Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0939915	12/06/2023
Name of Provider or Supplier	**Street Address, City, State**	
Jackson Clinic, Pa Of Huntingdon,The	20719 East Main Street, Huntingdon, 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
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 observation of the laboratory, review of the laboratory procedure manual, testing personnel competency assessment records, and staff interview, the laboratory failed to follow its' own policy for assessing testing personnel competency in 2022 and 2023 for two of four competency assessment documents reviewed. The findings include: 1. Observation of the laboratory on 12/06/23 at 12:10 pm revealed a microscope in use for performing patient testing for urine microscopy and wet prep, and a Sysmex XP-300 (serial #4227) in use for performing patient testing for Complete Blood Count (CBC). 2. Review of the laboratory procedure manual revealed testing personnel competency would include the six elements required in Subpart M (direct observation of patient testing, monitoring the recording and reporting of test results, review of worksheets, proficiency testing results and preventive maintenance, direct observation of instrument maintenance and function checks, blind testing to include either internal blind sample or external proficiency testing samples, assessment of problem solving skills). 3. Review of the annual competency assessments performed for testing person one in 2022 and 2023, revealed no documentation of direct observation of patient testing, direct observation of instrument maintenance, monitoring of result recording and reporting, review of worksheets, proficiency testing results and preventive maintenance records for urine microscopic, wet prep and CBC; no documentation of assessment of test performance with blind samples for CBC. 4. Interview with the technical consultant on 12/06/23 at 4:25 pm confirmed the laboratory failed to follow its' own policy for testing personnel competency assessment when it did not document competency using all six

	requirement elements for the annual competencies performed for testing person one in 2022 and 2023.
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 review of a final patient test report, the laboratory procedure manual, and interview with the technical consultant, the laboratory procedure for urine microscopy failed to include criteria for reporting of urine crystals on the date of the survey (12/06 /23). The findings include: 1. Review of a final patient test report for urine microscopy revealed reporting of calcium oxalate crystals as 1+ for patient sample number 23144426 on 11/13/23. 2. Review of the laboratory procedure for urine microscopy revealed no criteria for reporting of urine crystals. 3. Interview with the technical consultant on 12/06/23 at 4:25 pm confirmed the laboratory reported crystals in urine sediment and the laboratory procedure for urine microscopy did not include criteria for reporting of urine crystals.
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 observation of the laboratory, review of the Sysmex XP-300 operator's manual, the laboratory humidity range in use in 2022 and 2023, the laboratory's environmental monitoring records, and interview with the technical consultant, the

	laboratory failed to define humidity requirements that were consistent with the Sysmex XP-300 manufacturer operating requirements in 2022 and 2023, resulting in the operation of the Sysmex XP-300 on days when the humidity was outside the manufacturer requirement. The findings include: 1. Observation of the laboratory on 12/06/23 at 12:10 pm revealed a Sysmex XP-300 (serial # 4227) on the counter in use for performing patient complete blood testing (CBC). 2. Review of the Sysmex operator's manual revealed an operating humidity of 30-85%. 3. Review of the laboratory's environmental monitoring records from 2022 and 2023 revealed a humidity range of 25-60%. 4. Review of the laboratory's environmental records revealed the following: One of twenty-one days outside the manufacturer requirement in October 2022. Five of twenty-three days outside the manufacturer requirement in March 2023. Four of twenty days days outside the manufacturer requirement in November 2023. 5. Interview with the technical consultant on 12/06/23 at 4:25 pm confirmed the laboratory failed to define humidity ranges that were consistent with manufacturer requirements for operation of the Sysmex XP-300 in 2022 and 2023.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual, final patient test reports for urine microscopy, final patient test reports for CBC, quality assessment review documents, quality assessment monitoring form and staff interview, the laboratory's quality assessment process was ineffective in detecting and correcting problems with units of measure on the final patient test report in 2022 and 2023. The findings include: 1. Review of the laboratory procedure for urine microscopy revealed mucus is to be reported per low power field (/LPF). 2. Review of final patient test reports for urine microscopic revealed unit of measure for mucus as per high power field (/HPF) (patient sample number 22100457 performed on 08/08/22, patient sample number 23083381 performed on 06/30/23). 3. Review of final patient test reports for CBC revealed incorrect units of measure for the granulocyte % and monocyte % for patient sample number 22059306 (performed on 05/05/22), patient sample number 23031048 (performed on 03/07/23) and patient sample number 23144640 (performed on 11/14 /23). 4. Review of the laboratory's quality assessment documents revealed the following: Chart reviews for CBC were performed on 06/20/22 and 07/26/23. The final patient test reports reviewed had the incorrect units of measure for both the granulocyte % and monocyte %. 4. Review of the laboratory's quality assessment monitoring form revealed units of measure was not included in the review criteria. 5. Interview with the technical consultant on 12/08/23 at 4:25 pm confirmed the laboratory's quality assessment process was ineffective when it did not detect or correct problems with units of measure for granulocyte % and monocyte % in 2022 and 2023, and incorrect units of measure for mucus reported on the urine microscopic.