Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0921688	02/16/2022
Name of Provider or Supplier	**Street Address, City, State**	
Jackson Clinic,Pa North Internal, The	2863 Hwy 45 Bypass, 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
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 review of the laboratory procedure manual, personnel records, and staff interview, the laboratory failed to follow the procedure for annual competency assessments in 2021 and 2022 for six of seven established testing personnel. The findings include: 1. Review of the laboratory procedure manual revealed that annual competency assessments would be performed on established personnel. 2. Review of testing personnel records revealed that annual competencies were not performed in 2021 for six of seven established testing personnel (testing personnel numbers two, three, four, five, six and seven). No competency assessment had been performed in 2022 as of the date of the survey (02/16/2022). 3. Interview with the technical consultant on 02/16/2022 at approximately 5:30pm confirmed the laboratory failed to follow its' own policy for annual competency assessment in 2021 and 2022.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records and staff interview, the laboratory failed to verify the accuracy of Estradiol and Parathyroid Hormone (PTH)

	tests twice a year in 2021. The findings include: 1. Review of the laboratory's proficiency testing records revealed the laboratory participated in proficiency testing to verify the accuracy of Estradiol and PTH in 2021. The laboratory received two events per year for the analytes. The laboratory failed 2021 event one for Estradiol with a score of 33% and PTH with a score of 0%. No other records were available that verified the accuracy of the Estradiol and PTH twice a year in 2021. 2. Interview with the technical consultant on 02/16/2022 at approximately 5:30pm confirmed the laboratory failed to verify the accuracy of Estradiol and PTH when it failed 2021 event one, and did not perform any other type of alternative assessment in 2021.
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 and staff interview, the laboratory failed to label chemistry controls and calibrators with open dates and corrected expiration dates in 2022. The findings include: 1. Observation of the laboratory on 02/15/2022 at approximately 10am revealed multiple vials of chemistry controls and calibrators in use that were not labeled with either open date or corrected expiration date. The quick reference guide in the control box indicated shortened stability of products after they were opened. None of the products were labeled. 2. Interview with the technical consultant on 02/16/2022 at approximately 5:30pm confirmed controls and calibrators were not labeled with open dates or corrected expiration dates. The products have shortened stability after opening. The controls and calibrators were in use for chemistry tests performed on the Vitros 5600.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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 of the laboratory, review of patient test records and staff interview, the laboratory failed to ensure controls were not used past their expiration date from 02/10/2022 to 02/15/2022 with 30 patients reported. The findings include: 1. Observation of the laboratory on 02/15/2022 at approximately 10am revealed expired controls in use for performing quality control for C-Reactive Protein on the Ortho Vitros 5600, Lot numbers Q8625 and R8626, expiration date of 02/09/2022. 2. Review of patient number 13-049-019 revealed C-Reactive Protein results reported on 02/10/2022 when controls were expired. 3. Review of patient data logs revealed that 30 patient C-Reactive Protein results were reported when the expired controls were in use. 4. Interview with the technical consultant on 02/15/2022 at approximately 5:30 pm confirmed the survey findings.

D5451	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iii)(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-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (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 patient test results, laboratory records, laboratory procedure and staff interview, the laboratory failed to include a titered control for the rheumatoid arthritis factor (RA) when reporting positive patients with a titered result in 2020. The findings include: 1. Observation of the laboratory on 02/15/2022 at approximately 10am revealed the Rheumajet RF kit in use for patient testing for rheumatoid arthritis factor (RA). 2. Review of patient number 13-266-031 revealed RA reported as "RA Positive, RA Titer 64" on 09/08 /2020. 3. Review of the quality control for the RA test for 09/08/2020 revealed no titered control was included. 4. Review of the laboratory procedure for RA revealed titered control is not included as part of the quality control protocol when patient results are reported as a titer. 5. Interview with the technical consultant on 02/16/22 at approximately 5:30pm confirmed the survey findings.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of patient test reports and laboratory records, and staff interview, the laboratory failed to have a process in place to ensure dermatophyte testing medium (DTM) fungal culture lot numbers were traceable to DTM lot number quality control (QC) records in 2022. The findings include: 1. Review of patient number 11-314-009 revealed fungal culture qualitative results reported on 01/05/2022. 2. Review of laboratory records revealed no indication of the lot number of DTM used to perform the testing on patient 11-314-009. There was no method to track or determine if quality control had been performed on the medium used on patient 11-314-009. 3. Interview with the technical consultant on 02/15/2022 at approximately 10am revealed the following: DTM is ordered for their satellite dermatology clinic. The DTM is sent directly to the satellite location from the vendor. After the patient specimen is placed into the DTM, the test is sent to the main lab. The satellite clinic also sends vials from each box to the main lab for QC testing, however, there was no

	way to trace the lot number of the dermatophyte testing medium used on the patient to the QC records. The technical consultant confirmed there was no way to determine that QC had been performed for the DTM lot number used on the patient.
D5543	HEMATOLOGY CFR(s): 493.1269(a)(d) (a) For manual cell counts performed using a hemocytometer-- (a)(1) One control material must be tested each 8 hours of operation; and (a)(2) Patient specimens and control materials must be tested in duplicate. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual, patient test reports, request for laboratory quality control records, and interview with the technical consultant, the laboratory failed to perform quality control for sperm count performed on the hemacytometer in 2020, 2021, and 2022. The findings include: 1. Review of the laboratory procedure manual revealed testing for sperm count is performed using a hemacytometer. The laboratory procedure did not address quality control requirements. 2. Review of patient test reports revealed semen analysis for sperm count for patient ID number 09-256-030 performed on 08/04/2020, patient ID number 21-134-022 performed on 05/14/2021, and patient ID number 19-252-008 performed on 01/13/2022. 3. Request on 02/22/2022 at approximately 10:30 am for hemacytometer quality control records revealed no quality control is performed on the hemacytometer for the quantitative sperm counts. 4. Interview with the technical consultant on 02/16/2022 at approximately 5:30pm confirmed the laboratory does not perform quality control on the hemacytometer for quantitative sperm count.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of laboratory documentation, patient test results, document request and staff interview, the laboratory failed to perform comparison between the two Vitros 5600 chemistry instruments in 2020, 2021, and 2022. The findings include: 1. Observation of the laboratory on 02/15/2022 at approximately 10am revealed two Ortho Vitros 5600 chemistry instruments in use for patient testing (J56002716 and J56003437). 2. Review of documentation provided by the laboratory revealed that both instruments are used to perform the certain identical patient tests. Tests that are performed on both chemistry instruments includes comprehensive metabolic panel, lipid panel, basic metabolic panel, hepatic function panel, thyroid stimulating hormone, free thyroxine, vitamin D, ferritin, magnesium, and B-type natriuretic peptide, and urine chemistry for microalbumin and creatinine. 3. Review of patient test reports revealed comprehensive metabolic panel performed on patient 17-013-042 on Vitros 1 (J56002716) on 05/04/2021 and comprehensive

	metabolic panel performed on patient 09-254-123 on the Vitros 2 (J56003437) instrument on the same date. 4. Request on 02/15/2022 at 2pm for instrument to instrument comparison studies between the two instruments revealed no comparison studies were available. 5. Interview with the technical consultant on 02/16/2022 at approximately 5:30pm confirmed the laboratory did not perform comparisons twice a year between the two Vitros 5600 chemistry instruments in 2020, 2021 or 2022.