

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 17D0453273	<b>(X3) Date Survey Completed</b> 01/11/2018
<b>Name of Provider or Supplier</b> Hamilton County Hospital	<b>Street Address, City, State</b> 700 Huser Street, Syracuse, KS	
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: A review of manufacture ' s package H Pylori Test revealed this assay has not been established for patients under 18 years of age revealed the laboratory failed to follow manufactures instructions. Findings were as follows a. Based upon a review of the H Pylori Test revealed the laboratory performed 1 patient under the age of 18 November 14, 2017 .Patient was 11 years old Therefore, the accuracy of the testing cannot be verified.</p>
<b>D2015</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p>

	<p>This STANDARD is not met as evidenced by: Based on a review of lab policies and procedures, proficiency testing (PT) records during calendar years 2017 through the PT provider, American Proficiency Institute API and staff interview, the laboratory failed to document each step in the testing and reporting of results for all proficiency test samples. Findings were: a. A review of the laboratory's Proficiency API for 2017 all three events the Laboratory Director and Testing Person"s failed to sign the Attestation Statement</p>
<p><b>D5209</b></p>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on a review of laboratory and personnel policies/procedures, competency records and staff interview, the laboratory director failed to define by policy /procedure the manner in which competency was assessed for technical consultant . Findings were as follows: a. The laboratory must have policies and procedures to assess competency based on the position responsibilities listed on Form CMS 209. Technical Consultant failed to have a competency documented at the time of the survey 01/11/2018. .</p>
<p><b>D5217</b></p>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: A review of American Proficiency Institute (API) proficiency, Quality Control, Quality Assessment, and Interview with staff revealed the laboratory failed to verify the accuracy for the analyte Ammonia for the 1 st and 2nd events of 2017. Finding were as follows: 1. Based upon a review of API 1 st event Ammonia received a 33% grade 2 nd event 67%. The laboratory failed to produce corrective action. This was confirmed in interview with Technical Consultant and Testing Person #1 on 01/10 /2018 at 15:30 hrs</p>
<p><b>D5413</b></p>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p>

This STANDARD is not met as evidenced by:  
 A review of Temperature and humidity logs and interview with staff revealed the laboratory failed the humidity for the laboratory as the Dimension EXL the chemistry analyzer requires Findings were as follows: a. Based upon review of manufacture's operators guide the laboratory failed the humidity 20% to 80% for the laboratory/1/18 15%,1/2/18 15%,1/3/18 15%,1/4/18 17% the humidity failed the manufacture's range b. At the time of the survey 01/10/2018 the laboratory failed to produce corrective action documentation of humidity, This was confirmed by the Technical Consultant from the CMS 209 form on 01/11/2018 at 14:30 hours.

**D5429**

**MAINTENANCE AND FUNCTION CHECKS**  
 CFR(s): 493.1254(a)(1)

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.

This STANDARD is not met as evidenced by:  
 Review of , 2017 and 2018 instrument records and operator's manuals reveals that the laboratory fails to perform maintenance on equipment as defined by the manufacturer. The findings as follows a. Based upon a review of the Dimension EXL Weekly and Monthly Maintenance records for November 2017 ,December 2017 Weekly and Monthly Maintenance failed to be performed, January 2018 no weekly for first week of January no maintenance . .

**D5435**

**MAINTENANCE AND FUNCTION CHECKS**  
 CFR(s): 493.1254(b)(2)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:  
 A review of Quality Control , Quality Assessment Calibration records revealed the laboratory failed to perform calibration on the Dimension EXL chemistry analyzer before patient testing and interview with laboratory staff. Findings were as follows; a Based upon calibration records an patient reports November 1, 2017 T Bili Cal Expired 2 patients were tested (51344,51354) November 14, 2017 Bun cal expired 9 patients were tested (51667,51461,51656,51684,51696,51700,51705,5173,51718) November 16,2017 Bun cal expired 4 patients were tested (51799,51816,51808,51790). b.Based upon the Calibration records for BNP (LNTTP) for January 2018 revealed the laboratory performed Quality Control and Patients before calibration was performed 1/3/2018 Quality Control was out of the range 70.6 -106.0 result 55 and 59 with cal expired 1 patient was tested (52729), January 8, 2018 DGNA cal expired 1 patient was tested( 52891), January9,2018 MALB cal expired 1 patient was tested (52954) January 9,2018 BP (LENT) Quality Control was out of

control result 58.74 3 patients were tested (52952, 52914,52886) January 11, 11,2018 Quality Control was tested and Out of Control resulted 58 rerun 56. c. This was confirmed in interview with the Technical Consultant on 01/11/2018 at 14:00 hrs in the conference room.

**D5439**

**CALIBRATION AND CALIBRATION VERIFICATION**

CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

A review of calibration verification records for the Dimension EXL, and interview with staff. A review of revealed that the laboratory failed to calibration verification once every six months Finding were as follows 1. Based upon a review of the Dimension EXL calibration verification documentation revealed the laboratory failed to perform at least once every six months that was due in August 2016. This was confirmed in interview with Technical Consultant 01/11/2018 at 10:00 hrs.

**D5469**

**CONTROL PROCEDURES**

CFR(s): 493.1256(d)(10)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
A review of Quality Control, Quality Assessment and interview with staff revealed the laboratory failed to establish or verify the criteria for acceptability of all control (mean and standard deviation). Findings were as follows: Based upon Quality Control data that was presented to surveyor at the time of the survey 1/11/2018 at 11:00 hrs. The laboratory was using the manufacture 's ranges for the BIO-RAD chemistry quality controls and Sysmex e-check hematology quality control. This was confirmed in interview with Technical Consultant. example BNP Quality Control range 70.6 -106.0 laboratory was reporting 55, 58 .

**D5791**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:  
A review of Quality Control Quality Assessment and Interview with staff revealed the laboratory failed to follow the laboratory ' s Quality Control Corrective Action policy. Finding were as follows: a..Based upon the QC Corrective Action plan the laboratory failed to establish a action plan for any QC failure. Therefore, the accuracy or reliability of the QC plan cannot be verified. This was confirmed in interview with Technical Consultant 01/11/2018 at 12;00 example the BNP (LNTP) failure and Platelet failure.