

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2111663	(X3) Date Survey Completed 08/20/2026
Name of Provider or Supplier Wellmont Medical Associates Inc	Street Address, City, State 671 Hwy 58 East, Norton, VA	
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 Wellmont Medical Associates, INC (DBA - Ballad Health Medical Associates) August 19-20, 2026 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Wellmont Medical Associates, INC (DBA - Ballad Health Medical Associates) was not in compliance with applicable Standards and Conditions under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows and include the Conditions: D2016 - 42 CFR. 493.803 Condition: Successful Participation D5400 - 42 CFR 493.1250 Condition: Analytic Systems D6000 - 42 CFR 493.1403 Condition: Laboratory Director
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.

	This CONDITION is not met as evidenced by: Based on a review of the Center for Medicaid and Medicare Services CASPER 0155D and 0096D reports, the laboratory's proficiency testing records and interviews, the laboratory failed to successfully participate within the Chemistry specialty for the Blood Urea Nitrogen analyte. The laboratory had unsatisfactory scores for the first and second event of 2026. Refer to D2096
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) (f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a review of the Center for Medicaid and Medicare Services CASPER 0155D (CMS 0155) and CASPER 0096D (CMS 0096) reports, the laboratory's proficiency testing (PT) records, and interviews, the laboratory failed to attain a score of at least eighty percent (80%) of acceptable responses for Blood Urea Nitrogen (BUN) for two consecutive chemistry events in calendar year 2026 resulting in an initial unsuccessful PT performance. Findings include: 1. A review of the CMS 0155 and 0096 reports revealed the laboratory participated in the American Proficiency Institute (API) program and received the following unsatisfactory scores for regulated analyte #0505 BUN: API 2026 Event 1 - 40% API 2026 Event 2 - 60% 2. A review of the laboratory's PT records (2025 Events 1-3, 2026 Events 1-2), a total of five events, revealed BUN scores of less than 80% for the following 2 consecutive chemistry events: API 2026 Event 1: BUN scored 40% (challenge sample CH-02 reported as 2 with acceptable range 4-9, CH-03 reported as 2 with acceptable range 4-9, CH-04 reported as 13 with acceptable range 14-19); API 2026 Event 2: BUN scored 60% (challenge sample CH-07 reported as 22 with acceptable range 16-21, CH-10 reported as 26 with acceptable range 20-25); resulting in an unsuccessful PT performance noted by API. 3. Interviews with the laboratory's two Medical Technologists and the Technical Specialist (TS) Manager at 4 PM on 8/19/26 and TS Manager at 12:30 PM on 8/20/26 confirmed the above findings.
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: A. Based on a tour of the laboratory, review of protocols, maintenance records, lack of documentation, and interviews, the laboratory failed to retain documentation of weekly maintenance protocols for one of one personnel eyewash station for 52 of 52 weeks in calendar year 2025. Findings include: 1. During a tour of the laboratory on 8/19/26 at 11 AM, the inspector noted one sink eyewash station in use perpendicular to the Beckman AU680 chemistry analyzer in core lab room #2. 2. Review of the laboratory's maintenance records revealed a safety protocol (titled: Weekly Eyewash

Form) that stated, "Initial and date verifying the eyewash station is checked weekly for the following: pathway to eyewash is free of obstructions, the eyewash fixture is free of obstructions in all directions, the nozzle dust caps/covers are in place and working properly, flush for 3 minutes and if problems are evident, call plant operations." 3. Review of the laboratory's maintenance logs for calendar year 2025 revealed no record of the eyewash weekly maintenance protocols outlined above. The inspector requested to review documentation that the eyewash station was flushed /checked weekly in calendar year 2025. The documentation was not available for review. 4. Interviews with the laboratory's two Medical Technologists and the Technical Specialist (TS) Manager at 4 PM on 8/19/26 and TS Manager at 12:30 PM on 8/20/26 confirmed the above findings. B. Based on tours of the laboratory, review of maintenance records, and interviews, the laboratory failed to follow established protocol to ensure a safe unobstructed pathway to one of one eyewash station as observed during the recertification survey, August 19-20, 2026. Findings include: 1. During a tour of the laboratory at 11 AM on 8/19/26, the inspector noted one sink eyewash station in use perpendicular to the core chemistry Beckman AU680 analyzer in lab room #2. 2. Review of the laboratory's maintenance records revealed a safety protocol (titled: Weekly Eyewash Form) that stated, "Initial and date verifying the eyewash station is checked weekly for the following: pathway to eyewash is free of obstructions." 3. During an additional tour/walk through of the laboratory at 3:30 PM on 8/19/26, the inspector noted no eye wash station in use for lab room #1. The inspector inquired regarding safety eyewash protocol for for the urinalysis processing and immunoassay laboratory room #1, noting that the laboratory's one single eyewash station was located in a different room and that the pathway would be obstructed if needed. The TS Manager stated at 3:30 PM on 8/19/26, "Currently the techs would have to go into the next laboratory room by the AU680 to get to the eyewash if needed. I can order an eyewash station to place near the analyzer and processing area so that they would be able to get to it unobstructed." 4. Interviews with the laboratory's two Medical Technologists and the TS Manager at 4 PM on 8/19/26 and TS Manager at 12:30 PM on 8/20/26 confirmed the above findings.

