Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0895915	09/24/2025
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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload 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 Director and TP failed to attest to the routine integration of proficiency testing (PT) samples into the patient workload using the laboratory's routine methods for three out of six College of American Pathologists (CAP) PT events for arterial blood gas (ABG) testing in the subspecialty of Routine Chemistry. This deficient practice had the potential to affect 300 out of 300 patient tests performed in this laboratory between 10/16/2023 and 09/24/2025. Findings Include: 1. Review of the laboratory's "ABG Proficiency Testing" policy and procedure, approved via signature and date by the Laboratory Director on 11/26/2024, did not find any instructions for the Laboratory Director and TP to attest to the routine integration of proficiency testing (PT) samples into the patient workload using the laboratory's routine methods for each testing event. 2. Review of the laboratory's 2023, 2024 and 2025 CAP PT documentation lacked documentation of the Laboratory Director and/or TP attestations on the following PT events: AQIS-C 2023 - no LD or TP attestations AQIS-A 2024 - no TP attestations AQIS-C 2024 - no LD attestation AQIS-B 2025 - no LD or TP attestations LD; Laboratory Director 3. The Inspector requested the laboratory's approved PT policy and procedure to include instructions for Laboratory Director and TP attestations on PT events and the laboratory's 2023, 2024 and 2025 CAP PT attestations signed by the Laboratory Director and TP from TP#1. TP#1 confirmed that the laboratory's PT policy and procedure did not include attestation instructions. TP#1 further confirmed the Laboratory Director did not attest to the routine integration of PT samples into the patient workload using the laboratory's

	routine methods for the third events of 2023 and 2024 and the second event of 2025. TP#1 also confirmed the TP did not attest to the third event of 2023, the first event of 2024 and the second event of 2025. TP#1 was unable to provide the requested documentation on the date of the inspection. The interview occurred on 09/24/2025 at 9:25 AM.
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (e)(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. 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 actions taken for two unacceptable pCO2 (partial pressure of carbon dioxide) out of six College of American Pathologists (CAP) proficiency testing (PT) events in 2023, 2024 and 2025 in the subspecialty of Routine Chemistry. This deficient practice had the potential to affect 25 out of 25 patient pCO2 tests results from 10/20/2024 through 09/24/2025. Findings Include: 1. Review of the laboratory's 2023, 2024 and 2025 CAP ABG (arterial blood gas) PT documentation, provided on the date of the inspection, revealed the following unsatisfactory analyte testing scores without any documented evaluations: Third PT Event 2024 pCO2; 80% First PT Event 2025 pCO2; 80% 2. The Inspector requested the laboratory's documented investigation, technical assistance and TP training activities for the unacceptable pCO2 PT results from TP#1. TP#1 confirmed the laboratory did not investigate, document and implement any corrective actions for the unacceptable pCO2 PT results and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 09/24/2025 at 9:45 AM.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on record review and an interview with Testing Personnel (TP) #1, the laboratory failed to establish and follow written policies and procedures and document all assessment activities of the ongoing mechanism to monitor, assess, and correct problems identified in the general laboratory systems. This deficient practice had the potential to affect 338 out of 338 patient ABG (arterial blood gas) test results in the subspecialty of Routine Chemistry from 05/23/2023 through 09/24/2025. Findings Include: 1. Review of the laboratory's "ABG Lab Reporting Quality Assurance" policy and procedure, approved via signature and date by the Laboratory Director on

	11/26/2024 and provided on the date of the inspection, found it was the only policy and procedure that mentioned any quality assessment activities and lacked general laboratory system components. 2. Review of the laboratory's 2024 and 2025 quarterly "Quality Assurance Assessment" form revealed quality monitors for competency assessment and proficiency testing with no mention of any issues or corrective actions. 3. Review of the laboratory's 2024 and 2025 competency assessment documentation found the TP competency assessments were not conducted by a listed and qualified Technical Consultant. TP#1 confirmed they conducted the competency assessments on the TP and then obtained the Laboratory Director's signature and date. The interview occurred on 09/24/2025 at 10:45 AM. 4. Review of the laboratory's 2023, 2024 and 2025 College of American Pathologists (CAP) proficiency testing (PT) found the Laboratory Director and/or the TP failed to attest to the routine integration of PT samples into the patient workload using the laboratory's routine methods. Additionally, the laboratory did not evaluate and document activities of unacceptable PT test results in 2024 and 2025. TP#1 confirmed, on 09/24/2025 at 9: 25 AM, the lack of consistent attestation of the Laboratory Director and TP. TP#1 further confirmed on 09/24/2025 at 9:45 AM, the laboratory lacked evaluating and documenting unacceptable PT results and the laboratory's quality assessment activities did not identify these failures. 5. The Inspector requested the laboratory's quality assessment policy and procedure to include the general laboratory systems from TP#1. TP#1 confirmed the laboratory did not have any other quality assessment policy and procedure established, only documented corrective action if/when a problem was identified, did not document any other quality assessment activities and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 09/24/2025 at 10:45 AM.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) (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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on record review and an interview with Testing Personnel (TP) #1, the laboratory failed to establish and follow their own written policies and procedures and accurately document all assessment activities of the ongoing mechanism to monitor, assess, and correct problems identified in the preanalytic test systems. This deficient practice had the potential to affect 338 out of 338 patient ABG (arterial blood gas) test results in the subspecialty of Routine Chemistry from 05/23/2023 through 09/24/2025. Findings Include: 1. Review of the laboratory's "ABG Lab Reporting Quality Assurance" policy and procedure, approved via signature and date by the Laboratory Director on 11/26/2024 and provided on the date of the inspection, found it was the only policy and procedure that mentioned any quality assessment activities and lacked preanalytic laboratory system components. 2. Review of the laboratory's 2024 and 2025 quarterly "Quality Assurance Assessment" form revealed quality monitors for "Appropriate Patient Identification", "Time Specimen Collected" and "Time Specimen Resulted" with no indication of any issues or corrective actions. 3. The Inspector requested the laboratory's quality assessment policy and procedure to include the preanalytic laboratory systems from TP#1. TP#1 confirmed the laboratory did not have any other quality assessment policy and procedure established, only documented corrective action if/when a problem was identified, did not document any

