

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  03D2093418	<b>(X3) Date Survey Completed</b>  01/24/2025
<b>Name of Provider or Supplier</b>  Lake Havasu Primary Care	<b>Street Address, City, State</b>  89 Civic Center Blvd, Lake Havasu City, AZ	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A complaint survey was performed on January 25, 2025. The facility was found to be NOT in compliance with the following CLIA requirements under 42 CFR for Waived testing: 493.15(e) - Certificate of Waiver Tests
<b>D1001</b>	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of Clinitek Status+ and Cholestech LDX testing records and laboratory personnel interview on January 24, 2025, (A) the laboratory failed to maintain documentation indicating that the laboratory followed the manufacturer's instructions for performing Quality Control (QC) on the Clinitek Status+ and performing an optical check on the Cholestech LDX analyzer each day of use, and; (B) the laboratory failed to maintain the manufacturer's instructions for the Identify Diagnostics Drug Screen test. Findings included: A1. It is the practice of the laboratory to perform microalbumin testing on urine specimens using the waived test system Clinitek Status+. The manufacturer's instructions state, "For CLIA-Waived settings, test positive and negative quality controls with new lots, new shipment of reagents, and when you open a new bottle of urinalysis strips. Test reagents monthly that are stored more than 30 days." A2. The laboratory maintained no documentation to indicate that positive and negative controls were tested on the Clinitek Status+ analyzer with each new lot, each shipment of reagents, each time a new bottle of urinalysis strips were opened and monthly for reagents that are stored more than 30 days. The lot in use on January 24, 2025 was Lot Number: 310047, expiration date: 4 /30/25. A3. It is the practice of the laboratory to perform cholesterol testing on patient specimens using two separate Abbott Cholestech LDX analyzers. The manufacturer's</p>

instructions state, "A Cholestech LDX Optics Check Cassette is supplied with the analyzer. Run the Cholestech LDX Optics Check Cassette once each day before patient samples are tested (and) after the Cholestech LDX System has been moved." A4. The laboratory maintained no documentation for either Abbott Cholestech LDX analyzer to indicate that the Cholestech LDX Optics Check Cassette was performed each day before patient samples were tested on each analyzer. B1. The laboratory failed to maintain evidence of the current package insert and/or manufacturer's instructions for the Identify Diagnostics Drug Screen Test. The lot in use on January 24, 2025 was lot# DOA2406066, expiration date: 5/31/26. C. The laboratory personnel interviewed on January 24, 2025 at 2:30 PM confirmed that the laboratory failed to follow the manufacturer's requirements for the Clinitek Status+ and the Cholestech LDX analyzers as indicated above, and failed to maintain a copy of the manufacturer's instructions for the Identify Diagnostics Drug Screen Test.