Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0219525	07/15/2021
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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on procedure manual and quality control (QC) record review and interview with the technical consultant (TC), the laboratory did not follow manufacturer's instructions for performing waived hemoglobin testing with the HemoCue Hb 201 analyzer. Findings: 1. The "HemoCue Hb201 Hemoglobin Procedure" states "After opening, QC material is good for only 30 days at RT or 60 days when refrigerated or until the printed manufacturer's expiration date (whichever comes first)." 2. HemoCue hemoglobin QC record review was performed for April and September of 2019 and 2020. The laboratory records the "Open Vial Expiration Date" of the HemoCue QC on a daily QC log. 3. The "Open Vial Expiration Date" was not documented 12 of 14 days in April 2019; 12 of 15 days in September 2019; 13 of 16 days in April 2020; and 9 of 19 days in September 2020. 4. On 4/23/2019 and 4/24/2019 expired HemoCue controls were run (Low Control, Lot Number 82665, expiration date 4/22 /19 and High Control, Lot number 83467, expiration date 4/22/19). 7 patients were run on each of these days. 5. During an interview on 7/15/2021 at 2:00 PM, the TC confirmed that the laboratory did not follow the manufacturer's instructions for performing waived hemoglobin testing with the HemoCue Hb 201 analyzer.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the

	laboratory's routine methods This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and interview with the technical consultant (TC), the laboratory did not ensure that all the testing personnel who tested patient samples performed the PT. Findings: 1. The laboratory currently has 5 testing personnel listed on the "Laboratory Personnel Report (CMS-209)" who perform Chemistry (serum hCG pregnancy) and Nonchemistry (D (Rho) Typing) testing. 2. A review of Chemistry PT attestation worksheets from 2019 and 2020 showed that PT was performed by the same testing person in 5 of 6 events; and 3. A review of Nonchemistry PT attestation worksheets from 2019 and 2020 showed that PT was performed by the same testing person in 3 of 6 events. 4. During an interview on 7/15 /2021 at 2:00 PM, the TC confirmed that PT samples were not tested each year by all the staff who perform patient testing to ensure accurate and reliable patient test results.
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 quality control (QC) record review and interview with the technical consultant (TC), the laboratory failed to ensure that hematology and Rh factor blood typing QC was not used after it exceeded its expiration date. Findings: 1. The laboratory performs Rh factor blood typing and waived hemoglobin testing. QC record review was performed for April and September of 2019 and 2020. 2. Record review showed that on 4/27/2019 the laboratory ran the Immucor "Rh Positive Cell" and "Rh Negative Cell" QC, lot number 07545 which expired on 4/26/2019. 6 patients were also tested that day; and 3. The laboratory ran expired HemoCue hemoglobin QC on 2 days in April 2019. Cross-refer to D1001. 4. During an interview on 7/15 /2021 at 2:00 PM, the TC confirmed that QC was run using controls which had exceeded their expiration date.