Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2287217	02/04/2026
Name of Provider or Supplier	**Street Address, City, State**	
Aventa Genomics Llc	6555 Sanger Rd #231, Orlando, FL	

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
D0000	An announced CLIA recertification survey was conducted at Aventa Genomics LLC on January 28, 2026 to February 4, 2026. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D5400 493.1250 Condition: Analytic Systems D5800 493.1290 Condition: Postanalytic Systems D6076 493.1441 Condition: Laboratory Director D6108 493.1447 Condition: Laboratory Technical Supervisor D6168 493.1487 Condition: Laboratory Testing Personnel
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to establish performances specifications including accuracy, precision , analytical sensitivity , analytical specificity, interfering substances, reportable range and specimen stability for solid tumor and lymphoma next generation sequencing (NGS) testing before patient testing (See D5423) and failed to establish positive control for all gene sequences used in solid tumors and lymphoma next generation sequencing (NGS) testing before patient testing(See D5425).
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2)

(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:
Based on record review and interview, the laboratory failed to establish performances specifications: accuracy, precision , analytical sensitivity , Analytical specificity, interfering substances , reportable range and specimen stability for solid tumor and lymphoma next generation sequencing (NGS) testing before patient testing. Finding Included: 1. Review of Validation of Aventa Fusion Plus signed by the Laboratory Director on 1/22/2024 revealed the following: a. Accuracy section was missing specimen samples that identified what gene sequences were present. b. Precision section had no identification of what quality control (QC) or sample was run multiple times and what the sequence was. c. There was no documentation of analytical specificity to identify the lowest concentration for this test. d. There was no documentation of interfering substance. e. There was no documentation of analytical sensitivity. f. There was no documentation on what determined a positive sequence and what the negative sequence was. g. Test menu for gene-level detection of structural variants near or within 311 medically actionable or diagnostically relevant cancer genes and 50 control genes in human genome, for a total of 361 total genes were: ABL1 BRD4 CREB1 ETS1 FOXO1 KMT2C MXI1 PALB2 PRKD2 SEC31A TFG ACTB BRIP1 CREB3L1 ETV1 FOXO4 KRAS MYB PARP3 PRKD3 SEM1 TGFBR3 ACVR2A BTK CREB3L2 ETV4 FOXP1 LAMP1 MYBL1 PATZ1 PTCH1 SEPTIN9 THBS1 ADGRF5 C11orf95 CRTC1 ETV5 FOXR2 LAMTOR1 MYC PAX3 PTEN SERPINE1 THRAP3 AHRR CAMTA1 CRTC3 ETV6 FUS LPP MYH9 PAX7 PTK7 SET TIGIT AKT1 CARS1 CSF1 EWSR1 GATA6 MAGED1 NAB2 PBX1 RAB2A SETBP1 TMPRSS2 AKT3 CCNB3 CSF1R EXOC7 