Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0895915	02/27/2019
Name of Provider or Supplier	**Street Address, City, State**	
Munson Healthcare Dba Heather Hill Care	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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on record review and an interview with testing personnel (TP) #1, the laboratory failed to examine or test three out of three of the 2018 arterial blood gas (ABG), sodium (Na), potassium (K) and ionized calcium (Ca++) proficiency testing (PT) events or 15 out of 15 PT samples by five out of the six individuals listed as TP who routinely performed moderately complex ABG, Na, K and Ca++ testing in the laboratory. Findings Include: 1. Review of the laboratory's Form CMS-209, provided on the date of the inspection, revealed six individuals listed and credentialed by the Laboratory Director via signature and date on 02/26/2019, to perform moderately complex testing. 2. Review of the laboratory's "Proficiency Testing" policy and procedure, approved, signed, and dated by the Laboratory Director on 06/16/2017, revealed "All employees are required to participate in proficiency testing. An employee rotation log will be monitored by the department head/Supervisor." 3. Review of the laboratory's 2018 College of American Pathologists (CAP) ABG, Na, K and Ca++ PT records, provided on the date of the inspection, did not find that TP#2, TP#3, TP#4, TP#5 and TP#6 participated in PT testing in 2018, however revealed TP#1 performed them all. 4. The Inspector requested the laboratory's 2018 documentation indicating that TP#2, TP#3, TP#4, TP#5 and TP#6 participated in PT testing in 2018 from TP#1. TP#1 confirmed that TP#2, TP#3, TP#4, TP#5 and TP#6 did not participate in any PT activities in 2018, as required, and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 02/27/2019 at 8:20 AM.

D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: **This is a repeat deficiency as cited on the 04/03/2017 CLIA inspection** Based on record review and an interview with testing personnel (TP) #1, the laboratory failed to test three out of 15 of the 2018 arterial blood gas (ABG), sodium (Na), potassium (K) and ionized calcium (Ca++) proficiency testing (PT) samples the same number of times that it routinely tested patient samples. Findings Include: 1. Review of the laboratory's "Proficiency Testing" policy and procedure, approved, signed, and dated by the Laboratory Director on 06/16/2017, did not find any instructions to test PT samples the same number of times that it routinely tested patient samples. 2. Review of two out of three of the laboratory's 2018 College of American Pathologists (CAP) ABG, Na, K and Ca++ PT events, provided on the date of the inspection, revealed the laboratory tested PT samples more times than it routinely tested patient samples prior to the submission due date assigned by the PT provider for three out of 15 testing samples, as listed below: 2018 AQ-B-06; tested on 07/13/2018 TP time run pH /pCO2/ Na /Ca++ *52960 10:24:52 7.53/ 18 /149/1.08 52960 09:59:28 7.52/ 19 /151/1. 11 2018 AQ-C-13; tested on 11/08/2018 TP time run pO2 / Ca++ *52960 09:58:24 115 / 1.20 52960 10:17:48 113 / 1.19 2018 AQ-C-14; tested on 11/08/2018 TP time run pO2 *52960 10:01:44 75 52960 10:21:08 73 52960; instrument operator number for TP#1 pCO2; partial pressure of carbon dioxide Na; sodium Ca++; ionized calcium pO2; partial pressure of oxygen *; testing results reported 3. TP#1 confirmed the laboratory tested the above mentioned 2018 PT samples more times than it routinely tested patient samples prior to the result submission due date set by CAP. The interview occurred on 02/27/2019 at 9:05 AM.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on record review and an interview with testing personnel (TP) #1, the laboratory failed to follow their written policies and procedures to assess the competency of TP performing moderately complex arterial blood gas (ABG), sodium (Na), potassium (K) and ionized calcium (Ca++) testing procedures by the Laboratory Director. This deficient practice had the potential to affect 100 percent (%) of the patient ABG, Na, K and Ca++ samples tested. Findings Include: 1. Review of the laboratory's Form CMS-209, approved, signed, and dated by the Laboratory Director on 02/26/2019, revealed six individuals listed as TP and one individual newly listed as a TC (also listed as TP#1). 2. Review of the laboratory's "ABG Competency Assessment" policy and procedure, approved via signature and date by the Laboratory Director in 06/2015 and provided on the date of the inspection, found the following statements: "Policy: ...Arterial Blood Gas Competency Assessment is to be performed by the lab director." "Procedure: ...5. The Lab director will evaluate through direct

