

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 34D2131699	<b>(X3) Date Survey Completed</b> 02/08/2019
<b>Name of Provider or Supplier</b> Chestnut Family Practice, PLLC	<b>Street Address, City, State</b> 1013 Chestnut Lane, Suite 110, Matthews, NC	
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>D1001</b>	<p><b>CERTIFICATE OF WAIVER TESTS</b> CFR(s): 493.15(e)</p> <p>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 manufacturers' instructions, review of the laboratory's policies and procedures, observation, review of 2018 and 2019 patient logs, and interview with TP (testing personnel) 2/8/19, the laboratory failed to follow manufacturers' instructions for storage and use of test kits, reagents, and supplies to ensure accurate and reliable test performance. Findings: 1. Review of the laboratory's procedure manual revealed the laboratory did not have manufacturer's instructions available for all tests performed. The following procedures in the manual were not consistent with the test kits observed by the surveyor during a tour of the laboratory at approximately 10:15 a. m.: a. Consult Diagnostics Strep A Tests Dipstick procedure in manual, Henry Schein One Step + Strep A Dipstick kit in use; b. Binax NOW Influenza A+B procedure in manual, OSOM Ultra Flu A+B kit in use. 2. Review of manufacturers' instructions and observation revealed the laboratory failed to observe manufacturers' expiration dates for the use of test kits, reagents, and supplies and failed to discard items which had exceeded their expiration dates. The laboratory used expired supplies for patient testing. During a tour of the laboratory approximately 10:15 - 10:30 a.m., the surveyor observed the following expired supplies, available for use: In cabinets, drawers, and racks a. 1 open box and 3 unopened boxes of Hemocue Hemoglobin 201 microcuvettes - lot #1703190, expiration date 6/12/18; b. 9 vials Para-Pak C&amp;S transport solution - lot #169430J, expiration date 08/2018; c. 1 open box of McKesson Consult Diagnostics Mononucleosis Tests Cassette - lot #226M21, expiration date 9/30/18; d. 1 open box of McKesson Consult Diagnostics hCG Urine Tests Dipstick - lot #HCG6110134, expiration date 10/31/18; e. 100 red top BD Vacutainer tubes - lot</p>

#7135833, expiration date 10/31/18; f. 1 open vial and 1 unopened vial of Quintet AC blood glucose test strips - lot #2116B1407, expiration date 11/20/18; g. 2 blue top BD Vacutainer Trace Element 10.8 mg (milligram) tubes - lot #7305714, expiration date 11/30/18; h. 2 vials Consult Diagnostics Blood Glucose Control Solution (1 Normal, 1 High) - lot #2QC14A, expiration date 1/31/19. In the refrigerator a. 1 box Biosys Plus Liquid Urine Dip Control - lot #233637, expiration date August 2018; b. 3 vials Level 1 Urine Control Solution - lot #233633, expiration date August 2018; c. 3 vials Level 2 Urine Control Solution - lot #233634, expiration date August 2018. Review of 2018 and 2019 patient logs revealed the laboratory tested 1 patient on 8/8/18 using an expired Hemocue cuvette and tested 1 patient 12/27/18 using an expired Mononucleosis kit. 3. Review of manufacturers' instructions and interview with TP #1 revealed the laboratory failed to monitor and document room and refrigerator temperature and humidity daily to ensure proper instrument operation and proper storage of supplies. The Operator's Manual for the URiSCAN optima urine analyzer states in Section 2 "Installation 2.4 ... Environmental Conditions Performance and safety of URiSCAN Optima are warranted at all times if it is operated under the following environmental conditions: ... - In locations with temperatures between 20 degrees C and 28 degrees C. - In locations where the relative humidity is lower than 70%. ..." Manufacturer's instructions for the Level 1 and Level 2 urine control solutions specify storage at 2-8 degrees Celsius. Manufacturers' instructions for the following specify storage at 15-30 degrees Celsius: the OSOM Ultra Flu A+B, the Henry Schein One Step + Strep A Dipstick, the McKesson Consult Diagnostics hCG Urine Tests Dipstick, the McKesson Consult Diagnostics Mononucleosis Tests Cassette, the Quintet AC Blood Glucose test strips, and the Hemocue Hemoglobin 201 microcuvettes. During interview at approximately 11:00 a.m., TP #1 stated that she had not monitored room and refrigerator temperature and humidity daily. She stated she looks at the refrigerator temperature every day, but she does not record it anywhere. 4. Review of manufacturer's instructions and interview with TP #1 revealed the laboratory failed to test quality control material as specified by the manufacturer to ensure proper test performance. Patient testing was performed when quality control was not tested as required. The Operator's Manual for the URiSCAN optima urine analyzer states in Section 6 "6.4 Quality Controls Performance Check with Urine Control Solutions ... Perform two levels of controls under the following conditions: a. With each new shipment of reagent strips and every 30 days to check the storage of the reagent strips; b. When using a new bottle of reagent strips; c. When training instrument operators; d. Whenever test results are in doubt; ... If the QC results are not acceptable, do not test the patient samples until you solve the problem. ... 6.10 CLIA Waived Laboratories: Test positive and negative quality controls with new lots, new shipments of reagents, and when you open a new bottle of reagent strips. Test reagents monthly that are stored for more than 30 days. Run QC tests to ensure reagent strips integrity; train new users; confirm test performance; and when patients' clinical conditions or symptoms do not match. ..." Review of 2018 and 2019 patient logs revealed approximately 78 patients were tested on the URiSCAN optima urine analyzer in 2018 with no quality control testing documented. During interview at approximately 12:50 p.m., testing personnel #1 confirmed that she had not performed any quality control testing. She stated she did not realize quality control testing was required.