Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2166916	12/05/2024
Name of Provider or Supplier	**Street Address, City, State**	
Southeast Pathology Consultants	1815 Back Creek Drive, Charlotte, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation and interview with general supervisor (GS) 12/05/24, the laboratory failed to retain temperature and humidity records for the anatomic pathology department. Findings: The laboratory had no documentation of the recording of temperature and humidity for the anatomic pathology department during 2023 and 2024. Interview with GS 12/05/24 at approximately 2:00 p.m. confirmed the laboratory could not locate the folder containing the temperature and humidity records for the anatomic pathology department. The GS stated they had recently reviewed them prior to preparing for the survey and either they were misplaced or possibly accidentally thrown out.
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 validation records, review of laboratory test list, absence of documentation, review of laboratory procedures, review of pathology reports sent for verification of accuracy, interview with laboratory director (LD) 12/05/24, and follow-up phone conference with GS 12/18/24, the laboratory failed to verify accuracy of the

	histopathology staining performed on the Ventana automated stainer at least twice a year since testing began in January of 2023, approximately 24 months. The laboratory also failed to verify accuracy of the pathology testing at least twice a year. 1. The laboratory failed to verify the accuracy of the histopathology staining performed on the Ventana automated stainer at least twice a year since testing began in January of 2023. Findings: Review of validation records revealed the laboratory began testing on the Ventana automated stainer in January of 2023. Review of test list for the Ventana automated stainer revealed the following stains are performed by the laboratory: 1. Anti-Pan Keratin 2. Ber Ep4 (antihuman epithelial antigen) 3. HPV HR (high-risk human papillomavirus) 4. CEA (serial plasma carcinoembryonic antigen) 5. CD 34 (cluster of differentiation 34) 6. CD 68 (cluster of differentiation 68) 7. Cd 138 (Syndecan-1) 8. CK-7 (cytokeratin 7) 9. CK-20 (cytokeratin 20) 10. Desmin 11. EMA (epithelial membrane antigen) 12. Factor XIIIa 13. HMB 45 (human melanoma black 45) 14. HSV I (herpes simplex virus 1) 15. HSV II (herpes simplex virus 2) 16. KI 67 (antigen Kiel 67 mitotic index) 17. P 16 (p 16 protein) 18. Melan A (melanocyte antigen) 19. PGP 9.5 (protein gene product 9.5) 20. P 40 (deltaNp63) 21. SM Actin (smooth muscle actin) 22. S 100 (soluble protein) 23. SOX 10 (SRY-box transcription factor 10) Review of laboratory records revealed no documentation the laboratory had performed a twice a year verification of accuracy for the the testing performed on the Ventana automated stainer since testing began in January of 2023. Follow-up phone conference with GS on 12/18/24 confirmed the laboratory had not performed a verification of accuracy for the testing performed on the Ventana automated stainer since testing began in January of 2023. The GS also stated they were unaware of this requirement and many of the stains are rarely performed. 2. The laboratory failed to verify the accuracy of the pathology testing at least twice a year. Findings: Review of laboratory procedure "Professional Competency" revealed "3. The AP department will send 10% of randomly selected cases that were screened by the SEP pathologists to a different pathologist to screen as quality assurance. 4. The results obtained in steps 1-3 will be evaluated and documented. Corrective will be taken, as necessary." Review of 7 laboratory pathology reports presented as documentation of verification of accuracy revealed the cases sent for review included the original pathology report and notes requesting a consultation from a referring pathologist. The cases were not sent as blind samples, a pathology report was not generated from the referring pathologist and there was no documentation of a comparison of pathology test results. Interview with LD 12/05/24 at approximately 2:30 p.m. confirmed the pathology cases were not sent as blind samples, a pathology report was not generated from the referring pathologist and there was no documentation of a comparison of pathology 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 surveyor observation and interview with GS 12/05/24, the laboratory failed to ensure expired reagents were not available for use. Findings: At approximately 10: 00 a.m. 12/5/24, surveyor observed the following reagents on the grossing bench in the anatomic pathology department of the laboratory, available for use: 1. One clear plastic container labeled "Formalin reagent 10% NBF" with a preparation date of 03 /12/24 and expiration date of 07/01/24. 2. One clear plastic squirt bottle labeled