	observation the six areas of minimum requirements as defined by CLIA in this hospital's ABG Lab Competency Assessment." 3. Review of the laboratory's 2017 and 2018 competency assessment documentation, provided on the date of the inspection, revealed that the newly listed non-qualified TC had conducted all of the competency assessments for TP#2, TP#3, TP#4, TP#5 and TP#6 and TP#6, a non-listed/non-qualified TC, conducted the competency assessments for TP#1. 4. Review of the education documentation provided for the sole and newly listed TC and TP#6 revealed the individuals achieved an Associates in Specialized Technology degree in Respiratory Therapy and did not meet the minimum TC qualification requirements. 5. TP#1 confirmed that the individual newly listed as the sole TC and TP#6 did not meet the minimum TC qualification requirements, the laboratory did not follow their own policy and procedure and the Laboratory Director did not assess the competency of TP#1, TP#2, TP#3, TP#4, TP#5 and TP#6. The interview occurred on 02/27/2019 at 9: 22 AM.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) 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. This STANDARD is not met as evidenced by: Based on record review and an interview with testing personnel (TP) #1, the laboratory failed to define criteria consistent with the manufacturer's instructions and document humidity conditions for reliable arterial blood gas (ABG), sodium (Na), potassium (K) and ionized calcium (Ca++) testing procedures on the GEM Premier 4000 analyzer and for test result reporting. This deficient practice had the potential to affect 100 percent (%) of the patient ABG, Na, K and Ca++ testing procedures performed. Findings Include: 1. Review of the laboratory's "Arterial Blood Gasses - GEM4000" policy and procedure manual, provided on the date of the inspection, did not find any instructions to monitor and document humidity conditions consistent with manufacturer's operating specifications. 2. Review of the "GEM Premier 4000 Reference Guide" revealed the following: "Ambient Environmental Requirements ... Relative Humidity Limits: 15-85% RH" RH; relative humidity 3. The Inspector requested the laboratory's policy and procedure for the humidity criteria consistent with the manufacturer's instructions and the humidity documentation from 2017, 2018 and 2019 from TP#1. TP#1 confirmed the laboratory did not establish a policy and procedure to monitor and document humidity criteria consistent with the manufacturer's instructions, did not monitor and document humidity in 2017, 2018 and 2019 and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 02/27/2019 at 11:15 AM.
D5800	POSTANALYTIC SYSTEMS CFR(s): 493.1290 Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in 493.1291 unless HHS approves a procedure,

	specified in Appendix C of the State Operations Manual (CMS Pub. 7) that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the postanalytic systems and correct identified problems as specified in 493. 1299 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and an interview with testing personnel (TP) #1, the laboratory failed to meet the post analytic systems requirements in 493.1291 for 100 percent (%) of the final test reports. Findings Include: 1. The laboratory failed to ensure that 100 percent (%) of the final test report indicated the name and address of the laboratory location in which the moderately complex arterial blood gas (ABG), sodium (Na), potassium (K) and ionized calcium (Ca++) testing procedures were performed. (Refer to D5805) 2. The laboratory failed to issue any corrected reports when the potassium (K) or any other test result was found to be incorrectly reported on the patients' final test reports. This deficient practice had the potential to affect 100 percent (%) of the patient testing performed. (Refer to D5821) 3. The laboratory failed to review the effectiveness of their quality assessment program of the post analytic systems. This deficient practice had the potential to affect 100 percent (%) of the patient testing performed. (Refer to D5893)
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 ensure that 100 percent (%) of the final test report indicated the name and address of the laboratory location in which the moderately complex arterial blood gas (ABG), sodium (Na), potassium (K) and ionized calcium (Ca++) testing procedures were performed. Findings Include: 1. Review of one of the laboratory's final test reports, printed out of the electronic medical record (EMR) and copied out of the patients' paper chart and provided on the date of the inspection, did not find any indication of the name and address of the laboratory location in which the moderately complex ABG, Na, K and Ca++ testing was performed. 2. The Inspector requested the laboratory's ABG, Na, K and Ca++ final test reports that indicated the name and address of the laboratory location in which the testing was performed from TP#1. TP#1 stated that the final test report is printed out of the EMR and put in the patients' paper chart. TP#1 confirmed that the name and address of the laboratory location in which the testing was performed was not indicated on 100% of the final test reports and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 02/27/2019 at 9:48 AM.
D5821	TEST REPORT

	CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: Based on record review and an interview with testing personnel (TP) #1, the laboratory failed to issue any corrected reports when the potassium (K) or any other test result was found to be incorrectly reported on the patients' final test reports. This deficient practice had the potential to affect 100 percent (%) of the patient testing performed. Findings Include: 1. Review of the laboratory's 2018 "ABG Quality Assurance" logs, provided on the date of the inspection, revealed only one documented incident, on 10/06/2018, in which the K result was manually transcribed from the GEM4000 instrument printout into the electronic medical record (EMR) incorrectly. ABG; arterial blood gas 2. TP#1 stated, on 02/27/2019 at 9:48 AM, the TP manually enter the test results into the EMR from the GEM4000 instrument printout. The EMR final test report is printed out of the EMR, the instrument printout is affixed along the right margin of EMR report, a copy is generated which is provided to the ordering physician and the original is kept in the laboratory. The EMR is the final test report, is printed and put in the patients' paper chart. 3. Further review of the test records and final test report in the EMR, as well as the patients' paper chart, revealed the following: a. The K result indicated on the instrument printout is 4.4 b. The K result was manually transcribed into the EMR as 4.7 c. TP#4 conducted and documented quality assessment activities, including result transcription by TP#1, within seven days from the date tested. d. TP#4 corrected the reported K result on the laboratory's copy of the EMR report with the affixed instrument printout by putting one line through the incorrectly reported K result of 4.7 and hand wrote the correct K result, 4.4, next to it. 4. The Inspector requested the final test report filed in the patients' paper chart and the final test report printed out of the EMR from TP#1. TP#1 provided the requested documentation which did not indicate the corrected K result. 5. TP#1 confirmed the laboratory did not correct the final test report in the EMR, did not correct the final test report in the patients' paper chart and did not issue a corrected final test report for the incorrect patient K result reported. The interview occurred on 02/27/2019 at 9:48 AM.
D5893	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(b)(c) (b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on record review and an interview with testing personnel (TP) #1, the laboratory failed to review the effectiveness of their quality assessment program of the

	post analytic systems. This deficient practice had the potential to affect 100 percent (%) of the patient testing performed. Findings Include: 1. Review of the laboratory's "ABG Quality Assurance" manual, a royal blue 3-ring binder, found the "ABG Lab Reporting Quality Assurance" policy and procedure, approved, signed and dated by the Laboratory Director on 07/19/2017, which revealed instructions to conduct quality assessment reviews within seven days on 100% of patient arterial blood gas (ABG), sodium (Na), potassium (K) and ionized calcium (Ca++) testing procedures performed. Additionally, five random patient reports are re-reviewed and documented quarterly. 2. Review of the laboratory's test resulting and reporting processes found the TP manually enter the test results into the electronic medical record (EMR) from the GEM4000 instrument printout. The EMR final test report is printed out of the EMR, the instrument printout is affixed along the right margin of the EMR report, a copy is generated which is provided to the ordering physician and the original is kept in the laboratory. The EMR is the final test report and is printed and put in the patients' paper chart. 3. Review of a patients' test records and final test report from 10 /06/2018, did not find a corrected report for the inaccurately reported K result of 4.7 to indicate the correct K result of 4.4 in the EMR and in the patients' paper chart. 4. Review of the laboratory's quality assessment records revealed "ABG Quality Assurance" logs which indicated the patient testing reviewed, problems identified, if any and the corrective action, if applicable. However, there was no indication that the post analytic quality assessment activities were assessed as effective, accurate and completed through to the final test report. 5. TP#1 confirmed the laboratory did not issue any corrected test reports in the EMR or in the patients' paper chart and did not assess the effectiveness of the post analytic quality assessment program to ensure the problems identified were corrected completely through to the final test report in the EMR and in the patients' paper chart. The interview occurred on 02/27/2019 at 9:48 AM.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on record review and an interview with testing personnel (TP) #1, the laboratory failed to have a Technical Consultant (TC) who met the qualification requirements of 493.1411 of this subpart and who provided technical oversight of the moderately complex arterial blood gas (ABG), sodium (Na), potassium (K) and ionized calcium (Ca++) testing procedures performed in accordance with 493.1413 of this subpart. This deficient practice had the potential to affect 100 percent (%) of the patient testing performed. Findings Include: 1. The laboratory failed to have a TC who met the qualification requirements and who provided technical oversight of the moderately complex ABG, Na, K and Ca++ testing procedures performed. (Refer to D6034) 2. A qualified Technical Consultant (TC) failed to evaluate and document the competency of the testing personnel (TP) #2, TP#4 and TP#5 who were responsible for moderate complexity ABG, Na, K and Ca++ testing procedures at least semiannually during the first year the individual tested patient specimens. (Refer to D6053) 3. A qualified Technical Consultant (TC) failed to evaluate and document the

