Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0219525	12/16/2024
Name of Provider or Supplier	**Street Address, City, State**	
David Oneil Md Pa	17 Fontana Lane Suite 201, Baltimore, MD	

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
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 procedure and temperature record review and interview with the technical consultant (TC), the laboratory failed to ensure that room and refrigerator temperatures were recorded every day. Findings: 1. The procedure titled "Instrument Maintenance Program" stated that "Many of the devices and small analyzers will operate between 16-35C or 61-95F. Reagents and controls are refrigerated between 2-8C or 35-46F when not in use. Record all temperature taken on the daily worksheet book." 2. Review of the daily worksheets from 07/22/2023-10/31/2024 showed that the refrigerator temperature was not recorded 1 of 15 days recorded in 01/2024 (on 01/24/2024) and the room and refrigerator temperature were not recorded 1 of 22 days recorded in 02/2024 (02/19/2024), 2 of 19 days recorded in 10/2023 (10/24/2023 and 10/30/2023), and 2 of 17 days recorded in 11/2023 (11/16/2023 and 11/22/2023). 3. During the exit interview on 12/16/2024 at 1:15 PM, the TC confirmed that the room and refrigerator temperatures were not consistently recorded on the daily worksheets.
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 record review and interview with the technical consultant (TC), the laboratory failed to ensure quality control (QC) reagents for Rhesus (Rh) factor were not used beyond their expiration date. Findings: 1. The laboratory documented daily Rh QC results on a daily worksheet that included the lot numbers and expiration dates of the QC reagents. 2. Daily worksheets for 01/30/2024 and 01/31/2024 listed a positive QC lot number 198790 and negative QC lot number 398790 that both expired on 01/26/2024. A total of 3 patients were tested for Rh factor over the two days. 3. During the exit interview on 12/16/2024 at 1:15 PM, the TC confirmed that expired QC reagents were used on 01/30/2024 and 01/31/2024.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on procedure and record review and interview with the technical consultant (TC), the laboratory failed to document Rhesus (Rh) factor quality control (QC) results for 1 of 19 days of testing in 10/2023. Findings: 1. The procedure titled "Rh Typing: Tube Method" stated that "In this Lab, both levels of quality control are tested just like patient samples at the beginning of each day when patient samples are tested. Results of controls are documented on a worksheet. Patient results are not reported unless the results for both levels of controls are acceptable." 2. The laboratory documented daily Rh QC results on a daily worksheet. 3. Review of daily worksheets showed that QC results from 1 of 19 days in 10/2023 (10/30/2023) were not documented. 4. During the exit interview on 12/16/2024 at 1:15 PM, the TC confirmed that Rh QC results were not documented as performed in 1 of 19 days in 10 /2023.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on procedure and record review and interview with the technical consultant (TC), the laboratory failed to document results from repeat Rhesus (Rh) factor testing.

	Findings: 1. The procedure titled "Rh Typing: Tube Method" stated that "If the test result is negative or doubtful repeat the testing to confirm the negative agglutination before reporting the result." 2. All patient test results were documented on a daily worksheet. 3. Review of the daily worksheets from 07/22/2023-10/31/2024 showed that testing personnel did not document that negative test results were confirmed by repeat testing. There were a total of 31 negative patient results documented in the reviewed timeframe. 4. During the exit interview on 12/16/2024 at 1:30 PM, the TC confirmed that testing records did not show that negative results were repeated to confirm the negative agglutination before reporting patient results.