GLI1 MAGI1 NBN PBX3 RAD51 SFMBT1 TNFSF4 ALK CCND3 CTBS EZH2 GPC5 MAML1 NCOA2 PDCD1 RAD51B SLC27A4 TP53 APC CD274 CTNNB1 EZHIP GPC6 MAML2 NCOA3 PDGFB RAD51C SMARCA5 TPM3 AR CD63 DDIT3 EZR GRID1 MAML3 NCOA4 PDGFRA RAD51D SMARCB1 TPM4 ARAF CDH11 DDX3X FANCA GSE1 MAP2K1 NF1 PDGFRB RAD54L SMO TPR ARID1A CDK12 DHX57 FANCD2 HAS2 MAP2K2 NFATC2 PDPN RAF1 SP3 TSC1 ASPSCR1 CDK4 DICER1 FANCF HEY1 MAPK1 NFE2 PER1 RANBP2 SQSTM1 TSC2 ATF1 CDK6 DNAJB1 FANCL HIP1 MAST1 NFE2L2 PGR RASA1 SRC USP6 ATIC CDK8 DROSHA FAT1 HIRA MAST2 NFIB PHF1 RB1 SRF VCL ATM CDKN1B DST FBXW4 HMGA2 MBTD1 NOTCH1 PIK3CA RECQL4 SRGAP3 VEGFA ATR CDKN1C DUX4 FBXW7 HRAS MDM2 NOTCH2 PIK3CB REAL SRSF3 VGLL2 AURKA CDKN2A DVL2 FEV IDH1 MEAF6 NOTCH3 PIM1 RET SS18 VGLL3 AUTS2 CDX1 DYNC2I2 FGFR1 IDH2 MED12 NPM1 PKHD1 RGPD3 SS18L1 VHL AXL CEP128 EGFR FGFR2 IL7R MEF2C NR4A3 PLAG1 RNF213 SSX1 WRN B3GALT9 CHEK1 ELP6 FGFR3 INHBA MET NRAS PLPP3 ROS1 SSX2 WT1 BACH2 CHEK2 EML4 FGFR4 INPP4A MGMT NRG1 PMS2 RPA1 SSX4 WWOX BAP1 CHST9 EP300 FGR INSR MLH1 NTRK1 POU5F1 RPS6KB1 STAT6 WWTR1 BARD1 CIC EP400 FH IRF2BP2 MLLT3

NTRK2 PPARG RPS6KB2 SUFU XRCC2 BCL2 CITED2 EPC1 FLCN JAZF1 MN1 NTRK3 PPFIBP1 RRAGB SUZ12 YAP1 BCLAF1 CLDN18 EPCAM FLI1 KAT6A MOB3B NUMA1 PPM1D RSPO2 TAF15 YWHAE BCOR CLTC EPS8 FLT1 KDR MRTFA NUP214 PRDM10 RSPO3 TAFA1 ZC3H7B BCR CNBP ERBB2 FLT3 KIF5B MRTFB NUTM1 PRKACA RUNX2 TCF12 ZFP36 BLM COL1A1 ERBB3 FN1 KIRREL1 MSANTD3 NUTM2A PRKAR1A S100A10 TEAD1 ZNF444 BRAF COL1A2 ERCC2 FNBP1 KIT MSH2 NUTM2B PRKCA SDHA TEK ZNF521 BRCA1 COL3A1 ERG FOS KLC1 MSH6 OMD PRKCB SDHB TERT ZNF703 BRCA2 COL6A3 ESR1 FOSB KLF17 MTOR OPHN1 PRKCD SDHC TFE3 BRD3 COLEC12 ETNK1 FOXL2 KMT2A MUSK PAG1 PRKD1 SDHD TFEB 2. Review of 'Validation of Aventa Lymphoma Test for Lymphoma Samples' signed by the Laboratory Director on 4/15/2026 revealed the following: a. Accuracy section was missing specimen samples that identified what gene sequences were present. b. Precision section had no identification of what qc or sample was run multiple times and what the sequence was. c. The was no documentation of analytical specificity to identify the lowest concertation for this test. d. There was no documentation of interfering substance. e. There was no documentation of analytical sensitivity. f. There was no documentation of what determined a positive sequence and what a negative sequence was. g. The test menu for gene-level detection of structural variants (SV) across 417 genes that were medically actionable or diagnostically relevant to lymphoma cancer were: ARHGAP26 CCND2 CYB5R2 FEV IGH MEF2B NSD2 PRDM16 SART3 TNFRSF11A ARHGEF12 CCND3 DDIT3 FGFR1 IGK MEF2D NSD3 PRKAR2B SEC31A TNFRSF13B ARID1A CCP110 DDX10 FGFR2 IGL MIGA1 NTRK1 PRKCA SERPINA9 TNFRSF14 ARNT CD274 DDX6 FGFR3 IKZF1 MLF1 NTRK2 PRKCB SET TNFSF4 ASB13 CD28 DEK FIP1L1 IL16 MLLT1 NTRK3 PRKCD SF3B1 TNKS2 ASXL1 CD44 DENND3 FLI1 IL21R MLLT10 NUMA1 PRRX1 SH3BP5 TOP1 ATF1 CD79A DLEU1 FLT3 IL3 MLLT3 NUP214 PSIP1 SH3GL1 TP53 ATG5 CD79B