Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0910650	01/23/2024
Name of Provider or Supplier	**Street Address, City, State**	
Jackson Clinic Pa South, The	1893 South Highland Avenue, 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 review of the laboratory's proficiency testing (PT) records and staff interview, the testing personnel and/or lab director/designee failed to sign two of fifteen PT attestation statements from 2022 and 2023. The findings include: 1. Review of the laboratory's 2022 and 2023 PT attestation statements revealed the following: The lab director/designee and testing person failed to sign Chemistry 2022 event three. The lab director/designee failed to sign Chemistry 2023 event three. 2. During an interview on 01/23/24 at 3:45 pm, the technical consultant confirmed the testing person and/or the lab director/designee failed to sign the PT attestation statements for Chemistry event three in 2022 and Chemistry event three in 2023 (two of fifteen events reviewed).
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: Based on review of the laboratory's College of American Pathologists (CAP) PT records, lack of procedure, and interview with the technical consultant, the laboratory failed to test PT samples the same number of times it routinely tests patient samples

	for three of fifteen events reviewed from 2022 and 2023. The findings include: 1. Review of the laboratory's proficiency testing records for Hematology revealed the laboratory performed PT samples multiple times for three of three Hematology events in 2023 as follows: 2023 event one-performed three times for all five samples 2023 event two-performed three times for all five samples 2023 event three-performed two times for all five samples 2. Review of the laboratory procedure manual revealed no requirement to re-test every patient CBC sample. 3. During an interview with the technical consultant on 01/23/24 at 3:45 pm, the technical consultant confirmed the laboratory failed to test proficiency testing samples the same number of times it routinely tests patient samples for three of fifteen PT events reviewed from 2022 and 2023.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory's Complete Blood Count (CBC) quality control (QC) records, lack of documentation, and staff interview, the laboratory failed to retain QC limits in use for seven of seven parent lots of CBC QC in 2022 and 2023. The findings include: 1. Observation of the laboratory on 01/23 /24 at 8:45 am revealed the Sysmex XP 300 (serial #B3614) instrument used for patient testing for CBC with automated White Blood Cell differential (CBC w/Diff). 2. Review of the laboratory's CBC w/Diff quality control records revealed the following: Lot 2109 used from 07/01/22 to 07/22/22, Lot 2193 used from 07/25/22 to 10/14/22, lot 2277 used from 10/17/22 to 01/06/23, lot 2361 used from 01/09/23 to 03 /31/23, lot 3080 used from 04/03/23 to 06/21/23, lot 3164 used from 06/23/23 to 09/19 /23, lot 3248 used from 09/20/23 to 12/08/23. Each 'parent' lot contained three sub-lots (Low, Normal and High level) (3 levels per parent lot). 3. The laboratory was asked to provide documentation of the QC ranges used for each of the lot numbers. QC range documentation could not be provided. 4. During an interview on 01/23/24 at 3:45 pm, the technical consultant confirmed the laboratory failed to retain records of QC ranges used in 2022 and 2023 for seven of seven parent CBC QC lots (21 of 21 lots).
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in

	the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory procedure manual, and staff interviews, the procedure for the Sysmex XP 300 CBC instrument failed to include procedures to follow if the results were outside the reportable range of the instrument, resulting in the potential for reporting of patient results that were outside the laboratory's established reportable range limits. The findings include: 1. Observation of the laboratory on 01/23/24 at 8:45 am revealed the Sysmex XP 300 instrument used for performing patient testing for CBC w/Diff. 2. Review of the laboratory procedure for the Sysmex XP 300 revealed the procedure failed to include protocol to follow if the results were outside the reportable range of the instrument. 3. On 01/23/24 at 3:30 pm, the lead testing person was asked to describe how she would report any value that was outside the reportable range of the Sysmex XP 300 instrument. She stated that she would repeat the test and if she got the same result it would be reported. 4. During an interview on 01/23/24 at 3:45 pm, the technical consultant confirmed the laboratory failed to establish protocol to follow for reporting of results that were outside the reportable range of the Sysmex XP 300 CBC w/Diff instrument.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of manufacturer package inserts, and staff interview, the laboratory failed to label saline used for preparing patient specimens for wet prep with lot number and expiration date, and failed to label five of five cardiac marker controls with the correct after-opening expiration date on the date of the survey. The findings include: 1. Observation of the laboratory on 01/23/24 at 8: 40 am revealed the following: A microscope used for performing patient testing for wet prep, urine microscopics, and manual differentials. A Polymedco PathFast instrument used for performing cardiac testing to include Troponin I, B-Type Natriuretic Peptide, and Fibrin Degradation Products (D-Dimer). The saline used for preparing wet prep samples for examination was not labeled with lot number or expiration date. The Biorad cardiac marker controls were labeled as follows: Troponin I control lots 67703 and 67705 labeled with an open date of 01/22/24 and an expiration date of 02/28/26; BNP control lots 67701 and 67703 labeled with an open date of 01/22/24 and an expiration date of 02/28/26; D-Dimer control lots 74421 and 74424 labeled with an open date of 01/22/24 and expiration date of 07/31/25. 2. Review of the manufacturer package insert for the Biorad cardiac marker controls

