

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D0893555	<b>(X3) Date Survey Completed</b>  01/29/2020
<b>Name of Provider or Supplier</b>  Tanner Healthcare For Women	<b>Street Address, City, State</b>  706 Dixie Street, Suite 200, Carrollton, GA	
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 Provider Performed Microscopy (PPM) Clinical Laboratory Improvement Amendments (CLIA) survey was completed on January 29, 2020. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
<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 the Waived testing Quality Control (QC) Documents and manufacturer's package inserts/operators guides, QC log sheets, and staff interview, the laboratory was not performing external QC per manufacturer directions. Findings include: 1. Review of manufacturer package insert or operators guide on the Immunocard STAT hCG Combo test, Hemacue Hb 201, and the McKesson Consult urine analyzer revealed the lab was not performing external QC as required: Per the STAT hCG Combo package insert the external QC should be ran with each new lot and with each new untrained operator (no QC was documented on the log sheet). Review of the Hemacue Hb 201 operators guide revealed external QC should be ran each day of testing (QC was ran 1 time in December 2019, and 4 days in January 2020 on analyzers 18MK0998 and 18MK0995; and 3 days in January on analyzer 18MK0776 to date). Review of the McKesson Consult urine analyzer operators guide revealed external QC be performed with each new shipment of reagent strips and every 30 days, when a new canister of strips are opened, when test results seem inaccurate, after analyzer maintenance, and new operator training (QC was documented 1 time each month in November 2019, December 2019, and January 2020). 2. An interview with the medical assistant/ lab aid in the storage office of the</p>

1st hall on 1/29/2020 at approximately 12:30 p.m. confirmed the QC was not performed at the frequency in the manufacturer's guides.

**D5417**

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT  
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on observation and staff interview, the laboratory failed to ensure reagents and solutions not be used when they have exceeded their expiration date as required.

Findings include: 1. Observation during the laboratory tour on 1/29/2020 at approximately 11 a.m. revealed 2 bottles of 10% Potassium Hydroxide (KOH) reagent on the laboratory counter near the microscope which had expired on 01/23/20.

Observation during the same tour at approximately 11 a.m. on 1/29/2020 revealed a bottle of 9% Saline reagent on the laboratory counter near the microscope which had expired in March 2018. 2. An interview with the medical assistant/ lab aid in the laboratory on 1/29/2020 at approximately 11:15 a.m. confirmed the KOH and saline solutions in the lab had expired.