DLEU2 FNBP1 IL3RA MLLT6 NUP98 PTCH1 SLC1A2 TP63 ATIC CD96 DLEU7 FOXO1 IRAG2 MME NUTM1 PTEN SNX29 TPM3 ATM CDC25A DNMT3A FOXO3 IRF4 MN1 NUTM2A PTK2B SOCS1 TPM4 B2M CDK5RAP2 DNMT3B FOXO4 IRF8 MNX1 OMD PTK7 SRSF3 TRA BARD1 CDK6 DNTT FOXP1 ITK MRTFA P2RY8 PTPN1 SS18 TRAF1 BATF3 CDKN2A DUSP22 FSTL3 ITPKB MSI2 PABPC4 PTPRD SSBP2 TRAF2 BAX CDKN2B DUX4 FUS JAK1 MSN PACSIN2 PYCR1 SSX1 TRB BCL10 CDKN2C E2F2 FUT8 JAK2 MTCP1 PAFAH1B2 RAB29 SSX2 TRD BCL11A CDX2 EBF1 GAS7 JAK3 MUC1 PAICS RABEP1 SSX4 TRG BCL11B CEBPD EGFR GATA1 JAZF1 MYB PAX3 RAD51B STAT3 TRIM24 BCL2 CEBPE EIF4A1 GATA2 KAT6A MYBL1 PAX5 RAF1 STAT5B TRIP11 BCL2A1 CEBPG EIF4A2 GLI1 KDSR MYC PAX7 RAG1 STAT6 TTL BCL3 CEP43 ELF4 GLIS2 KIF5B MYD88 PBX1 RAG2 STIL TYK2 BCL6 CHIC2 ELL GMPS KLF2 MYH11 PCLAF RALGDS STRBP USP6 BCL7A CHN1 ELN GPHN KMT2A MYH9 PCM1 RANBP1 STRN WT1 BCL9 CIC EML4 H4C13 KMT2D MYO18A PCSK7 RANBP2 SYK XPO1 BCOR CIITA ENTPD1 HERPUD1 KRAS NACA PDCD1 RAP1GDS1 TAF15 YPEL5 BCR CKS1B EP300 HEY1 LAIR1 NBEAP1 PDCD1LG2 RARA TAL1 ZBTB16 BIRC3 CLIP3 EPOR HIP1 LASP1 NCOA2 PDE4DIP RB1 TAL2 ZMYM2 BLNK CLP1 EPS15 HLF LCP1 NDRG1 PDGFB RBM15 TARBP1 ZNF384 BMF CLTC ERBB2 HMGA1 LIMD1 NEK6 PDGFRA REL TBL1XR1 ZNF501 BMP7 CLTCL1 ERG HMGA2 LMNA NF1 PDGFRB RET TCF3 BRAF CNTRL ETS1 HOXA11 LMO1 NF2 PER1 RFTN1 TCL1A BRCA1 COL1A1 ETV1 HOXA13 LMO2 NFKB1 PHF1 RHOA TCL1B 3. Review of Test SOP for FFPE (Formalin Fixed Paraffin Embedded Tissues) revealed there was no documentation of specimen stability and specimen storage. 4. Review of Clinical Laboratory Improvement Amendments Application for Certification revealed 200

	patients were tested for Routine Chemistry. 5. On 1/30/2026 at 12:36 PM, the Technical Supervisor and Director of Operations confirmed the laboratory failed to establish performances specifications: accuracy, precision, analytical sensitivity, Analytical specificity, interfering substances, reportable range and specimen stability for solid tumor and lymphoma next generation sequencing (NGS) testing before patient testing.
D5425	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(3) (b)(3) The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to establish positive control for all gene sequences used in solid tumors and lymphoma next generation sequencing (NGS) testing before patient testing. Finding Included: 1. Review of Aventa Quality Control program signed by the Laboratory Director on 4/15/2025 read "Controls are run on clinical instruments as appropriate for each instrument and following manufacturer's guidelines. Control results are checked against expected ranges and values are recorded." 