

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D0394644	<b>(X3) Date Survey Completed</b>  05/08/2018
<b>Name of Provider or Supplier</b>  Bellin Hfmc Denmark	<b>Street Address, City, State</b>  595 County Trunk R, Denmark, 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>D2094</b>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(e)</p> <p>(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing (PT) records, laboratory policies, and interview with the Technical Consultant, the laboratory did not evaluate "Not Scored /Non-Consensus" PT scores for Chemistry Event-2 in 2016 and Chemistry Event-1 in 2017 and no remedial action was taken. Findings include: 1. Review of Chemistry PT records for Event-2 in 2016 and Event-1 in 2017 shows the laboratory had "Not Scored /Non-Consensus" and "Not Scored/Insufficient Peer Group" for several analytes in each event. The laboratory did not perform a self-grade of these analytes. 2. Surveyor evaluation of the Chemistry "Not Scored/Non-Consensus" and "Not Scored /Insufficient Peer Group" for the following analytes during the survey showed that Alanine Transaminase (ALT) in Event-2 2016 would have had a score of 60%. ALT in Event-1 2017 would have received a score of 20% and Aspartate Aminotransferase (AST) would have received a score of 80%. No remedial action was taken by the lab for the unacceptable PT scores. 3. Review of the laboratory "Quality Assurance Plan" policy states "When non-consensus results are reported back to the clinic, the above proficiency testing failure protocol will be implemented." The policy was not followed and the PT testing failure protocol was not implemented. 4. Interview with the Technical Consultant on May 8, 2018 at 2:30 PM confirms the unacceptable "Not Scored" PT results were not evaluated and no remedial action was taken.</p>

**D5311**

**SPECIMEN SUBMISSION, HANDLING, AND REFERRAL**

CFR(s): 493.1242(a)

The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:

Based on surveyor observation of specimens in the laboratory, review of procedures, and interview with the Technical Consultant, the laboratory did not follow their written policies and procedures for specimen labeling. Findings include: 1. On May 8, 2018 at 3:45 PM of a specimen tube in the test tube rack by the Piccolo analyzer it was observed that the specimen was not labeled with any patient information. Two patient labels were laying on the counter by the Piccolo analyzer and a sample from the unlabeled specimen was running on the analyzer. 2. Review of the Specimen Processing procedure shows the procedure specifically states "Properly label tube with type of specimen and name of patient." 3. Interview with the Technical Consultant, who also observed the unlabeled specimen, on May 8, 2018 at 3:45 PM confirmed the specimen was not labeled and the procedure for specimen labeling was not followed.

**D5411**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**

CFR(s): 493.1252(a)

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:

Based on surveyor review of manufacturer's instructions, quality control (QC) results, the Individualized Quality Control Plan (IQCP), and interview with the Technical Consultant, the laboratory failed to perform QC testing as required. Findings include: 1. Review of manufacturer instructions for the Piccolo chemistry analyzer recommends QC testing to follow federal guidelines which is two levels of QC for every analyte each day of testing. 2. The laboratory developed and the Laboratory Director approved an IQCP which states that 2 levels of QC will be performed on the Piccolo analyzer every thirty days. 3. Review of QC results show that QC has not consistently been performed every 30 days and records reveal that QC is being performed greater than 30 days. The following dates are when QC has been performed on the Piccolo for Complete Metabolic Panels (CMP) and Lipid Panel testing: 2018: 1/4/18, 2/12/18, 3/9/18, 4/19/18 2017: 11/30/17, 11/3/17, 9/29/17, 8/29/17, 7/14/17, 6/9/17, 5/11/17, 4/12/17, 3/2/17, 1/18/17 2016: 12/27/16, 11/29/16, 10/28/16, 9/15/16, 8/18/16 4. Interview with the Technical Consultant on May 8, 2018 at 3:00 PM confirmed that QC was not performed as frequent as the IQCP required. This is a repeat deficiency previously cited June 1, 2010.