Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0644540	03/14/2024
Name of Provider or Supplier	**Street Address, City, State**	
Johnson Memorial Hospital Inc	201 Chestnut Hill Rd, Stafford Springs, CT	

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
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, 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 preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and staff interview the laboratory failed to meet the requirements specified in 493.1241, 493.1242 and 493.1249 to ensure positive identification of patient samples throughout the entire testing process. The cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results. Refer to D 5311 and D 5393.
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: A. Based on record review and staff interview, the laboratory failed to follow its

established procedure for proper patient and sample identification. Findings Include: 1. Record review on 03/14/2024 of the laboratory's quality assurance (MIDAS) report revealed the following: a. Event number 23-28375 dated 05/01/2023 revealed: i. "Patient #1 (P1) arrived for laboratory work and was registered under Patient #2 (P2)." Laboratory test results for P1 were reported under P2. ii. "P1 called the laboratory inquiring about his/her test results 7 days later." iii. "A corrected report was issued for P1 on 05/09/2023." iv. Lack of documentation of a corrected report and provider notification for P2. b. Event number 23-66922 dated 11/14/2023 revealed a urinalysis sample from the emergency room was collected, labeled correctly and sent to the laboratory for testing. "The laboratory ran a urinalysis test for the patient in room # 14 under the name of the patient in room # 7. The provider went to discuss results with the patient in room # 7 and the patient stated no urine sample was provided for testing." The above urinalysis sample was collected at 11:55 AM, reported at 12:06 PM on the wrong patient and the laboratory issued a corrected report at 03:13 PM. 2. Record review of the laboratory's 'Patient and sample Identification' procedure on 3/14/2024 revealed "Positive patient identification (ID) is the crucial first step to ensuring patient safety in the delivery of health care process, regardless of the clinical setting. Failures in accurate patient ID can have serious and adverse consequences for patients, including incorrect treatment, lack of treatment, injury, disability and death. A minimum of two unique identifiers are to be used when identifying a patient, labeling laboratory specimen and/or providing results to a licensed practitioner." 3. Staff interview on 03/14/2024 from 12:25 PM through 02:18 PM with the laboratory manager (LM) confirmed the above findings. B. Based on record review and staff interview, the laboratory failed to establish a written policy /procedure for specimen aliquoting and labeling of aliquoted samples. Findings include: 1. Record review on 03/14/2024 of the laboratory's quality assurance (MIDAS) report revealed the following: a. Event number 24-9563 dated 02/09/2024 revealed "at 12:38 AM, the laboratory reported a Troponin of 1,963 ng/L. A heparin bolus of 4,000 units was administered followed by 1,000 units/hr., or 10 mL/hr. At 1: 46 AM the laboratory resulted a second Troponin of 7 ng/L." 2. Record review on 03 /14/2024 of the laboratory's Troponin - Situation, Background, Assessment, Recommendation (SBAR) record for the above listed Troponin result revealed the following: i. "Situation: On Friday 02/09/2024, a plasma separator tube (light green top) was received into the laboratory with orders for Troponin and other chemistries. The initial Troponin result was in error at 1,963 ng/L. Repeat Troponin's were 7 ng/L and 8 ng/L. The initial result was from a specimen from another patient whose blood sample was in the laboratory at the same time." ii. "Assessment: During the aliquot process, the laboratory technologist (LT) mislabeled the tube. The specimen from a different patient was used to make the aliquot. Once the mistake was identified, the specimen containers were inspected and a marked difference in hemolysis was observed. The difference was not noted during the aliquot process. Also, the aliquot tube was not initialed by the laboratory staff performing the task. Upon further investigation, it was determined that there was no policy and procedure for aliquoting specimens. In this case, the LT did not check the specimen labels on the primary tube and compare it to the aliquot tube." 3. Staff interview on 03/14/2024 from 12:25 PM through 02:18 PM with the laboratory manager (LM) confirmed the above (B1-2) findings. The LM further commented: i. The above listed (B) finding was a mislabeling in the laboratory when the sample was aliquoted by the laboratory staff; tested and reported on the wrong patient resulting in treatment based on the incorrect Troponin results. ii. The laboratory did not have a policy and procedure for aliquoting specimens and labeling when the mislabeling incident happened. C. Based on record review and staff interview, the laboratory failed to follow its policies and procedures for specimen measurement/testing requirements. Findings Include: 1. Record review