2. Review of Validation of Aventa Fusion Plus signed by the Laboratory Director on 1/22/2024 read, "Aventa Fusion Plus requires the use of the positive control for each Arima-HiC library preparation and sequencing run. A unique positive control should be prepared for each batch of samples processed. K562 FFPE Cell Pellet is used as the control material. K562 are lymphoblast cells isolated from bone marrow from a female patient with leukemia. K562 is a well characterized cell line with a significant number of structural variants that overlap with Aventa FusionPlus virtual panel. In the validation study, K562 was not used as a control sample but was chosen as one of the samples for the sensitivity study to assess the detection of structural variants." There was no documentation of positive control for 361 gene sequences for solid tumor next generation sequence testing. There was no documentation for positive quality control that showed that it met 361 sequences. 3. Review of Validation of Aventa Lymphoma Test for Lymphoma Samples signed by the Laboratory Director on 4/15/2026 read, "This test requires the use of the positive control for each Arima-HiC library preparation. A unique positive control should be prepared for each batch of samples processed. K562 FFPE Cell Pellet is used as the control material. K562 are lymphoblast cells isolated from bone marrow from a female patient with leukemia. K562 is a well characterized cell line with a significant number of structural variants that overlap with Aventa Fusion Plus virtual panel. There was no documentation for positive quality control that showed it met 417 sequences. 4. Review of K-562 Product Data Sheet read, "K-562 are lymphoblast cells isolated from the bone marrow of a 53-year-old chronic myelogenous leukemia patient. The K-562 cell line is widely used in immune system disorder and immunology research." 5. Review of Test menu revealed the following: a. The gene sequences for solid tumor: ABL1 BRD4 CREB1 ETS1 FOXO1 KMT2C MXI1 PALB2 PRKD2 SEC31A TFG ACTB BRIP1 CREB3L1 ETV1 FOXO4 KRAS MYB PARP3 PRKD3 SEM1 TGFBR3 ACVR2A BTK CREB3L2 ETV4 FOXP1 LAMP1 MYBL1 PATZ1 PTCH1 SEPTIN9 THBS1 ADGRF5 C11orf95 CRTC1 ETV5 FOXR2 LAMTOR1 MYC PAX3 PTEN SERPINE1 THRAP3 AHRR CAMTA1 CRTC3 ETV6 FUS LPP MYH9 PAX7 PTK7 SET TIGIT AKT1 CARS1 CSF1 EWSR1 GATA6 MAGED1 NAB2 PBX1 RAB2A SETBP1 TMPRSS2 AKT3

CCNB3 CSF1R EXOC7 GLI1 MAGI1 NBN PBX3 RAD51 SFMBT1 TNFSF4 ALK CCND3 CTBS EZH2 GPC5 MAML1 NCOA2 PDCD1 RAD51B SLC27A4 TP53 APC CD274 CTNNB1 EZHIP GPC6 MAML2 NCOA3 PDGFB RAD51C SMARCA5 TPM3 AR CD63 DDIT3 EZR GRID1 MAML3 NCOA4 PDGFRA RAD51D SMARCB1 TPM4 ARAF CDH11 DDX3X FANCA GSE1 MAP2K1 NF1 PDGFRB RAD54L SMO TPR ARID1A CDK12 DHX57 FANCD2 HAS2 MAP2K2 NFATC2 PDPN RAF1 SP3 TSC1 ASPSCR1 CDK4 DICER1 FANCF HEY1 MAPK1 NFE2 PER1 RANBP2 SQSTM1 TSC2 ATF1 CDK6 DNAJB1 FANCL HIP1 MAST1 NFE2L2 PGR RASA1 SRC USP6 ATIC CDK8 DROSHA FAT1 HIRA MAST2 NFIB PHF1 RB1 SRF VCL ATM CDKN1B DST FBXW4 HMGA2 MBTD1 NOTCH1 PIK3CA RECQL4 SRGAP3 VEGFA ATR CDKN1C DUX4 FBXW7 HRAS MDM2 NOTCH2 PIK3CB REAL SRSF3 VGLL2 AURKA CDKN2A DVL2 FEV IDH1 MEAF6 NOTCH3 PIM1 RET SS18 VGLL3 AUTS2 CDX1 DYNC2I2 FGFR1 IDH2 MED12 NPM1 PKHD1 RGPD3 SS18L1 VHL AXL CEP128 EGFR FGFR2 IL7R MEF2C NR4A3 PLAG1 RNF213 SSX1 WRN B3GALT9 CHEK1 ELP6 FGFR3 INHBA MET NRAS PLPP3 ROS1 SSX2 WT1 