

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 38D2103061	(X3) Date Survey Completed 11/06/2019
Name of Provider or Supplier Lags Medical Centers, Or, Pc	Street Address, City, State 169 Ne 102nd Street, 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	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of patients records and interview with the staff the laboratory were performing tests beyond the scope of the certificate held by the laboratory. Findings include: 1. A patient record showed that on 01/03/2019 at 01:52:57 PM (+) for Fentanyl and (+) for Oxycodone were performed by testing personnel LG. The Fentanyl was tested using the test kit labeled Cat. No. HDFN-114 Fentanyl Panel Test "For Forensic Use Only". The Oxycodone was tested using the test kit "Urine Multi Drug Rapid Test Cup" , CLIA Waived 8 drug panel. 2. Another patient record showed that on 09/05/2019 at 02:16:40 PM (+) for Tramadol and (+) for Oxycodone were performed by testing personnel DK. The Tramadol was tested using the test kit labeled Cat. No. HDTR-114 Tramadol Panel Test "For Forensic Use Only". The Oxycodone was tested using the test kit "Urine Multi Drug Rapid Test Cup" , CLIA Waived 8 drug panel. 3. The surveyor interviewed the Regional Manager and the</p>

Assistant Manager and they both confirmed that "Tramadol and Fentanyl Urine test were being performed in the laboratory. These 2 Urine test kits are labeled " For Forensic Used Only" and NOT categorized by FDA as CLIA Waived. 4. A Urine Hcg kit labeled Cat. No GAHCG-105a hCG Rapid Test dipcard (urine) lot#1810240 Exp. 2020-09 For professional used only did not have CLIA Waived categorization in the package insert. An email dated 11/7/2019 @ 2:55 PM from the manufacturer confirmed that this product is in the process of being cleared by FDA within the next 30-40 days. 5. The Regional Manager Manager and the Assistant Manager confirmed all these findings 11/06/2019 @ 11:00 AM.