Sw 13th Ave, Portland, OR	

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
D2089	ROUTINE CHEMISTRY CFR(s): 493.841(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3)The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Review of the WSLH proficiency testing (PT) showed a score of 0 % for the Glucose 3rd Event 2019. Finding include: 1. 3rd Event 2019 Glucose = 0% 2. There was no documentation of corrective action for the failed Glucose PT results. 3. The Laboratory Manager / Technical Supervisor concur with these findings on 08/06/2020 at 14:00.
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: Review of the Individualized Quality Control Plan (IQCP) Procedures revealed that there were no writtten Quality Control Plans (QCP) for the BD Max and the Solana Test Systems. Findings include: 1. The BD Max Test system do not have a written QCP for the Chlamydia Trachomatis/ Niesseria Gonorrhea (CT/GC) and the Max Vaginal Panel (MVP). 2. The Solana test system do not have a written QCP for the Molecular Direct Strep Panel and Herpes Simplex Virus/ Varacella Zozter Virus (HSV /VZV) . 3. The Laboratory Manager/Technical Supervisor concur with these findings on 08/06/2020 at 14:00.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Review of the WSLH proficiency testing (PT) showed a score of 0 % for the Glucose 3rd Event 2019. Finding include: 1. 3rd Event 2019 Glucose = 0% 2. There was no documentation of corrective action for the failed Glucose PT results. 3. The Laboratory Manager / Technical Supervisor concur with these findings on 08/06/2020 at 14:00.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Review of the Individualized Quality Control Plan (IQCP) Procedures revealed that there were no writtten Quality Assessment Plan (QAP) for the BD Max and the Solana Test systems. Findings include: 1. The BD Max Test system do not have a written QAP for the Chlamydia Trachomatis/ Niesseria Gonorrhea (CT/GC) and the Max Vaginal Panel (MVP). 2. The Solana test system do not have a written QAP for the Molecular Direct Strep Panel and Herpes Simplex Virus/ Varacella Zozter Virus (HSV/VZV) . 3. The Laboratory Manager/Technical Supervisor concur with these findings on 08/06/2020 at 14:00.