Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0990742	(X3) Date Survey Completed 02/04/2022
Name of Provider or Supplier Carolina Doctors Med Care	**Street Address, City, State** 1024 South Horner Boulevard, Sanford, NC	

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
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 surveyor observation and testing personnel (TP) #1 interview 2/4/22, the laboratory failed to dispose of supplies and reagent that had exceeded their expiration date. Findings: Surveyor observed the following expired supplies in the laboratory cabinet drawers: 1. SteriPack Polyester Spun Swab - Lot #13516, expiration (exp.) 11/3/21. Approximately 20 swabs. 2. Hologic Aptima Urine Specimen Collection Kit - Lot #34400H, exp. 1/31/21. Approximately 5 kits. 3. BD Vacutainer - Lot #7279807, exp. 4/30/19. Approximately 25 tubes. 4. BD Vacutainer - Lot #7097721, exp. 4/30/19. Approximately 25 tubes. 5. BD Vacutainer - Lot # 0100314, exp. 4/30/21. Approximately 15 tubes. 6. BD Vacutainer - Lot #0003589, exp. 4/30/21. Approximately 50 tubes. Surveyor observed the following expired reagent in the laboratory cabinet: 1. Occult Blood Developer Consult Diagnostic - Lot #14-15-551622, exp. 7/18. One bottle. Interview with TP #1 at approximately 2:00 p.m. confirmed the supplies and reagent were expired. She stated the BD Vacutainer tubes were being saved by a past employee for students and she did not realize they were in the drawers and not marked as "do not use". She also stated none of the reagent or supplies would have been used for patient testing or specimen collection. All expired supplies and reagent were disposed of at time of survey. .
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory

	must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of Cell-Dyn Emerald operator's manual, review of 2019, 2020 and 2021 laboratory maintenance logs, review of Cell-Dyn Emerald on-board maintenance log and interview with TP #1 2/4/22, the laboratory failed to perform monthly maintenance on the Cell-Dyn Emerald analyzer 8 of 16 months reviewed. Findings: Review of Cell-Dyn Emerald operator's manual revealed under Section 9 "Preventive Maintenance Schedule...Monthly Maintenance...Bleach Cleaning...Cleaning the system with a bleach solution is performed monthly...". Review of 2019, 2020 and 2021 laboratory maintenance logs for the Cell-Dyn Emerald revealed no documentation the laboratory performed monthly maintenance in June and August of 2019, and January, April, May, June, August and September of 2020. Review of Cell-Dyn Emerald on-board maintenance logs revealed the logs could not be retrieved to determine monthly maintenance in 2019 and 2020. Interview with TP #1 at approximately 2:00 p.m. confirmed monthly maintenance was not performed. She stated she was sure it was performed but she may have not documented it. She also confirmed review of on-board maintenance records could not be retrieved to confirm all monthly maintenance in 2019 and 2020 was performed.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on surveyor record review and laboratory director (LD) interview 2/4/22, the LD failed to ensure the laboratory's approved corrective action plan was followed to evaluate unacceptable proficiency testing (PT) results. Findings: See D6019. This deficiency was previously cited in 2019.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of laboratory procedures, review of 2020 and 2021 American Proficiency Institute (API) PT records and interview with laboratory director (LD) 2/4/22, the LD failed to ensure the laboratory's approved corrective action plan was followed to evaluate unacceptable PT results. Findings: Review of laboratory procedure "Receipt and Evaluation of PT Results" revealed "2. Any PT result of less

	than 100 % must be reviewed and an investigation performed to determine the cause of failure. If the participant summary has any unacceptable results or upgraded results, there must be documentation that the "unacceptable result" was evaluated. A description of the PT investigation and corrective action with any supporting documentation will be forwarded to the QA manager for review. If the corrective action is deemed acceptable, it is then forwarded to the Director and/or Assistant Director for a final review and approval." The "Receipt and Evaluation of PT Results" procedure was submitted as the laboratory's corrective action for same deficiency cited in 2019. Review of laboratory procedure "American Proficiency Institute Checklist for Corrective Action" revealed a checklist for unacceptable PT results. The checklist for corrective action includes reviews of "Specimen Handling", "Clerical Errors", "Quality Control", "Calibration", "Instrument", and "Reagents". The "American Proficiency Institute Checklist for Corrective Action" was submitted as the laboratory's corrective action for same deficiency cited in 2019. Review of 2020 and 2021 APT PT records revealed the following API testing events failed to include documentation the laboratory's approved corrective action plan was followed to evaluate unacceptable PT results: 1. API 2020 2nd event, unacceptable result for HEM-06, red blood cell (RBC). No corrective action documented. 2. API 2021 1st event, unacceptable results for HEM-03 and HEM-04, RBC and HEM-05, hematocrit (HCT). The corrective action states "mix samples - ran QC on clinitex, bring to room temperature." The corrective action fails to follow the laboratory's approved corrective action plan to evaluate the probable cause of the unacceptable results. 3. API 2021 2nd event, unacceptable result for HEM-09, platelet count (PLT). No corrective action documented. During exit interview at approximately 2:30 p.m., the LD stated he thought they had done all corrective action for the unacceptable PT results. This deficiency was previously cited in 2014, 2017, and 2019.