Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2025887	06/20/2024
Name of Provider or Supplier	**Street Address, City, State**	
Jackson Clinic, Pa - Innovation Park, The	145 Innovation Drive, Jackson, TN	

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) 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 a review of the laboratory's College of American Pathologists (CAP) proficiency testing (PT) attestation statements and staff interview, testing personnel failed to sign four of thirty proficiency testing attestation statements from 2023 and 2024. The findings include: 1. A review of the laboratory's CAP PT records revealed the following attestation statements that had not been signed by testing personnel: 2023 CGL-C (Coagulation-event three), 2023 CM-B (Clinical Microscopy-event two), 2024 CM-A (Clinical Microscopy-event one), 2024 U-A (Urine Chemistry-event one). 2. During an interview on 06/20/24 at 11:30 a.m., the laboratory director confirmed testing personnel failed to sign four of thirty attestation statements from 2023 and 2024.
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: CITATION ONE: Based on observation of the laboratory, review of the laboratory

	procedure manual, lack of documentation, and staff interview, the laboratory failed to follow the procedure for performing revolutions per minute (RPMs) and timer checks on the Stat Spin centrifuge used for processing patient specimens for Prothrombin Time (PT) and activated Partial Thromboplastin Time (aPTT) in 2023 and 2024. The findings include: 1. Observation of the laboratory on 06/18/24 at 8 a.m. revealed the Sysmex CA 620 instrument (serial number 23742) used for performing patient testing for PT and aPTT. Next to the instrument was a Stat Spin centrifuge (serial number 1603M50110085) used to process specimens for PT and aPTT testing. 2. A review of the laboratory's procedure manual revealed that the laboratory would check the RPMs and timers of centrifuges biannually. 3. There was no documentation of RPM or timer checks for the Stat Spin centrifuge. 4. The laboratory director confirmed during interview on 06/20/24 at 11:30 a.m. that the laboratory did not follow its own policy for performing RPM and timer checks on the Stat Spin centrifuge in 2023 or 2024. CITATION TWO: Based on observation of the laboratory, review of the laboratory procedure manual, lack of records, review of a patient test report and staff interview, the laboratory failed to ensure the procedure for use of platelet-poor plasma for testing PT and aPTT analytes was followed when it did not validate the Stat Spin centrifuge to ensure platelet-poor plasma was produced during sample processing. The findings include: 1. Observation of the laboratory on 06/18/24 at 8 a.m. revealed the Sysmex CA 620 instrument (serial number 23742) used for performing patient testing for PT and aPTT. Next to the instrument was a Stat Spin centrifuge (serial number 1603M50110085) used to process specimens for PT and aPTT testing. 2. A review of the laboratory procedure for PT and aPTT revealed the following statement under the section for "Handling Conditions:" "Centrifuge the capped specimen tube for a minimum of 15 minutes at 1500 g to consistently produce platelet-poor plasma" The criteria listed as the definition for platelet poor plasma was a platelet count of less than 10 x 10^9 per Liter. 3. There was no documentation that the centrifuge had been tested to ensure the production of platelet-poor plasma. 4. Review of a patient test report revealed patient testing for PT and aPTT on patient sample number 23147634 on 11/20/23. 5. During an interview on 06/20/24 at 11:30 a.m., the laboratory director confirmed that the laboratory failed to test the Stat Spin centrifuge to ensure it could produce the platelet-poor plasma required for PT and aPTT testing.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of patient test reports, review of laboratory procedure, and staff interview, the laboratory failed to ensure the procedure for the Sysmex XN 530 Complete Blood Count with automated White Blood Cell Differential (CBC w/Diff) was approved by the laboratory director before patient testing that began on 11/20/23. The findings include: 1. Observation of the laboratory on 06/18/24 at 8 a.m. revealed the Sysmex XN 530 CBC w/Diff instrument (serial number 12245) used for patient testing. This instrument was new since the last survey date. 2. A review of patient test reports revealed that the first CBC from the Sysmex XN 530 occurred on 11/20/23 for patient sample number 23147634. 3. A review of the laboratory procedure for the Sysmex XN 530 revealed that the laboratory director approved the procedure on 12/01/23. 4. The laboratory director confirmed during the interview on 06/20/24 at 11:30 a.m. that the laboratory director did not approve the

	procedure for the Sysmex XN 530 CBC instrument before patient testing, which began on 11/20/23.