	revealed the controls for Troponin I and BNP were good for 5 days after opening; the D-Dimer controls were good for 15 days after opening. 3. The technical consultant confirmed during interview on 01/23/24 at 9:10 am, that the laboratory failed to label the saline used for preparing patient wet prep specimens with lot number and expiration date, and the cardiac marker controls were not labeled with the correct after-opening expiration date.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory's CBC QC records, lack of documentation, and staff interview, the laboratory failed to have a process in place to monitor CBC QC for accuracy and precision over time in 2022 and 2023 for seven of seven parent lots reviewed. The findings include: 1. Observation of the laboratory on 01/23/24 at 8:45 am revealed a Sysmex XP 300 (serial #B3614) instrument used for patient testing for CBC w/Diff. 2. Review of the laboratory's CBC w/Diff QC records revealed the following: Lot 2109 in use from 07/01/22 to 07/22/22, Lot 2193 in use from 07/25/22 to 10/14/22, lot 2277 in use from 10/17/22 to 01/06/23, lot 2361 in use from 01/09/23 to 03/31/23, lot 3080 in use from 04/03/23 to 06/21/23, lot 3164 in use from 06/23/23 to 09/19/23, lot 3248 in use from 09/20/23 to 12/08/23. Each 'parent' lot contained three sub-lots (Low, Normal and High level) (3 levels per parent lot). 3. The laboratory failed to have documentation of cumulative QC data or evidence of a process in place to monitor the CBC QC for accuracy and precision over time for seven of seven parent lots reviewed from 2022 and 2023. 4. During an interview on 01/23/24 at 3:45 pm, the technical consultant confirmed the laboratory failed to have a process in place to monitor CBC QC performed on the Sysmex XP 300 instrument for accuracy and precison over time in 2022 and 2023.
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. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of laboratory records, and staff interview, the laboratory failed to review and assess one of three calibration

	verification studies for the Polymedco PathFast instrument in 2022, and two of three calibrations performed on the Sysmex XP 300 CBC instrument in 2023. The findings include: 1. Observation of the laboratory on 01/23/24 at 8:45 am revealed a Sysmex XP 300 CBC instrument and a Polymedco PathFast instrument used for patient testing. The Sysmex XP 300 was used for performing patient testing for CBC w/Diff. The Polymedco PathFast instrument was used for performing patient testing for Troponin I, BNP and D-Dimer. 2. Review of laboratory records for calibration and calibration verification revealed the following: The calibraton verification performed on 09/29/22 for tests performed on the Polymedco Pathfast were not sent for data evaluation (one of three calibration verifications reviewed). The Sysmex XP 300 calibrations performed on 03/17/23 and 08/31/23 had not been reviewed (two of three calibrations reviewed). 3. During an interview on 01/23/24 at 3:45 pm, the technical consultant confirmed the laboratory failed to evaluate one of three calibration verifications performed for the Polymedco Pathfast, and failed to review and evaluate two of three calibrations performed on the Sysmex XP 300 CBC instrument.
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 observation of the laboratory, review of the laboratory procedure manual, patient test reports, patient test management form, and staff interview, the laboratory failed to have an effective quality assessment mechanism in place to detect and correct problems with units of measure (UOM) on the final patient test report. The findings include: 1. Observation of the laboratory on 01/23/24 at 8:45 am revealed a microscope used for performing urine microscopic analysis. 2. Review of the laboratory's procedure for urine microscopic revealed epithelial cells are reported per high power field (/HPF). 3. Review of patient test reports for urine microscopic revealed UOMs for urine epithelial cells reported per low power field (/LPF) for four of four final patient test reports reviewed (chart #5728183-reported on 02/28/23, patient MRN#100123960-reported on 05/05/23, chart #9077157-reported on 08/02 /23, patient MRN#4114567-reported on 01/23/24). 4. Review of the laboratory's form titled "Patient Test Management" revealed review of the units of measure was not included in the assessment of final patient test reporting. 5. During an interview on 01 /23/24 at 3:45 pm, the technical consultant confirmed the laboratory's quality assessment process was ineffective when it did not include monitoring for correct units of measure in its' patient test management process. Word Key: #=Number MRN=Medical Record Number