

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0895915	(X3) Date Survey Completed 05/23/2023
Name of Provider or Supplier Munson Healthcare Db a Heather Hill Care	Street Address, City, State 12340 Bass Lake Road, Chardon, OH	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review and an interview with Testing Personnel (TP) #1, the laboratory failed to evaluate and document their assessments of the College of American Pathologists (CAP) Proficiency Testing (PT) analytes scored below 100% (percent). This deficient practice had the potential to affect all 150 patient Arterial Blood Gas (ABG) tests performed in this laboratory in the subspecialty of Routine Chemistry between the first PT testing events of 2022 and 2023. Findings Include: 1. Review of the laboratory's "ABG Proficiency Testing" policy and procedure, approved by the Laboratory Director on 01/03/2022 and provided for the inspection, did not find instructions to conduct and document the laboratory's assessment when the analytes are scored below 100% by the PT provider. 2. Review of the laboratory's 2022 and 2023 CAP PT documentation revealed the partial pressure of oxygen (pO2) was scored 80% for the first testing event of 2022 and the pH, pO2 and partial pressure of carbon dioxide (pCO2) were each scored 80% for the first testing event of 2023 with no documented evidence of any assessments for the unacceptable reported results. 3. TP#1 confirmed, in an electronic mail (email) on 05/24/2023 at 9:30 AM, that the laboratory did not evaluate/document the PT evaluations of the unacceptable results for AQI-A 2022/PO2=80%, AQI-A 2023/pH, PCO2 and PO2=80%.</p>
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it</p>

can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on record review and an interview with Testing Personnel (TP) #1, the laboratory failed to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for arterial blood gas (ABG), sodium (Na), potassium (K) and ionized calcium (Ca++) testing for accuracy, precision and reportable range. This deficient practice had the potential to affect 125 out of 125 patient test results from the implementation of the iSTAT test system in July 2022 to 05/23/2023. Findings Include: 1. Review of the laboratory's policies and procedures provided for the inspection, did not find any instructions for any performance specification activities for the iSTAT test system that was implemented in July 2022. 2. The Inspector requested the laboratory's policy and procedure for performance specification activities and all performance specification documentation for the iSTAT test system from Testing Personnel (TP) #1. TP#1 confirmed, via a telephone conversation on 05/30/2023 at 11:12 AM, that the laboratory did not establish a policy and procedure for performance specification activities for ABG, Na, K and Ca++ testing procedures, did not conduct and document any performance specification activities and was unable to provide the requested documentation.

D5805

TEST REPORT

CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on record review and an interview with Testing Personnel (TP) #1, the laboratory failed to indicate the name and address of the laboratory location where the arterial blood gas (ABG), sodium (Na), potassium (K) and ionized calcium (Ca++) testing were performed on the final test reports. This deficient practice had the potential to affect 238 out of 238 patient ABG, Na, K and Ca++ tests performed in the subspecialty of Routine Chemistry between the last CLIA inspection on 10/12/2021 and 05/23/2023. Findings Include: 1. Review of a sample of the laboratory's 2023 patient final test reports provided for the inspection, revealed six out of six reports had the instrument ABG, Na, K and Ca++ result printouts attached to a template worksheet that was completed by hand, specific to the patient's information, scanned into the hospital's electronic medical record (EMR) system and then made available to the ordering provider. 2. Further review of the same six out of six sample of the laboratory's 2023 patient ABG, Na, K and Ca++ final test reports did not find any indication of the name and address of the laboratory location where the testing was

performed. 3. TP#1 confirmed, via an electronic mail (email) on 05/24/2023 at 9:30 AM, that the result forms had been recently updated and do not contain the laboratory's address.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

****This is a repeat deficiency as cited on the 02/27/2019 CLIA inspection.**** Based on record review and an interview with Testing Personnel (TP) #1, the Technical Consultant (TC) failed to evaluate and document the second semi-annual competency of TP#1 and TP#6 who were responsible for moderate complexity arterial blood gas (ABG), sodium (Na), potassium (K) and ionized calcium (Ca++) testing procedures during the first year the individuals tested patient specimens utilizing the newly implemented iSTAT test system in January 2022. This deficient practice had the potential to affect all patient testing performed by two out of eight TP between 01/03/2022 and 05/23/2023. Findings Include: 1. Review of the laboratory's Form CMS-209, provided on the date of the inspection, approved, signed and dated by the Laboratory Director on 05/16/2023, revealed eight individuals listed as TP. 2. Review of the laboratory's "ABG Competency Assessment" policy and procedure, provided on the date of the inspection, approved, signed and dated by the Laboratory Director on 11/11/2015, found the following statements: "Policy ...competency assessment is completed...at six months of employment and then annually by all employees involved on the testing or reporting of Arterial Blood Gasses. Arterial Blood Gas Competency Assessment is to be performed by the lab director." 3. Review of the laboratory's 2022 and 2023 semiannual competency assessment records, provided for the inspection, did not find any record that a 12 month assessment was conducted on TP#1 and TP#6 during their first year of testing patient ABG specimens on the newly implemented iSTAT test system in 01/2022 as indicated below: TP#1 TP#6 Initial 01/06/2022 04/22/2022 6 month 07/15/2022 10/19/2022 12 month not done not done 4. The Inspector requested the laboratory's second semiannual competency assessment records for TP#1 and TP#6, as indicated above from TP#1. TP#1 confirmed that the laboratory did not assess the 12 month competency of TP#1 and TP#6 during the first year of testing patient specimens on the newly implemented iSTAT test system and was unable to provide the requested documentation on the date of the inspection. The interview occurred via electronic mail (email) on 05/24/2023 at 9:30 AM.