BACH2 CHEK2 EML4 FGFR4 INPP4A MGMT NRG1 PMS2 RPA1 SSX4 WWOX BAP1 CHST9 EP300 FGR INSR MLH1 NTRK1 POU5F1 RPS6KB1 STAT6 WWTR1 BARD1 CIC EP400 FH IRF2BP2 MLLT3 NTRK2 PPARG RPS6KB2 SUFU XRCC2 BCL2 CITED2 EPC1 FLCN JAZF1 MN1 NTRK3 PPFIBP1 RRAGB SUZ12 YAP1 BCLAF1 CLDN18 EPCAM FLI1 KAT6A MOB3B NUMA1 PPM1D RSPO2 TAF15 YWHAE BCOR CLTC EPS8 FLT1 KDR MRTFA NUP214 PRDM10 RSPO3 TAFA1 ZC3H7B BCR CNBP ERBB2 FLT3 KIF5B MRTFB NUTM1 PRKACA RUNX2 TCF12 ZFP36 BLM COL1A1 ERBB3 FN1 KIRREL1 MSANTD3 NUTM2A PRKAR1A S100A10 TEAD1 ZNF444 BRAF COL1A2 ERCC2 FNBP1 KIT MSH2 NUTM2B PRKCA SDHA TEK ZNF521 BRCA1 COL3A1 ERG FOS KLC1 MSH6 OMD PRKCB SDHB TERT ZNF703 BRCA2 COL6A3 ESR1 FOSB KLF17 MTOR OPHN1 PRKCD SDHC TFE3 BRD3 COLEC12 ETNK1 FOXL2 KMT2A MUSK PAG1 PRKD1 SDHD TFEB B. Gene sequences for lymphoma are: ARHGAP26 CCND2 CYB5R2 FEV IGH MEF2B NSD2 PRDM16 SART3 TNFRSF11A ARHGEF12 CCND3 DDIT3 FGFR1 IGK MEF2D NSD3 PRKAR2B SEC31A TNFRSF13B ARID1A CCP110 DDX10 FGFR2 IGL MIGA1 NTRK1 PRKCA SERPINA9 TNFRSF14 ARNT CD274 DDX6 FGFR3 IKZF1 MLF1 NTRK2 PRKCB SET TNFSF4 ASB13 CD28 DEK FIP1L1 IL16 MLLT1 NTRK3 PRKCD SF3B1 TNKS2 ASXL1 CD44 DENND3 FLI1 IL21R MLLT10 NUMA1 PRRX1 SH3BP5 TOP1 ATF1 CD79A DLEU1 FLT3 IL3 MLLT3 NUP214 PSIP1 SH3GL1 TP53 ATG5 CD79B DLEU2 FNBP1 IL3RA MLLT6 NUP98 PTCH1 SLC1A2 TP63 ATIC CD96 DLEU7 FOXO1 IRAG2 MME NUTM1 PTEN SNX29 TPM3 ATM CDC25A DNMT3A FOXO3 IRF4 MN1 NUTM2A PTK2B SOCS1 TPM4 B2M CDK5RAP2 DNMT3B FOXO4 IRF8 MNX1 OMD PTK7 SRSF3 TRA BARD1 CDK6 DNTT FOXP1 ITK MRTFA P2RY8 PTPN1 SS18 TRAF1 BATF3 CDKN2A DUSP22 FSTL3 ITPKB MSI2 PABPC4 PTPRD SSBP2 TRAF2 BAX CDKN2B DUX4 FUS JAK1 MSN PACSIN2 PYCR1 SSX1 TRB BCL10 CDKN2C E2F2 FUT8 JAK2 MTCP1 PAFAH1B2 RAB29 SSX2 TRD BCL11A CDX2 EBF1 GAS7 JAK3 MUC1 PAICS RABEP1 SSX4 TRG BCL11B CEBPD EGFR GATA1 JAZF1 MYB PAX3 RAD51B STAT3 TRIM24 BCL2 CEBPE EIF4A1 GATA2 KAT6A MYBL1 PAX5 RAF1 STAT5B TRIP11 BCL2A1 CEBPG EIF4A2 GLI1 KDSR MYC PAX7 RAG1 STAT6 TTL BCL3 CEP43 ELF4 GLIS2 KIF5B MYD88 PBX1 RAG2 STIL TYK2 BCL6 CHIC2 ELL GMPS KLF2 MYH11 PCLAF RALGDS STRBP USP6 BCL7A CHN1 ELN GPHN KMT2A MYH9 PCM1 RANBP1 STRN WT1 BCL9 CIC EML4 H4C13 KMT2D MYO18A PCSK7 RANBP2 SYK XPO1 BCOR CIITA ENTPD1 HERPUD1 KRAS NACA PDCD1 RAP1GDS1 TAF15 YPEL5 BCR CKS1B EP300 HEY1 LAIR1 NBEAP1

	PDCD1LG2 RARA TAL1 ZBTB16 BIRC3 CLIP3 EPOR HIP1 LASP1 NCOA2 PDE4DIP RB1 TAL2 ZMYM2 BLNK CLP1 EPS15 HLF LCP1 NDRG1 PDGFB RBM15 TARBP1 ZNF384 BMF CLTC ERBB2 HMGA1 LIMD1 NEK6 PDGFRA REL TBL1XR1 ZNF501 BMP7 CLTCL1 ERG HMGA2 LMNA NF1 PDGFRB RET TCF3 BRAF CNTRL ETS1 HOXA11 LMO1 NF2 PER1 RFTN1 TCL1A BRCA1 COL1A1 ETV1 HOXA13 LMO2 NFKB1 PHF1 RHOA TCL1B 6. Review of Clinical Laboratory Improvement Amendments Application for Certification revealed 200 patients were tested for Routine Chemistry. 7. On 1/30/2026 at 12:36 PM, the Technical Supervisor and Director of Operations confirmed failure to establish positive control for all gene sequences used in solid tumor and lymphoma next generation sequencing (NGS) testing before patient testing.
