

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D0391053	<b>(X3) Date Survey Completed</b>  11/05/2019
<b>Name of Provider or Supplier</b>  Milwaukee Health Service Systems, Llc	<b>Street Address, City, State</b>  4800 S 10th St, Unit 1, Milwaukee, WI	
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>D5429</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of maintenance records and interview with the general supervisor, the laboratory did not document daily and weekly maintenance performed on two AU-640 chemistry analyzers as required by the manufacturer on eleven days of patient testing in May and August 2019. Findings include: 1. Review of maintenance records for the AU-640 chemistry analyzer 1 showed the laboratory did not document daily maintenance on the following dates: May 16 and 17, 2019 May 20 through 24, 2019 August 27 through 30, 2019 The laboratory did not document weekly maintenance from May 20 through 24, 2019. 2. Review of maintenance records for the AU-640 chemistry analyzer 2 showed the laboratory did not document daily maintenance on the following dates: August 27 through 30, 2019 3. Interview with the general supervisor on November 5, 2019 at 11:40AM, confirmed the laboratory did not document daily maintenance performed on AU-640 chemistry analyzer 1 on eleven days and did not document weekly maintenance during one week in May 2019. Further interview confirmed the laboratory did not document daily maintenance on AU-640 analyzers 1 and 2 on four days in August 2019.</p>
<b>D5781</b>	<p><b>CORRECTIVE ACTIONS</b> CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b),</p>

which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on surveyor review of temperature logs from January through June 2019 and interview with the general supervisor, the laboratory did not document corrective action on twenty-two days when the temperature readings were outside the defined acceptable range on Refrigerator 2. Findings include: 1. Review of Refrigerator 2 temperature logs revealed testing personnel did not document corrective action on temperature readings outside the acceptable range (36 -46 Fahrenheit) on the following days: January 15, 22, 23, 25, 28, 29, 31 February 18, 20 March 7, 12, 13 April 5, 9, 26, 30 May 1, 9, 14, 23, 24 June 10 2. Interview with the general supervisor on November 5, 2019 at 11:50AM, confirmed testing personnel did not document corrective action when the temperature readings of refrigerator 2 were outside the acceptable range on twenty-two days from January through June 2019.