D5215

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(b)(2)

The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:

A. Based on a review of proficiency testing (PT) records, procedures, lack of documentation, and interviews, the laboratory failed to evaluate 10 non-graded chemistry analyte challenges reported on three of five PT events in calendar year 2025 and year to date 2026. Findings include: 1. Review of the laboratory's American Proficiency Institute (API) PT results (2025 Events 1-3, 2026 Events 1-2), a total of five Chemistry Module events, revealed that API released non-graded analyte responses for: Total Bilirubin (T Bili) due to variance on the following 3 events: API 2025 Event 2 - T Bili challenges CH-07, CH-09, CH-10; API 2025 Event 3 - T Bili challenge CH-12, CH-15; API 2026 Event 1 - T Bili challenge CH-06; D-dimer on the following event: API 2025 Event 2 - Ddimer challenges CM-07, CM-08; Folate on the following event: API 2025 Event 2 - Folate challenges IA-07, IA-09; --a total of 10

non-graded Core Chemistry Module challenge samples were reported by API as outlined above; 2. Review of the laboratory's PT documentation revealed no evaluation/verification of accuracy recorded for the non-graded chemistry challenge sample results outlined above. The inspector requested to review an evaluation for the non-graded challenges. The documentation was not available. 3. Review of the laboratory's Standard Operating Procedure manual revealed a policy (title: Quality Assessment Plan) that stated (under heading: Proficiency Testing Policy), "We will grade any proficiency testing challenge that is not officially graded by the proficiency testing program due to lack of participant consensus or any other reason. We will respond/record this score in the same manner we respond to official score." 4. Interviews with the laboratory's two Medical Technologists and the Technical Specialist (TS) Manager at 4 PM on 8/19/26 and TS Manager at 12:30 PM on 8/20/26 confirmed the above findings. B. Based on a review of PT records, procedures, lack of documentation, and interviews, the laboratory failed to evaluate one non-graded hematology analyte challenge reported on one of five PT events in calendar year 2025 and year to date 2026. Findings include: 1. Review of the laboratory's API PT results (2025 Events 1-3, 2026 Events 1-2), a total of five hematology module events, revealed that API released a non-graded analyte response on 2025 API Event 3 - Blood Cell Identification challenge BCI-15. 2. Review of the laboratory's PT documentation revealed no evaluation/verification of accuracy recorded for the non-graded result outlined above. The inspector requested to review an evaluation for the non-graded hematology challenge. The documentation was not available. 3. Review of the laboratory's Standard Operating Procedure manual revealed a policy (title: Quality Assessment Plan) that stated (under heading: Proficiency Testing Policy), "We will grade any proficiency testing challenge that is not officially graded by the proficiency testing program due to lack of participant consensus or any other reason. We will respond/record this score in the same manner we respond to official score." 4. Interviews with the laboratory's two Medical Technologists and the TS Manager at 4 PM on 8/19/26 and TS Manager at 12:30 PM on 8/20/26 confirmed the above findings.

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 a review of procedures, instrument maintenance logs, quality control (QC) records, lack of documentation, a tour, and interviews, the laboratory failed to: 1. follow their policy to record monthly maintenance procedures during 3 of 26 months reviewed and failed to retain 1 of 26 monthly logs record of daily/weekly/monthly maintenance for one of one Cepheid GeneXpert (timeframe: June 7, 2024 to August 19-20, 2026) - Refer to D5401; 2. document four of four Aerospray Hematology Stain reagents' lot numbers as opened per manufacturer's maintenance protocol for 26 of the 26 months reviewed (timeframe outlined #1) - Refer to D5415; 3. establish/document QC protocols for manual urinalysis sediment microscopic examinations for 26 of 26 months reviewed (timeframe outlined #1) - Refer to D5449; 4. establish/document QC