on 03/14/2024 of the laboratory's quality assurance (MIDAS) report revealed the following: Event number 23-17951 dated 03/15/2023 revealed a lactic acid sample was drawn at 09:45 AM in the emergency room and sent to the laboratory at 10:21 AM. The laboratory's lactic acid test procedure states "sample measurements must be completed within 30 minutes of collection (on ice)." The sample did not meet these criteria and needed to be recollected resulting in treatment delay. 2. Record review on 03/14/24 of the laboratory's 'GEM Premier 4000 Critical Care System' procedure revealed "Place arterial or venous whole blood specimens for blood gas/venous pH /lactate analysis in the ice bath and transport to the laboratory immediately via pneumatic tube system or hand deliver. Prioritize processing of iced specimens. Analyze within 30 minutes of receipt." 3. Staff interview on 03/14/2024 from 9:35 AM through 12:30 PM with the laboratory manager (LM) confirmed the findings listed in (C1-2) above. 4. Event number 24-7432 dated 01/30/2024 revealed Partial prothrombin time (PTT) was not performed due to sample exceeding stability limit of 4 hours when received in the laboratory for testing. 5. Staff interview on 03/14/2024 at 02:05 PM with the administrative director (AD) confirmed the finding listed in (C4) above. The AD further stated: i. "PTT sample was collected at 02:22 PM at an outpatient center and received at the laboratory for testing at 08:32 PM. Testing was not performed as it exceeded the stability limit of 4 hours when received in the laboratory for testing." ii. "The laboratory personnel did not use STAT courier to transport coagulation samples." D. Based on record review and staff interview, the laboratory failed to follow it's policies and procedure for specimen collection and processing. Findings Include: 1. Record review on 03/14/2024 of the laboratory's quality assurance (MIDAS) report revealed the following: a. Event number 23-53870 dated 09/15/2023 and Event number 23-74511 dated 11/01/2023 revealed sodium heparin tube was drawn for carboxyhemoglobin testing instead of lithium heparin tube. b. Event number 23-66841 dated 11/13/2023 revealed "Vitamin B1 was drawn on patient but specimen was spun and unable to be processed due to incorrect processing. Patient will need to be redrawn." c. Event number 23-75648 dated 12/21 /2023 revealed "incorrect collection tube was used for Methylmalonic acidemia (MMA)" for Patient #10. d. Event number 24-15665 dated 02/28/2024 revealed "the patient collected a 24 hour urine sample as instructed and dropped off at the laboratory. The laboratory staff inadvertently discarded the sample thinking it was not properly collected." 2. Record review on 03/14/24 of the laboratory's 'GEM Premier 4000 Critical Care System' procedure revealed: "Collect venous blood for pH/blood gas analysis into a lithium heparin tube, mix well and immediately place on ice." 3. Record review on 03/14/2024 of the reference laboratory's 'Vitamin B1 (Thiamine) whole blood' specimen requirement document revealed: "Transfer 2.0 mL whole blood to an amber screw capped plastic vial and send frozen. Protect from light." 4. Staff interview on 03/14/2024 from 11:45 AM through 02:45 PM with the laboratory manager (LM) confirmed the above (D1-3) findings. The LM further commented: i. Incorrect collection tube was used for the finding listed in (D-1c) above. ii. The 24 hour urine sample listed in (D-1d) above was mistakenly discarded by the laboratory staff. E. Based on record review and staff interview, the laboratory failed to ensure specimens were sent and/or received in a timely manner at the reference laboratory (RL) as indicated in the 'Turn-around time and critical value' policy Findings Include: 1. Record review on 03/14/2024 of the laboratory's quality assurance (MIDAS) report revealed the following patient samples were not tested due to failure in receipt of the samples at the RL. a. Event number 23-66602 dated 06/29/2023 revealed "Patient had blood drawn on 06/30/2023 and two of the tests were not sent and/or received at the RL for testing." b. Event number 23-38508 dated 06/30/2023 revealed patient # 4's (P4) complete blood count (CBC) and Jak 2 samples were not received and processed by the RL resulting in P4 being re-drawn for CBC and Jak 2. c. Event number 23-

	62697 dated 10/25/2023 revealed "Forgot to send urine sample to RL, urine was sitting at room temperature all night, culture cannot be performed". d. Event number 23-74221 dated 11/20/2023 revealed "Patient had flow-cytometry drawn in infusion center on 11/20/2023, per RL, flow-cytometry specimen was never received. Patient requires labs redrawn as no specimen was ever processed." e. Event number 23-74891 dated 11/20/2023 revealed flow-cytometry sample was drawn but never received and /or processed at the RL. f. Event number 24-5565 dated 01/25/2024 revealed Patient #11's specimens drawn were never received and/or processed by the RL. 2. Record review on 03/14/2024 of the laboratory's 'Turn-around time and critical value' policy for result intervals revealed: a. "STAT and timed draw specimens are to be tested within 1 hour of collection." b. "Outpatient samples are to be available for testing in 4-6 hours of collection." 3) Staff interview on 03/14/2024 at 01:40 PM with the Quality Director (QD) confirmed the above findings listed in (E). The QD further commented specimens were either not received at the RL or not sent as indicated in E-2 above resulting in patient diagnosis/treatment(s) being delayed.
D5393	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(b)(c) The preanalytic systems 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 preanalytic systems quality assessment reviews with appropriate staff. The laboratory must document all preanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to take documented remedial action(s) to prevent recurrence of the deficient practice. Findings include: 1. Record review on 03/14/2024 of the laboratory's quality assurance (MIDAS) report from 03/15/2023 to 03/11/2024 revealed the lack of documentation for corrective action(s) to ensure positive sample identification throughout the entire testing process for the following pre-analytical process. (Refer to D 5311.) a. Mislabeled specimens. b. Samples exceeded its stability limit when received in the laboratory. c. Samples were improperly collected and/or processed. 2. Staff interview on 03/14/2024 from 10: 00 AM through 02:45 PM with the laboratory manager (LM) confirmed the above findings.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to follow it's 'Turn-around-time (TAT) and critical value' policy for STAT and routine specimens. Findings Include: 1) Record review on 03/14/2024 of the laboratory's quality assurance (MIDAS) report revealed the following: a. Event number 23-28367 dated 05 /16/2023 revealed an emergency room (ER) Patient #3's "CBC and Chem 7 blood