D5800	POSTANALYTIC SYSTEMS CFR(s): 493.1290 Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in 493.1291 unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7) that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the postanalytic systems and correct identified problems as specified in 493. 1299 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to identify the technical component for Hematoxylin and Eosin testing performed on 5(patient 1 -5) out of 5 patients' reports. (See D5805)
D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to identify the technical component for Hematoxylin and Eosin testing performed on 5 (patient 1 -5) out of 5 patients reports. Findings Included: 1. Review of Aventa Lymphoma Test for Lymphoma Samples read "When a formalin-fixed paraffin-embedded (FFPE) tumor sample and/or slides are submitted, the initial phase consists of formal pathologist review of appropriately stained histology or cytology slides to assess adequacy and, if needed, guide enrichment of tumor for sequencing analysis. The technical components of this early phase must pass established laboratory quality control (QC) metrics prior to initiating downstream sequencing protocols." 2. Review of Aventa Fusion Plus Report read, "A pathologist reviews an H&E-stained tissue section to assess adequacy; specimens with minimal tumor cells or insufficient volume may be

	rejected." 3. Review of the following patients' final reports revealed the following: a. Patient 1 was tested for Aventa Fusion Plus next generation sequencing on 5/23/2025 and final report had no documentation of what laboratory performed the Hematoxylin and eosin testing. b. Patient 2 was tested for Aventa Fusion Plus next generation sequencing on 6/10/2025 and final report had no documentation of what laboratory performed the Hematoxylin and eosin testing. c. Patient 3 was tested for Aventa Fusion Plus next generation sequencing on 7/16/2025 and final report had no documentation of what laboratory performed the hematoxylin and eosin testing. d. Patient 4 was tested for Aventa Fusion Plus next generation sequencing on 1/12/2026 and final report had no documentation of what laboratory performed the hematoxylin and eosin testing. e. Patient 5 was tested for Aventa Fusion Plus next generation sequencing on 1/21/2026 and final report had no documentation of what laboratory performed the hematoxylin and eosin testing. 4. On 1/28/2026 at 9:30 AM, the Technical Supervisor and Director of Operations confirmed final patient reports did not identify where the hematoxylin and eosin testing was performed.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to establish performances specifications: accuracy, precision, analytical sensitivity, analytical specificity, interfering substances, reportable range and specimen stability for solid tumor and lymphoma next generation sequencing (NGS) testing before patient testing. (See D6086), and failed to establish positive control for all gene sequences used in solid tumors and lymphoma for NGS testing before patient testing (See D6093)and failed to identify the technical component for Hematoxylin and Eosin testing performed on 5(patients 1 -5) out of 5 patients reports. (See D6098)
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to establish performances specifications: accuracy, precision, analytical sensitivity, analytical specificity, interfering substances, reportable range and specimen stability for solid tumor and lymphoma next generation sequencing (NGS) testing before patient testing. Findings included: 1. See D5423 2. On 2/4/2026 at 5:00 PM, the Laboratory Director confirmed the laboratory failed to establish performances specifications: accuracy, precision, analytical sensitivity, analytical specificity, interfering substances, reportable range and specimen stability for solid tumor and lymphoma next generation sequencing testing before patient testing.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to establish positive control for all gene sequences used in solid tumors and lymphoma next generation sequencing (NGS) testing before patient testing. Findings Included: 1. See D5425 2. On 2/4/2026 at 5:00 PM, the Laboratory Director confirmed failure to establish positive control for all gene sequences used in solid tumor and lymphoma NGS testing before patient testing.