	protocols for stain quality of hematology manual differential counts for 26 of 26 months reviewed (timeframe outlined #1) - Refer to D5473.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (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 a review of procedures, instrument maintenance logs, lack of documentation, and interviews, the laboratory failed to follow their protocol to record performance of monthly maintenance procedures during 3 of 26 months reviewed and failed to retain 1 of 26 monthly logs of daily/weekly/monthly maintenance for one of one Cepheid GeneXpert (timeframe: June 7, 2024 to August 19-20, 2026). Findings include: 1. Review of the laboratory's procedures revealed a "BHMA Southwest Virginia Cancer Center Cepheid GeneXpert Maintenance Log Serial Number 842138" that stated "For each maintenance activity listed below check the boxes under the day of the month that the activities were performed and enter tech initials. Save the maintenance file for each month for a retained complete record of maintenance activities." 2. During a review of the core laboratory analyzers' maintenance records for timeframe of 6/7/24 -8/20/26, the inspector noted Cepheid Serial Number 842138 logs that lacked documentation for monthly maintenance tasks (Archive Tests and Clean/Replace Fan Filter) recorded for the following 4 months: July 2025 December 2025 May 2026 July 2026 3. The inspector noted that the Cepheid Serial Number 842138 December 2025 monthly chart was missing from the provided core laboratory analyzers' maintenance folders therefore daily maintenance tasks (Clean work area, close module doors) and weekly maintenance tasks (Power Down, Hub 1) were not available for review. The inspector inquired regarding the lack of documentation of the monthly maintenance protocols as being performed for the 4 months outlined above and regarding the lack of retention for December 2025 Cepheid maintenance charting of daily/weekly tasks. The records were not available for review. 4. Interviews with the laboratory's two Medical Technologists and Technical Specialist (TS) Manager at 4 PM on 8/19/26 and TS Manager at 12:30 PM on 8/20/26 confirmed the above findings.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on a tour, review of instrument maintenance records, procedures, lack of documentation, and interviews, the laboratory failed to document four of four Aerospray Hematology Stain reagents' lot numbers when opened per manufacturer's

maintenance protocol for 26 of the 26 months reviewed (timeframe: June 7, 2024 to August 19, 2026). Findings include: 1. During a tour of the laboratory at 11 AM on 8/19/26, the inspector noted one Aerospray Hematology Stat Stainer (Serial Number 915105) in use to prepare hematology stained slides for manual white blood cell differential microscopy evaluation. The inspector noted four ELITechGroup Aerospray onboard reagents: Reagent A Eosin Rinse, Lot 530353, open date written as 8/19/26, open stability 90 days; Reagent B Thiazin AzureB/Methylene Blue, Lot 531494, open date 7/24/26, open stability 90 days; Reagent C Eosin Stain, Lot 529623, open date 7/30/26, open stability 90 days; Reagent D Aerofix Fixative, Lot 536654, open date 8/11/16; 2. Review of the laboratory's hematology maintenance logs for the timeframe of 6/7/24 to 8/19/26, revealed the laboratory utilized the manufacturer's monthly "ELITechGroup Aerospray Hematology Stat Preventative Maintenance Chart" which outlined the following required documentation: Daily - Clean Cycle and Wipe Down Weekly - Nozzle Performance Checks Monthly - Clean Reagent Nozzles and Instrument Cleaning Reagent Lot Record Form - Instructions: Each time reagent bottles are replaced, record lot number from the new bottle in the box that corresponds to the reagent changed (Reagent A, B, C, D) and date of date when new bottle is opened. 3. The inspector noted that the Aerospray Hematology Stat Preventative Maintenance Charts for each of the 26 months reviewed lacked documentation on the Reagent Lot Record Form. The inspector inquired regarding the lack of documentation and requested to review the reagent lot records per the manufacturer's protocol for the timeframe outlined above. No records were available. 4. Review of the laboratory's Standard Operating Procedure manual revealed the following titled protocols: Preventative Maintenance of Equipment and Instruments- stated, under heading: Equipment Checks, "Technical staff will document required checks at the time they are performed on maintenance logs. The supervisor will review records monthly to ensure compliance. Corrective actions will be taken when needed and documented."; Quality Assessment Plan - stated, under heading Test Systems, "We will ensure that we follow the manufacturer's instructions for maintenance and checks." 5. Interviews with the laboratory's two Medical Technologists and the Technical Specialist (TS) Manager at 4 PM on 8/19/26 and TS Manager at 12:30 PM on 8/20/26 confirmed the above findings.