	specimens were collected at 05:05 AM and sent through Pevco tube transport. Nurse called the laboratory at 06:45 AM looking for results. The specimen was located at the tube transport desk. Results were reported at 07:53 AM" missing TAT for STAT specimens. b. Event number 23-53722 dated 09/17/2023 revealed "Patient #5 had lactic acid blood was drawn in the ER at 12:06 AM, received in the laboratory at 12: 32 AM and resulted at 02:49 AM, resulting in missing the established TAT of 60 minutes for STAT specimens and the sample stability limit of 30 minutes." c. Event number 23-74493 dated 10/11/2023 revealed "Patient #6's morning routine blood work was collected at 05:35 AM and received in the lab at 06:50 AM was resulted at 02:32 PM." d. Event number 23-74479 dated 10/24/2023 revealed "Patient #7 had synovial fluid collected at 01:00 PM, received by the laboratory at 02:24 PM and resulted at 08:00 PM." e. Event number 23-74517 dated 12/07/2023 revealed "Patient #9's lactic acid from ER was tested and reported after 60 minutes of collection missing the laboratory's established TAT of 60 minutes for STAT specimens and the 30 minute stability limit of lactic acid sample." f. Event number 23-74491 dated 12/08 /2023 revealed the following: i. "Laboratory test (Troponin) was delayed due to technologist placing the sample onto the wrong chemistry analyzer and then filing it away in the "done" rack. Next shift technologist noticed it in the pending log, located sample and ran." ii. "Sample was collected at 12:41 PM in the ER, received at the laboratory at 12:49 PM and resulted at 02:40 PM" missing the established TAT for STAT specimen. 2. Records review on 03/14/2024 of the laboratory's 'Turn-around time and critical value' policy for result intervals revealed: a. "STAT and timed draw specimens are to be tested within 1 hour of collection." b. "Outpatient samples are to be available for testing in 4-6 hours of collection." 3. Record review on 03/14/24 of the laboratory's 'GEM Premier 4000 Critical Care System' procedure revealed: "Place arterial or venous whole blood specimens for blood gas/venous pH/lactate analysis in the ice bath and transport to the laboratory immediately via pneumatic tube system or hand deliver. Prioritize processing of iced specimens. Analyze within 30 minutes of receipt." 4. Staff interview on 03/14/2024 from 10:20 AM through 12:44 PM with the laboratory manager (LM) confirmed the above findings. The LM further commented: i. "All routine morning samples are to be tested and reported by 08:30 AM. The testing personnel failed to check the pending log to ensure proper TAT." ii. "All routine fluid samples are considered STAT and need to be performed onsite for item (1d) listed above."
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to follow its Quality Control (QC) policies and procedures in the specialty of chemistry. Findings Include: 1) Record review on 03/14/2024 of the laboratory's quality assurance 'MIDAS' report revealed the following events when patient samples were tested without running daily QC materials to ensure accurate test results are obtained: a. Event number 23-27515, dated 05/06/2023, a patient sample was tested for serum ketone. b. Event number 23-74513, dated 10/14/2023, a patient sample was tested for serum ketone. c. Event

	number 23-34457, dated 06/13/2023, 16 patient samples were tested for urinalysis. 2. Record review on 3/14/24 of the laboratory's 'K-Check Serum Ketone Test' procedure revealed: "Run all 3 levels of QC each day of patient testing, each time a new bottle of K-Check tablets are opened, or whenever it is necessary to test performance of the user or system." 3. Record review on 3/14/24 of the laboratory's 'Routine Urinalysis' procedure revealed: "Daily QC to be run on first shift as routine, whenever a new bottle of reagent strips is opened/placed into use, with new lot and with each new shipment." 4. Staff interview on 03/14/2024 from 10:35 AM through 11:55 AM with the laboratory manager (LM) confirmed the above findings.