	"Decal Reagent Decalcifier" with a preparation date of 09/28/22 and expiration date of 12/28/22. Interview with GS at approximately 10:00 a.m. on 12/5/24 confirmed the reagents were expired.
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 operator's manual, review of laboratory procedure, review of 2022, 2023 and 2024 maintenance logs, review of 2022, 2023 and 2024 analyzer service reports, review of CMS-116 submitted at time of survey and interview with testing personnel (TP #1) 12/04/24, the laboratory failed to perform and/or document monthly maintenance on the QuantStudio 7 Flex analyzer from June of 2022 until November of 2024, a period of approximatley 28 months, failed to perform semi-annual maintenance every six months and failed to ensure maintenance was documented and performed for each facility utilizing the QuantStudio 7 Flex analyzer. 1. The laboratory failed to perform and/or document monthly maintenance on the QuantStudio 7 Flex analyzer from June of 2022 until November of 2024, a period of approximately 28 months. Findings: Review of operator's manual revealed the following "Calibration and maintenance schedule...The QuantStudio 6 and 7 Flex Systems require regular calibration and maintenance for proper operation. To ensure proper operation of your instrument, perform weekly, monthly and semiannual maintenance as indicated in the following table.....Monthly...Perform a background calibration...Run disk cleanup and disk defragmentation...Perform an instrument self test....". Review of laboratory procedure "APPLIED BIOSYSTEMS QUANTSTUDIO FLEX 7 OPERATING PROCEDURE" revealed a copy of the maintenance table from the operator's manual, with monthly maintenance as stated in the operators manual. Review of 2022, 2023 and 2024 maintenance logs for the QuantStudio 7 Flex analyzer revealed no documentation of monthly maintenance from June of 2022 until November of 2024. 2. The laboratory failed to perform semi-annual maintenance every six months on the QuantStudio 7 Flex analyzer. Findings: Review of operator's manual revealed the following "Calibration and maintenance schedule...The QuantStudio 6 and 7 Flex Systems require regular calibration and maintenance for proper operation. To ensure proper operation of your instrument, perform weekly, monthly and semiannual maintenance as indicated in the following table.....Semi-annually (every 6 months)....Perform a ROI calibration...Perform a background calibration...Perform a uniformity calibration...Perform a dye calibration...". Review of laboratory procedure "APPLIED BIOSYSTEMS QUANTSTUDIO FLEX 7 OPERATING PROCEDURE" revealed a copy of the maintenance table from the operator's manual, with semi-annual maintenance as stated in the operators manual. Review of 2022, 2023 and 2024 maintenance logs for the QuantStudio 7 Flex analyzer revealed under the Semi-Annually section of the log "Performed by Service" and "See service report". Review of 2022, 2023 and 2024 service reports for the QuantStudio 7 Flex analyzer revealed semi-annual maintenance was performed 10/06/22 and 03/14/23. Semi-annual maintenance was not performed again until 04/03/24, a period of approximately 13 months. Semi-annual maintenance was due 10/03/24 and had not been completed at time of survey, a period of approximately 8 months. 3. The laboratory failed to ensure maintenance was

	documented for each facility utilizing the QuantStudio 7 Flex analyzer. Findings: Review of CMS-116 at time of survey listed "Hours of Laboratory Testing" as Monday through Friday, 6:30 a.m. - 3:00 p.m. The other facility who utilizes the analyzer listed different hours of operation Monday through Friday. Review of 2022, 2023 and 2024 maintenance logs for the QuantStudio 7 Flex analyzer revealed only one set of maintenance logs with no distinction as to which facility performed the maintenance. Interview with TP #1 on 12/04/24 at approximately 11:00 a.m. confirmed maintenance was not documented for each facility. TP #1 stated samples from each facility are run at the same time and not on different days or at different hours.
D5453	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iv)(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 test system that has an extraction phase, include two control materials, including one that is capable of detecting errors in the extraction process; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory procedure, review of 2023 and 2024 quality control (QC) records, lack of documentation, review of CMS-116 submitted at time of survey, and interview with TP #1 on 12/04/24, the laboratory failed to perform a positive extraction control (PEC) and negative extraction control (NEC) each day of patient testing and/or for each TaqMan Array Card (test system) and failed to ensure QC was documented and/or performed for each facility utilizing the QuantStudio 7 Flex analyzer. Approximately 750 patients were tested from January of 2023 until time of survey. The laboratory performs "Wound Infection Panel" and "Periungual Infection Panel" on the QuantStudio 7 Flex Analyzer utilizing a TaqMan Array Card test system. Each TaqMan Array Card can test up to 8 patient samples. 1. The laboratory failed to perform a PEC and NEC each day of patient testing and/or for each TaqMan Array Card (test system). Findings: Review of laboratory procedure "APPLIED BIOSYSTEMS QUANTSTUDIO FLEX 7 OPERATING PROCEDURE" revealed "QUALITY CONTROL (QC): There are several QC materials that are utilized on the Applied Biosystems QuantStudio 7 Flex...Positive Extraction Control (PEC) and Negative Extraction Control (NEC) will be performed monthly. NOTE: PEC and NEC may be performed more frequently if deemed necessary for troubleshooting." Review of 2023 QC records revealed the laboratory performed a NEC each day of patient testing but failed to perform a PEC approximately 152 of 164 days when patient testing was performed. Surveyor was unable to determine the number of patients tested each day or the number of TaqMan Array Cards (test systems) run each day. Review of 2024 QC records revealed the laboratory performed a NEC each day of patient testing but failed to perform a PEC approximately 24 of 32 days when patient testing was performed. Surveyor was unable to determine the number of patients tested each day or the number of TaqMan Array Cards (test systems) run each day. Interview with TP #1 on 12/04/24 at approximately 11:00 a.m. confirmed the PEC was not performed each day of patient testing. TP #1 stated the PEC is performed at least monthly and the NEC has been performed weekly since January of 2024 when the laboratory began to batch test patients weekly. TP #1 also confirmed the PEC and NEC were not performed for each TaqMan Array Card (test system)

	used in a daily run. Review of CMS-116 submitted at time of survey revealed the laboratory performs 375 test panels per year on the QuantStudio 7 Flex analyzer; approximately 750 patients were tested since January of 2023. 2. The laboratory failed to ensure QC was documented and/or performed for each facility utilizing the QuantStudio 7 Flex analyzer. Findings: Review of CMS-116 at time of survey listed "Hours of Laboratory Testing" as Monday through Friday, 6:30 a.m. - 3:00 p.m. The other facility who utilizes the analyzer listed different hours of operation Monday through Friday. Review of 2023 and 2024 QC logs for the QuantStudio 7 Flex analyzer revealed only one set of QC logs with no distinction as to which facility performed the QC. Interview with TP #1 on 12/04/24 at approximately 11:00 a.m. confirmed QC was not documented for each facility. TP #1 stated samples from each facility are batched together and run at the same time and not on different days or at different hours.