D5449

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(ii)(g)

(d)(3)(ii) Each qualitative procedure, include a negative and positive control material;

This STANDARD is not met as evidenced by:
Based on a tour, review of quality control (QC) records, procedures, lack of documentation, patient test logs, and interviews, the laboratory failed to establish and document QC protocols for negative and positive controls for their manual urinalysis sediment microscopy for 26 of 26 months reviewed while reporting 272 patient results (timeframe June 7, 2024 to August 19-20, 2026). Findings: 1. During a tour of the laboratory on 8/19/26 at 11 AM the inspector noted the laboratory's urinalysis microscopy testing area located in lab room #1 did not have photomicrographs or chart (s) displayed. The inspector noted that the daily check list posted in the urinalysis laboratory did not include verification of a daily negative/positive control. 2. Review of the laboratory's available daily checks/log sheets for all areas of the core laboratory revealed no record of daily urinalysis microscopy QC recorded during the timeframe of 6/7/24 to 8/20/26. 3. Review of the laboratory's Standard Operating Procedure manual revealed: Quality Assessment Plan protocol outlined under heading Quality

	Control stated, "All quality control testing are satisfactorily completed prior to patient testing. All actions are documented and kept for a minimum of two years."; Quality Assessment Plan protocol outlined under Quality Control heading Urinalysis stated, "A provider reads the microscopic, therefore no quality control is required." The inspector inquired regarding clarification of testing personnel responsible for reading patient urinalysis microscopy examinations. The Medical Technologists (2 of 2) stated at 2:30 PM on 8/19/26, "Here at our lab, we do those. We do not have providers that run tests or use the microscope." 4. The inspector requested to review urinalysis microscopy records for a daily negative/positive QC during the review timeframe of 6/7/24 to 8/20/26. The documentation was not available for review. 5. Review of patient test logs revealed that the laboratory resulted 272 urine microscopic reports during the review timeframe outlined above while not documenting daily QC. 6. Interviews with the laboratory's two Medical Technologists and the Technical Specialist (TS) Manager at 4 PM on 8/19/26 and TS Manager at 12:30 PM on 8/20/26 confirmed the above findings.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. This STANDARD is not met as evidenced by: Based on a tour, review of quality control (QC) records, lack of documentation, patient test logs, and interviews, the laboratory failed to establish/document QC procedures of hematology slides stained for manual differential microscopy for 26 of 26 months reviewed while reporting 1,143 patient results (timeframe June 7, 2024 to August 19-20, 2026). Findings: 1. During a tour of the laboratory at 11 AM on 8/19/28, the inspector noted one Aerospray Hematology Stat Stainer (Serial Number 915105) in use to prepare hematology stained slides for manual white blood cell (WBC) differential microscopy evaluation. The inspector noted four ELITechGroup Aerospray onboard reagents: Reagent A Eosin Rinse, Lot 530353, open date written as 8/19/26, open stability 90 days; Reagent B Thiazin AzureB/Methylene Blue, Lot 531494, open date 7/24/26, open stability 90 days; Reagent C Eosin Stain, Lot 529623, open date 7/30/26, open stability 90 days; Reagent D Aerofix Fixative, Lot 536654, open date 8/11/16. 2. Review of the laboratory's available daily checks /logsheets for all areas of the core laboratory revealed no records of hematology stain QC recorded during the timeframe of 6/7/24 to 8/20/26. The inspector requested to review hematology microscopy QC records for timeframe of 6/7/24 to 8/20/26. The documentation was not available for review. The inspector inquired regarding the laboratory's QC protocol for verifying proper nuclear and cytoplasmic coloration, red blood cell differentiation, and leukocyte granularity. The Technical Specialist (TS) Manager stated at 12:30 PM on 8/19/26, "I am in the process of updating our logsheets to include a check that the techs verify stain quality with a negative and positive for each day of manual differential examinations." 3. Review of the laboratory's Standard Operating Procedure manual revealed a Quality Assessment Plan protocol that outlined under Quality Control that, "All quality control testing are satisfactorily completed prior to patient testing. All actions are documented and kept for a minimum of two years." 4. Review of patient test logs revealed 1,143 patient manual WBC differential slide readings were resulted during the review timeframe outlined above. 5. Interviews with the laboratory's two Medical Technologists and the