D6098	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8) (e)(8) Ensure that reports of test results include pertinent information required for interpretation; This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to identify the technical component for Hematoxylin and Eosin testing performed on 5 (patient 1 -5) out of 5 patients' reports. Findings included: 1. See D5805 2. On 2/4/2026 at 5:00 PM, the Laboratory Director confirmed final patient reports did not identify where the hematoxylin and eosin testing was performed.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to have 1 Technical Supervisor (B) out of 2 licensed Technical Supervisors for Solid Tumor and Lymphoma Chemistry Testing. (See D6111)
D6111	TECHNICAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1449 (a) The technical supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory may perform anatomic and clinical laboratory procedures and tests in all specialties and subspecialties of services except histocompatibility and clinical cytogenetics services provided the individual functioning as the technical supervisor-- (b)(1) Is a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(2) Is certified in both anatomic and clinical pathology by the American Board of Pathology or the American

Osteopathic Board of Pathology. (c) Bacteriology, Mycobacteriology, Mycology, Parasitology or Virology- If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of bacteriology, mycobacteriology, mycology, parasitology, or virology, the individual functioning as the technical supervisor must- (c)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (c)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or (c)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (c)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months of experience in high complexity testing within the applicable microbiology subspecialty; or (c)(3)(i)(A) Have an earned doctoral degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (c)(3)(i)(B) Meet the requirements in 493.1443(b)(3)(i)(B); and(c)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months of experience in high complexity testing within the applicable subspecialty; or (c)(4)(i)(A) Have earned a master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (c)(4)(i)(B)(1) Meet bachelor's degree equivalency; and (c)(4)(i)(B)(2) Have at least 16 semester hours of additional graduate level coursework in chemical, biological, clinical or medical laboratory science, or medical technology; or (c)(4)(i)(C)(1) Meet bachelor's degree equivalency; and (c)(4)(i)(C)(2) Have at least 16 semester hours in a combination of graduate level coursework in biology, chemistry, medical technology, or clinical or medical laboratory science coursework and an approved thesis or research project related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; and (c)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months of experience in high complexity testing within the applicable subspecialty; or (c)(5)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (c)(5)(i)(B) Have at least 120 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either- (c)(5)(i)(B)(1) 48 semester hours of medical laboratory technology courses; or (c)(5)(i)(B)(2) 48 semester hours of science courses that include- (c)(5)(i)(B)(2)(i) 12 semester hours of chemistry, which must include general chemistry and biochemistry or organic chemistry; (c)(5)(i)(B)(2)(ii) 12 semester hours of biology, which must include general biology and molecular biology, cell biology or genetics; and (c)(5)(i)(B)(2)(iii) 24 semester hours of chemistry, biology, or medical laboratory science or technology in any combination; and (c)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months of experience in high complexity testing within the applicable subspecialty. (d) Diagnostic Immunology, Chemistry, Hematology, Radiobioassay, or Immunohematology - If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of diagnostic immunology, chemistry, hematology, radiobioassay, or immunohematology, the individual functioning as the technical supervisor must- (d)(1)(i) Be a doctor of medicine or a

doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (d)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or (d)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (d)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the applicable specialty; or (d)(3)(i)(A) Have an earned doctoral degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (d)(3)(i)(B) Meet the education requirement at 493.1443(b)(3)(i)(B); and (d)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the applicable specialty; or (d)(4)(i)(A) Have earned a master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (d)(4)(i)(B) Meet the education requirement at paragraphs (c)(4)(i)(B) or (C) of this section; and (d)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the applicable specialty; or (d)(5)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (d)(5)(i)(B) Meet the education requirement at paragraph (c)(5)(i)(B) of this section; and (d)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the applicable specialty. (e) Cytology- If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of cytology, the individual functioning as the technical supervisor must- (e)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (e)(1)(ii) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or (e)(2) An individual qualified under paragraph (b) or (e)(1) of this section may delegate some of the cytology technical supervisor responsibilities to an individual who is in the final year of full-time training leading to certification specified in paragraph (b) or (e)(1)(ii) of this section provided the technical supervisor qualified under paragraph (b) or (e)(1) of this section remains ultimately responsible for ensuring that all of the responsibilities of the cytology technical supervisor are met. (f) Histopathology - If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of histopathology, the individual functioning as the technical supervisor must- (f)(1) Meet one of the following requirements: (f)(1)(i)(A) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (f)(1)(i)(B) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or (f)(1)(ii) An individual qualified under paragraph (b) or (f)(1) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (f)(1)(i)(B) of this section, the responsibility for examination and interpretation of histopathology specimens. (f)(2) For tests in dermatopathology, meet one of the following requirements: (f)(2)(i)(A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (f)(2)(i)(B) Meet one of the following requirements: (f)(2)(i)(B)(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or (f)(2)(i)(B)(2) Be certified in dermatopathology by the American Board of Dermatology and the American Board of Pathology; or (f)(2)(i)(B)(3) Be certified in dermatology by the American Board of Dermatology; or (f)(2)(ii) An individual qualified under paragraph (b) or (f)(2)(i) of this section may delegate to an individual who is a resident in a training program leading to