	competency of TP#1 and TP#6 who were responsible for moderate complexity ABG, Na, K and Ca++ testing procedures at least annually after the first year the individual tested patient specimens. (Refer to D6054)
D6034	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section. This STANDARD is not met as evidenced by: Based on record review and an interview with testing personnel (TP) #1, the laboratory failed to have a Technical Consultant (TC) who met the qualification requirements and who provided technical oversight of the moderately complex arterial blood gas (ABG), sodium (Na), potassium (K) and ionized calcium (Ca++) testing procedures performed. This deficient practice had the potential to affect 100 percent (%) of the patient testing performed. Findings Include: 1. Review of the laboratory's Form CMS-209, approved, signed and dated by the Laboratory Director on 02/26 /2019, revealed one individual newly listed as the sole TC (also listed as TP#1). 2. Review of the education documentation for TP#1, provided on the date of the inspection, revealed TP#1 achieved an Associates in Specialized Technology degree in Respiratory Therapy and did not meet the minimum TC qualification requirements. 3. TP#1 confirmed that the newly listed and sole TC on the laboratory's Form CMS-209 did not achieve a Bachelor's of Science Degree in a chemical, physical or biological science or medical technology from an accredited institution and did not meet the minimum TC qualification requirements. The interview occurred on 02/27 /2019 at 8:45 AM.
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: Based on record review and an interview with testing personnel (TP) #1, a qualified Technical Consultant (TC) failed to evaluate and document the competency of the testing personnel (TP) #2, TP#4 and TP#5 who were responsible for moderate complexity arterial blood gas (ABG), sodium (Na), potassium (K) and ionized calcium (Ca++) testing procedures at least semiannually during the first year the individuals tested patient specimens. This deficient practice had the potential to affect 100 percent (%) of the patient testing performed by three out of six TP. 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 02/26/2019, revealed four out of the six listed individuals as TP were new since the last CLIA inspection on 04/03/2017 and the newly listed TC was the sole TC. 2. Review of the

	laboratory's "ABG Compentency Assessment" policy and procedure, provided on the date of the inspection, approved, signed and dated by the Laboratory Director in 06 /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 2018 and 2019 semiannual competency assessment records, provided on the date of the inspection, did not find any record that a six month assessment was conducted on TP#4 and did not find any record that a six month and 12 month assessment was conducted on TP#2 and TP#5 during their first year of testing patient specimens by a qualified TC as indicated below: TP#2 Hire date 11/29/2017 6 month done 04/2018, by TP#1-unqualified TC 12 month due 11/2018 not done TP#4 Hire date 08/09/2018 6 month due 02/2019 not done TP#5 Hire date 07/19/2017 6 month done 02/2018, by TP#1-unqualified TC 12 month due 07/2018 not done 4. Review of the education documentation for the sole and newly listed TC/TP#1, provided on the date of the inspection, revealed TC/TP#1 achieved an Associates in Specialized Technology degree in Respiratory Therapy and did not meet the minimum TC qualification requirements. 5. The Inspector requested the laboratory's 2018 and 2019 semiannual competency assessment records for TP#2, TP#4 and TP#5, conducted by a qualified TC, as indicated above from TP#1. TP#1 confirmed that the laboratory did not follow their written policy and procedure indicating the Laboratory Director would assess and document the competency of the TP, did not assess competency of new TP at least semiannually during the first year of testing patient specimens, as required, did not conduct competency assessments by a qualified TC and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 02/27/2019 at 9:22 AM.
D6054	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 annually, after the first year. This STANDARD is not met as evidenced by: Based on record review and an interview with testing personnel (TP) #1, a qualified Technical Consultant (TC) failed to evaluate and document the 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 at least annually after the first year the individual tested patient specimens. This deficient practice had the potential to affect 100 percent (%) of the patient testing performed by TP#1 and TP#6. 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 02/26/2019, revealed two out of the six listed individuals as TP had been employed, tested patient samples for more than one year and the newly listed TC was the sole TC. 2. Review of the laboratory's "ABG Compentency Assessment" policy and procedure, provided on the date of the inspection, approved, signed and dated by the Laboratory Director in 06/2015, found the following statements: "Policy ... competency assessment is completed...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 2017 and 2018 annual competency assessment records, provided on the date of the

	inspection, revealed TP#1 assessed the competency of TP#6 and TP#6 assessed the competency of TP#1. 4. Review of the education documentation for the sole and newly listed TC/TP#1 as well as TP#6, provided on the date of the inspection, revealed both TC/TP#1 and TP#6 achieved an Associates in Specialized Technology degree in Respiratory Therapy and did not meet the minimum TC qualification requirements. 5. The Inspector requested the laboratory's 2017 and 2018 annual competency assessment records for TP#1 and TP#6, conducted by a qualified TC from TP#1. TP#1 confirmed that the laboratory did not follow their written policy and procedure indicating the Laboratory Director would assess and document the competency of the TP, a qualified TC did not assess competency of TP#1 and TP#6 at least annually after the first year of testing patient specimens, as required and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 02/27/2019 at 9:22 AM.