	TS Manager at 4 PM on 8/19/26 and TS Manager at 12:30 PM on 8/20/26 confirmed the above findings.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. This STANDARD is not met as evidenced by: Based on a tour, review of procedures, lack of documentation, and interviews, the laboratory failed to follow their policy for method comparison for 14 of 14 routine chemistry analytes assayed by two methodologies during the review timeframe of June 7, 2024 to August 20, 2026. Findings include: 1. During a laboratory tour at 11 AM on 8/19/26, the inspector noted patient chemistry testing on a Beckman AU680 analyzer, Serial Number (SN) 2016074919. The inspector noted two Piccolo analyzers (SN P05482, P21204) on chemistry benches adjacent to the AU680. The inspector inquired regarding the use of the two Piccolo analyzers. The Technical Specialist Manager (TS Manger) stated at 11 AM on 8/19/26, "We use the Piccolo instruments for comprehensive metabolic panels when the AU680 is down. We use both of them as our backup chemistry instruments." 2. Review of the laboratory's Standard Operating Procedure manual revealed a policy (title: Quality Assessment Plan) that stated (under heading: Comparison of Test Results), "If a backup test system is available for use when the primary system is inoperable, we will evaluate the relationship of those results to the results from the primary system. We will document and keep the documentation with our quality assessment records." 3. Review of the laboratory's Quality Assessment (QA) records for the 26 months of review, 6/7/24 to 8/20/26, revealed no instrument comparisons for the following 14 analytes resulted by the two methods outlined above: Chloride, Creatinine, Potassium, Sodium, Alanine Transaminase, Carbon Dioxide, Aspartate Aminotransferase, Total Protein, Albumin, Total Bilirubin, Alkaline Phosphatase, Glucose, Blood Urea Nitrogen, and Calcium. The inspector requested to review the chemistry comparison results per the laboratory's QA protocol for the 14 analytes outlined above. The documentation was not available for review. 4. Interviews with the laboratory's two Medical Technologists and TS Manager at 4 PM on 8/19/26 and TS Manager at 12:30 PM on 8/20/26 confirmed the above findings.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on a review of procedures, temperature monitoring records, lack of documentation, and interviews, the laboratory failed to document corrective action when recorded temperatures were outside of acceptable limits for one of two reagent storage freezers for three consecutive days in December 2025. Findings include: 1. During a tour of the laboratory at 11 AM on 8/19/26, the inspector noted the

	following calibrator and quality control (QC) materials stored in Freezer #2: BioRad Multiquel, BioRad Liquichek Speciality Immunoassay, Liquichek Immunoassay Plus, Quidel Triage Cardiovascular, Beckman Coulter Thyroid Calibrator, Beckman Coulter Folate Calibrator, and Beckman Coulter Vitamin D Calibrator. The inspector noted that the freezer digital thermometer reading as -22 C. 2. Review of the laboratory's Standard Operating Procedure manual revealed a policy (titled, Preventative Maintenance of Equipment and Instruments) which outlined (under heading, Temperature Dependent Equipment): "Temperature dependent equipment containing reagents and patient specimens will be monitored daily and documented on temperature logs. If the acceptable temperature range is exceeded, corrective action will be documented by technical staff and when applicable contents will be evaluated for adverse effects." 3. The inspector selected six random monthly temperature monitoring charts for calendar year 2025 for the laboratory's two freezers. The inspector noted that Freezer #2 failed to meet stated criteria on the log(acceptable range -20 to -30 C) on the following dates: 12/15/25 - temperature recorded as -19 C; 12/16/25 - temperature recorded as -19 C; 12/17/25 - temperature recorded as -18 C; A total of three consecutive days for the identified device in December 2025 were recorded outside of acceptable range. 4. Review of available corrective action logs revealed no documentation of action taken when Freezer #2's temperature was outside of the acceptable range for the dates outlined above. The inspector requested to review documentation of the corrective action taken on 12/15 -12/17/26 for Freezer #2. The documentation was not available. 5. Interviews with the laboratory's two Medical Technologists and the Technical Specialist (TS) Manager at 4 PM on 8/19/26 and TS Manager at 12:30 PM on 8/20/26 confirmed the above findings.
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 a review of the Center for Medicaid and Medicare Services CASPER 0155D and CASPER 0096D reports, the laboratory's proficiency testing records, lack of documentation, and interviews, the laboratory director failed to ensure the overall quality of the laboratory services provided. Refer to D6016
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a review of the Center for Medicaid and Medicare Services CASPER 0155D and CASPER 0096D reports, the laboratory's proficiency testing (PT) records, and interviews, the laboratory director (LD) failed to ensure the overall quality of the laboratory services provided. The LD failed to ensure successful participation in their Health and Human Services (HHS) approved PT program. Refer to D2096