certification specified in paragraph (b) or (f)(2)(i)(B) of this section, the responsibility for examination and interpretation of dermatopathology specimens. (f)(3) For tests in ophthalmic pathology, meet one of the following requirements: (f)(3)(i)(A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (f)(3)(i)(B) Must meet one of the following requirements: (f)(3)(i)(B)(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or (f)(3)(i)(B)(2) Be certified by the American Board of Ophthalmology and have successfully completed at least 1 year of formal post-residency fellowship training in ophthalmic pathology; or (f)(3)(ii) An individual qualified under paragraph (b) or (f)(3)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (f)(3)(i)(B) of this section, the responsibility for examination and interpretation of ophthalmic specimens; or (g) Oral Pathology- If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of oral pathology, the individual functioning as the technical supervisor must meet one of the following requirements: (g)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (g)(1)(ii) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or (g)(2) Be certified in oral pathology by the American Board of Oral Pathology; or (g)(3) An individual qualified under paragraph (b) or (g)(1) or (2) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (g)(1) or (2) of this section, the responsibility for examination and interpretation of oral pathology specimens. (h) Histocompatibility - If the laboratory performs tests in the specialty of histocompatibility, the individual functioning as the technical supervisor must either- (h)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (h)(1)(ii) Have training or experience that meets one of the following requirements: (h)(1)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (h)(1)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (h)(1)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility; or (h)(2)(i) Have an earned doctoral degree in a biological, clinical or medical laboratory science, or medical technology from an accredited institution; or meet the education requirement at 493.1443(b)(3)(i)(B); and (h)(2)(ii) Have training or experience that meets one of the following requirements: (h)(2)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (h)(2)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (h)(2)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility. (i) Clinical cytogenetics- If the laboratory performs tests in the specialty of clinical cytogenetics, the individual functioning as the technical supervisor must- (i)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (i)(1)(ii) Have 4 years of laboratory training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics; or (i)(2)(i) Hold an earned doctoral degree in a biological science, including biochemistry, clinical or medical laboratory science, or medical technology from an accredited institution; or meet the education requirement at 493.1443(b)(3)(i)(B); and (i)(2)(ii) Have 4 years of laboratory training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics. (j) Notwithstanding any other provision of this section, an individual is considered qualified as a technical

	supervisor under this section if they were qualified and serving as a technical supervisor for high complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to have 1 (Technical Supervisor B) out of 2 licensed Technical Supervisors for Solid Tumor and Lymphoma Chemistry Testing. Findings Included: 1. Review of Clinical Laboratory Improvement Amendments Application for Certification noted the laboratory's Specialty was Chemistry and Subspecialty was Routine Chemistry. 2. Review of Technical Supervisor License revealed Technical Supervisor B had no State of Florida supervisor license for Chemistry. 3. Review of Independent Contractor Services Agreement read, "Laboratory Supervisor-Oversees Aventa laboratory equipment and inventory management." [written as seen] 4. Review of Element Aviti NGS Sequencing Machine Regular and Scheduled Maintenance revealed Technical Supervisor B signed off on Element Aviti NGS Sequencing Machine Regular and Scheduled Maintenance for 1/4/2024,12/11/2024 and 1/8/2025. 5. On 1/28/2026 at 4: 51 PM, the Director of Operations confirmed Technical Supervisor B did not have a State of Florida license.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to have 2 (Testing Personnel I and Testing Personnel J) out of 10 Licensed Testing Personnel for solid tumor and lymphoma chemistry testing. (see D6170)
D6170	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(a) Each individual performing high complexity testing must-- (a) possess a current license issued by the State in which the laboratory is located, if such licensing is required; and This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to have 2 (Testing personnel I and Testing Personnel J) out of 10 licensed Testing Personnel for solid tumor and lymphoma chemistry testing. Findings Included: 1. Review of Testing Personnel licenses revealed Testing Personnel I and Testing Personnel J had no State of Florida Technologist License. 2. Review of Proficiency Testing Report from January 1st to June 31, 2026, revealed Testing Personnel I and Testing Personnel J participated in the bioinformatics portion for solid tumor proficiency testing. 3. On 1 /28/2026 at 3:00 PM, the Director of Operations confirmed Testing Personnel I and Testing Personnel J did not have a State of Florida Testing Personnel license.