Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2025887	11/04/2025
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
D0000	During a recertification survey performed on November 4, 2025, the laboratory was found out of compliance with the following condition: 493.1210 Condition: Routine chemistry.
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on laboratory observation, procedure manual review, a review of quality control records, patient activity reports, lack of documentation and staff interview, the laboratory failed to follow the established procedure for quality control (QC) corrective actions (Refer to D5401), and failed to evaluate patient test results for potential adverse affects during periods of QC failures (Refer to D5783).
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 laboratory observation, a review of the laboratory procedure manual, a review of testing personnel records, and staff interview, the laboratory failed to follow the policy for training and competency assessment for four of five testing personnel in

	2024. The findings include: 1. Laboratory observation on 11/04/25 at 8:10 a.m. revealed the following non-waived test systems used for patient testing: The Sysmex XN 530 was used for Complete Blood Count with Automated White Blood Cell Differential. A microscope was used for performing urine microscopic examination, post-vasectomy semen analysis, wet prep, potassium hydroxide (KOH) slide examination, and manual differential. The Ortho Vitros 5600 was used for performing testing for chemistry, urine chemistry and endocrinology analytes. The Siemens CA 600 was used for performing prothrombin time (PT) and activated partial thromboplastin time (aPTT). The Siemens Clinitek Advantus was used for performing urinalysis testing. The Streck Diesse Mini-cube instrument was used for performing erythrocyte sedimentation rate (ESR). The Alere test kit was used for performing qualitative serum pregnancy test. 2. A review of the laboratory's policy and procedure for testing personnel revealed the following: "To perform non-waived testing (moderate and high complexity) laboratory personnel must have:" "4. Training must be well documented." The policy included a requirement for semiannual competency during the first year of testing and annual competency assessment thereafter. 3. A review of testing personnel records revealed the following: 2024 annual competencies were not performed for established testing persons one, two, and five. Testing person four competency assessment document dated 08/01/24 revealed that testing person four transferred to the current location "Oct. 2024" from a sister facility. Testing person four did not have documented training for the post vasectomy semen analysis, the Alere Serum pregnancy test kit (qualitative), the Sysmex XN 530, or the Streck Diesse ESR instrument after the transfer from the sister location. 4. The technical consultant confirmed the survey findings during an interview on 11/04/25 at 4:30 p.m.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (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 laboratory observation, a review of the laboratory procedure manual, a review of the September 2025 quality control (QC) records and patient activity reports, and staff interview, the laboratory failed to follow quality control corrective action procedures when it performed patient testing for Urine Microalbumin, Prostate Specific Antigen (PSA), and Total Bilirubin analytes on dates when QC was unacceptable according to established laboratory QC protocol in September 2025. The findings include: 1. Laboratory observation on 11/04/25 at 8:10 a.m. revealed the Ortho Vitros instrument (serial number 56004726) used for performing patient testing for chemistry, urine chemistry, and endocrinology analytes. 2. A review of the laboratory policy for quality control corrective action revealed the following: Control results are compared to acceptable ranges. Patient results are not reported unless the quality control data is within the acceptable limits specified. In the section titled "TESTS WHERE TWO LEVELS OF CONTROL ARE RUN" the procedure stated under section B: "Reject run if: 1. Both controls are greater than +/- 2SD from the mean and are not within your established range upon repeat. 2. Controls that read outside +/- 2SD from previous day not within your established range on the second day's run." 3. A review of the Ortho Vitros September 2025 QC records and patient activity reports revealed the following: For the urine microalbumin assay: QC was

	performed using two levels of the Biorad Urine Chemistry control. 09/22/25--QC was outside 3 SD for both levels with 10 patients tested. 09/23/25-QC was outside 3 SD for both levels; the repeat testing was outside 2SD for both levels with 13 patients tested. 09/24/25--- QC was outside 2SD for both levels with 10 patients tested. 09/26 /25-QC was outside 2SD for both levels with 12 patients tested. 09/29/25-QC was outside 2SD for both levels. On repeat, QC was outside 2SD on level one and outside 3SD on level two with 16 patients tested. For the Prostate Specific Antigen assay: QC was performed using two levels of Biorad QC material (Immunoassay - levels one and three) 09/10/25-QC was outside 3SD for level one, and outside 2SD for level three, with one patient tested. 09/11/25-QC was outside 3SD for level one, and outside 2SD for level three with 11 patients tested. 09/22/25-QC was outside 3SD for both levels with no repeat testing with 15 patients tested. 09/23/25-QC was outside 3SD for level one and level three. On repeat, level one was outside 2SD with six patients tested. 09 /29/25-QC was outside 2SD for level one with 18 patients tested. (next testing date after 09/26/25). For the Total Bilirubin assay: QC was performed using two levels of Biorad QC material (Multiqual - levels one and three) 09/15/25-QC was outside 3SD for level one, the first repeat was outside 3SD, and the second repeat was outside 2SD with 24 patients tested. 09/16/25-QC was outside 2SD for level one on initial run and repeat run with 75 patients tested. 09/17/25-QC was outside 2SD for level one on initial run and repeat run with 66 patients tested. 09/22/2025- QC was outside 3SD for level one with 63 patients tested. 09/23/24- QC was outside 2SD for level one with 68 patients tested. 09/24/25-QC was outside 2SD for level one with 62 patients tested. 09 /29/25 QC was outside 3SD for level one, the repeated value was outside 2SD, with 59 patients tested. 09/30/25 QC was outside 2SD for level one on the initial run and on the repeat run with 59 patients tested. The documented corrective actions did not include suspension of patient testing on the dates when QC was unacceptable, or when the QC was outside 2SD on consecutive dates. 4. The technical consultant confirmed the survey findings during an interview on 11/04/25 at 4:30 p.m. Word Key: SD=Standard Deviation
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation and interview, the laboratory failed to ensure that expired serum separator tubes were not used to collect patient samples for chemistry and endocrinology tests. The findings include: 1. Phlebotomy area observation on 11/04 /25 at 9:10 a.m. revealed expired serum separator tubes used for collecting patient samples for chemistry and endocrinology tests (Lot number 4302039, expired 09/30 /25). 2. The technical consultant confirmed the tubes had expired during an interview on 11/04/25 at 9:10 a.m.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (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 a review of the laboratory's September 2025 Quality Control (QC) data, patient activity reports, lack of documentation, and staff interview, the laboratory failed to evaluate patient results in the unacceptable QC run or patient results since the last acceptable QC run for Urine Microalbumin, Prostate Specific Antigen (PSA), and Total Bilirubin analytes on dates when QC was unacceptable with patient testing performed. The findings include: 1. A review of the laboratory's September 2025 QC data for the Urine Microalbumin, PSA, and Total Bilirubin analytes revealed multiple dates when the quality control was not acceptable according to the laboratory's established QC rules, with patient testing performed. (Refer to D5401). 2. The documented corrective action did not include a review of patients performed in the unacceptable run or a retrospective review back to the last date that QC was acceptable. 3. The technical consultant confirmed the survey findings during an interview on 11/04/25 at 4:30 p.m.