Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2136938	02/28/2024
Name of Provider or Supplier	**Street Address, City, State**	
College Park Medical Center	4701 Melbourne Place, College Park, 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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(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 review of the procedure, review of proficiency testing (PT) results, and interview with the technical supervisor (TS), the laboratory failed to investigate the cause of a PT score less than 100% as required in the procedure. Findings: 1. The "Proficiency Testing" section of the "Quality Management Plan" stated "Survey performance that demonstrates a score of less than 100% will require further investigation and corrective action." 2. The laboratory received an 80% for "Group C /G Strep (molecular)" in the 2023 3rd PT event. 3. There was no documentation of an investigation into the unacceptable result for "Group C/G Strep." 4. During the survey on 02/26/2024 at 2:30 PM, the TS confirmed that there was no documentation of an investigation into the cause of the unacceptable result for "Group C/G Strep" as required by the procedure.
D5427	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(c) (c) Documentation. The laboratory must document all activities specified in this section. This STANDARD is not met as evidenced by: Based on review of the assay verification documentation and interview with the

	technical supervisor (TS), the laboratory failed to document the evaluation of the verification results for the Quidel Solana Strep Complete assay. Findings: 1. The laboratory added two testing panels for the Quidel Solana instrument since the previous survey: 1) Herpes simplex virus (HSV) 1 and 2/Varicella zoster virus (VZV) and 2) Strep Complete which identified Streptococcus groups A and C/G. 2. For both assays a set of known samples supplied by Quidel was used to demonstrate accuracy. 3. Documentation for the verification of the HSV 1 and 2/VZV assay included the answer key for the known set of samples that was provided by Quidel as well as a "Quidel Molecular HSV 1+2/VZV Panel Results Form" where the laboratory documented their results. The Panel Results Form was signed by the TS indicating that the laboratory's results were compared with the expected results provided by Quidel and the assay was acceptable for patient testing. 4. The verification documentation for the Strep Complete assay only included the raw data from the instrument. There was no documentation of the evaluation of the results to ensure that the correct results were obtained and the assay was acceptable for patient testing. 5. During the survey on 02/26/2024 at 2:30 PM, the TS confirmed that documentation of the verification of the Strep Complete assay was not available.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on observation, procedure manual and record review, and interview with the technical supervisor (TS), the laboratory failed to perform and document the calibration of the centrifuge and pipettes used for molecular testing. Findings: 1. The laboratory's "Quality Management Plan" procedure, section "III. Analytical Phase," "c. Instrument Maintenance" states, "New instruments and equipment are installed, calibrated and documented by the vendor who assures satisfactory performance" and "All laboratory equipment must be monitored to assure acceptable performance. The laboratory has established performance characteristics for general laboratory equipment." 2. Section "ii. Pipettes" in the same procedure states, "Pipette maintenance should be performed at least once every six months. Pipette are sent out for calibration to a certified lab. Alternatively, qualified service contractors will come onsite to perform calibration." "Also, each Pipette should retain a sticker with the date it was calibrated and the next due date. Pipette maintenance should be performed at least once a year." 3. During a tour of the laboratory at 1:00 PM on 02/26/2024, it was observed that the pipettes used for molecular testing were not labeled with a sticker, documenting the date of calibration and when the next calibration was due. During an interview at the same time, the TS stated that the laboratory disposes of their pipettes and purchases new ones approximately every six months instead of calibrating them. The TS was not able to find documentation of when the pipettes were purchased, how long they had been in use, or when they needed to be replaced. 4. The laboratory uses a "Biofuge fresco" centrifuge for spinning down patient urine samples to perform molecular testing for sexually transmitted diseases. The procedure, "iAMP CT/NG/TV /MG Detection assay" states, "Centrifuge the tubes at 10000-13000 rpm for 10 mins. After the centrifugation, remove supernatant completely by a pipette and keep the cell pellet." 5. During an interview at 1:00 PM on 02/26/2024, the TS stated that the

	laboratory had been using the centrifuge since May 2023 but that the centrifuge had not been calibrated before being put into service or since. Procedure manual review showed that the laboratory did not have an approved procedure for how to perform maintenance and calibrations on the centrifuge, or how frequently to perform the calibrations. 6. During an interview on 02/26/2024 at 2:30 PM, the TS confirmed that the laboratory failed to perform and document maintenance and calibrations on the centrifuge and pipettes used in molecular testing.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on humidity log record review and interview with the technical supervisor (TS), the laboratory failed to document corrective action when laboratory humidity levels were out of range. Findings: 1. A review of "Temperature/Humidity Chart" logs from the "Extraction Room" showed that the acceptable humidity range is "40 - 70%." 2. From October 2023 to January 2024 the laboratory humidity in the "Extraction Room" was out of range 55 out of 122 times recorded. 3. There were no corrective actions documented for these dates. 4. During an interview on 02/26/2024 at 2:30 PM, the TS confirmed that there were no corrective actions documented for the days that the laboratory humidity was out of acceptable range.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on procedure manual and record review and interview with the technical supervisor (TS), the laboratory director (LD) failed to specify, in writing, the responsibilities and duties that the LD delegated to the TS. Findings: 1. The procedure, "Job Description: Laboratory Director" under the section, "Availability" states, "The director is not required to be on-site at all times testing is performed." "If the laboratory director reapportions performance of the above responsibilities, the responsibility for ensuring that all duties are properly performed remains the

	director's. All delegations of duties must be documented in writing." 2. Record review showed that the TS, not the LD, reviewed and signed proficiency testing (PT) documents on three out of three PT events in 2023, signed off on "Monthly Quality Assurance Checklists" from May 2023 to January 2024, and signed off their approval of the validation for testing on the Quidel Solana (cross-refer to D5427 for details). 3. There was no letter of delegation from the LD, specifying which duties and responsibilities the LD delegated to the TS. This was confirmed by the TS during an interview on 02/26/2024 at 2:30 PM.