	other quality assessment activities and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 09/24/2025 at 10:45 AM.
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. This STANDARD is not met as evidenced by: Based on record review and an interview with Testing Personnel (TP) #1, the laboratory failed to establish and follow their own written policies and procedures and accurately document all assessment activities of the ongoing mechanism to monitor, assess, and correct problems identified in the analytic test systems. This deficient practice had the potential to affect 338 out of 338 patient ABG (arterial blood gas) test results in the subspecialty of Routine Chemistry from 05/23/2023 through 09/24/2025. Findings Include: 1. Review of the laboratory's "ABG Lab Reporting Quality Assurance" policy and procedure, approved via signature and date by the Laboratory Director on 11/26/2024 and provided on the date of the inspection, found it was the only policy and procedure that mentioned any quality assessment activities and lacked analytic laboratory system components. 2. Review of the laboratory's 2024 and 2025 quarterly "Quality Assurance Assessment" form did not find any quality monitors for the analytic laboratory system. 3. The Inspector requested the laboratory's quality assessment policy and procedure to include the analytic laboratory system from TP#1. TP#1 confirmed the laboratory did not have any other quality assessment policy and procedure established, only documented corrective action if/when a problem was identified, did not document any other quality assessment activities and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 09/24/2025 at 10:45 AM.
D5807	TEST REPORT CFR(s): 493.1291(d) (d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. 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 accurate pO2 (partial pressure of oxygen), BE (base excess), sO2 (oxygen saturation), Na (sodium), K (potassium) and iCa (ionized calcium) reference ranges or normal values on the final test report consistent with the approved reference ranges or normal values in the subspecialty of Routine Chemistry. This deficient practice had the potential to affect 338 out of 338 pO2, BE, sO2, Na, K and iCa tests results in the subspecialty of Routine Chemistry from 05/23/2023 through 09/24/2025. Findings Include: 1. Review of the laboratory's "Arterial Blood Gasses-I-STAT" policy and procedure, approved by the Laboratory Director via signature and date on 11/26/2024 and provided on the day of the inspection revealed the following reference ranges: Na 135-145 (missing units of measure) K 3.5-5.0

	(missing units of measure) pO2 80-100 (missing units of measure) iCa 1.00-3.00 (missing units of measure) BE (-2)-(+2) (missing units of measure) sO2 95-99% 2. Review of three out of three of the laboratory's 2025 "Foundations Health Solutions ABG Result Log" final test reports found the patient name, date of birth, date collected, time collected, time tested, collected by, collector's signature, results reported to/on/at, oxygen status, vent settings and arterial puncture documentation were all hand written on the template worksheet. The i-STAT instrument test result printed strip was taped onto this template worksheet containing the tested analytes with the following reference ranges and units of measure: Na 138-146mmol/L K 3.5-4.9mmol/L pO2 80-105mmHg iCa 1.12-1.32mmol/L BE (-2)-(+3)mmol/L sO2 95-98% mmol/L; milli-moles per liter mmHg; milli-meters of mercury %; percent The completed final test report was then scanned into the patients electronic medical record. 3. TP#1 confirmed the laboratory did not indicate the approved analyte reference ranges listed above on the final test report. The interview occurred on 09/24 /2025 at 11:10 AM.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to-- This STANDARD is not met as evidenced by: Based on record review and an interview with Testing Personnel (TP) #1, the Technical Consultant (TC) failed to evaluate and document the competency of eight out of eight Testing Personnel (TP) in 2024 and 2025 assuring their competency was maintained in order to perform moderately complex arterial blood gas (ABG) testing in the subspecialty of Routine Chemistry and report the test results promptly, accurately, and proficiently. This deficient practice had the potential to affect 338 out of 338 patient ABG tests conducted by TP#1, TP#2, TP#3, TP#4, TP#5, TP#6, TP#7 and TP#8 from 05/23/2023 through 09/24/2025. Findings Include: 1. Review of the laboratory's "ABG Competency Assessment" policy and procedure, provided on the date of the inspection, found the following statements: "The ABG competency assessment is performed by the Lab Director." "2. The Lab Director will evaluate through direct observation the six areas of minimum requirements defined by CLIA in this facility's ABG Competency Assessment." 2. Review of the laboratory's Form CMS-209, approved via signature and date by the Laboratory Director on 09/23/2025, found the Laboratory Director was also listed as the sole Clinical Consultant and the sole TC along with eight TP listed and credentialed to perform moderate complexity patient ABG testing procedures. 3. Review of the laboratory's 2024 and 2025 competency assessment documentation provided on the date of the inspection revealed TP assessed the competency of TP and then obtained the Laboratory Director's signature and date. 4. TP#1 confirmed the Laboratory Director, also listed as the sole TC, did not assess the competency of TP#1, TP#2, TP#3, TP#4, TP#5, TP#6, TP#7 and TP#8 according to their own approved policy and procedure and the CLIA regulations. The interview occurred on 09/24/2025 at 10:17 AM.