Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D2027672	03/26/2019
Name of Provider or Supplier	**Street Address, City, State**	
Portland Clinic Of Holistic Health	833 Sw 11th Ave Ste 525, 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
D1000	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(c) Certificate of waiver tests. A laboratory may qualify for a certificate of waiver under section 353 of the PHS Act if it restricts the tests that it performs to one or more of the following tests or examinations (or additional tests added to this list as provided under paragraph (d) of this section) and no others: (1) Dipstick or Tablet Reagent Urinalysis (non-automated) for the following: (i) Bilirubin; (ii) Glucose; (iii) Hemoglobin; (iv) Ketone; (v) Leukocytes; (vi) Nitrite; (vii) pH; (viii) Protein; (ix) Specific gravity; and (x) Urobilinogen. (2) Fecal occult blood; (3) Ovulation tests-visual color comparison tests for human luteinizing hormone; (4) Urine pregnancy tests - visual color comparison tests; (5) Erythrocyte sedimentation rate-non-automated; (6) Hemoglobin-copper sulfate-non-automated; (7) Blood glucose by glucose monitoring devices cleared by the FDA specifically for home use; (8) Spun microhematocrit; and (9) Hemoglobin by single analyte instruments with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout. This STANDARD is not met as evidenced by: Based on record review and interviews with staff on 3/26/2019, the investigative survey reveals the Laboratory Director (LD) of the certificate of waiver failed to obtain a compliance certificate before performing and reporting patient results for tests not categorized as waived. Findings include: 1. Discussion with the LD and staff revealed the office performs a total sixteen (16) different tests for patients seen in the office. Of the sixteen (16) tests, ten (10) are classified as waived, four (4) are classified as moderately complex and two (2) are classified as highly complex. 2. One (1) out of the sixteen (16) tests performed on site did not have documents or a written procedure for performance readily available and was confirmed by staff. 3. The manufacturer of the Heavy Metal Toxicity test and the Polysan test (screening slide

	test for different groups of bacteria) were unable to be determined. Neither of these tests have been classified in the US Food and Drug Administration (FDA) categorization database and are considered highly complex.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based upon discussion with staff and inspection of current reagents in the laboratory, it was found that some expired reagents were in use and manufacturer's package inserts were not being followed. Findings include: 1. Upon inspection of the open bottle of Rapid Response Urinalysis Reagent Test Strips, it was noted that this bottle of test strips expired in February of 2019. On the shelf above the same testing area, two (2) more unopened vials of the same test strips with the same expiration date were found. 2. Upon inspection of the area with the microscope and supplies used to perform microscopic testing and discussion with the Laboratory Director, it was revealed to have a dropper bottle of 10% potassium hydroxide (KOH) that expired 3 /12/2014. 3. There were no records of temperature recordings that could be produced to verify proper storage and handling of the test kits.