Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2273388	08/12/2025
Name of Provider or Supplier	**Street Address, City, State**	
Aema Labs, Inc	567 Faith Rd, Mooresville, 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. In addition, retain the following: This STANDARD is not met as evidenced by: Based on review of calibration records, lack of documentation and interview with general supervisor (GS) #1, 08/12/25, the laboratory failed to retain calibration records for the Pictus 700 for at least 2 years. Findings: Review of calibration records for Albumin (ALB) testing revealed calibration documentation was retained from 11 /11/24 to time of survey 08/12/25, a period of approximately 10 months. Review of calibration records for High-Density Lipoprotein (HDL) testing revealed calibration documentation was retained from 01/21/25 to time of survey 08/12/25, a period of approximately 8 months. Review of calibration records for Triglycerides (TRIG) testing revealed calibration documentation was retained from 02/18/25 to time of survey 08/12/25, a period of approximately 7 months. Interview with GS #1 at approximately 1:30 p.m. confirmed the laboratory failed to retain at least 2 years of calibration records for the testing performed on the Pictus 700. They stated the analyzer only retains the last 19 calibrations and they were unaware the records needed to be retained for 2 years.
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 review laboratory's policies and procedures, review of product inserts and manufacturer's instructions, review of temperature and humidity logs, review of instrument maintenance records, review of quality control, calibration and calibration verification records, lack of documentation and surveyor observations 08/12/25, the laboratory failed to monitor and evaluate the ongoing and overall quality of the analytic systems to identify and correct problems and prevent their recurrence. Findings: 1. The laboratory failed to ensure the Access 2 quality control procedure was complete. See D5403. 2. The laboratory failed to ensure reagents were stored according to manufacturer's requirements. See D5411. 3. The laboratory failed to establish ranges for the environmental conditions required for the performance of testing and for the storage of all reagents used in the performance of testing. See D5413. 4. The laboratory failed to ensure quality control reagents were labeled with correct expiration date. See D5415. 5. The laboratory failed to perform and document required maintenance for the Access 2 analyzer. See D5429. 6. The laboratory failed to perform calibration verifications for the testing performed on the Pictus 700 analyzer. See D5439.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and interview with GS #1 on 8/12/25, the laboratory's Beckman Coulter Access 2 procedure did not include a complete quality control (QC) policy. Findings: Review of the laboratory's "Beckman Coulter Access 2 Operation and Maintenance" procedure revealed "... 3.0 REAGENTS, SUPPLIES, AND EQUIPMENT ... 3.2. Reagents & Supplies: ... Quality Control (QC) Material: Assayed controls at multiple levels (e.g., Low,

	Normal, High). ... QUALITY CONTROL (QC) 4.1. Daily QC: QC must be run at the beginning of each day before running any patient samples. Run at least two levels of controls for each analyte being tested. QC must also be run after a new reagent pack is loaded or after major maintenance. ..." The procedure did not include the specific control material used, the specific levels to be tested, and the criteria for acceptability. During interview at approximately 2:45 p.m. GS #1 confirmed the Access 2 QC policy was not complete.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, surveyor observation, review of 2023, 2024, and 2025 "Uranus" freezer temperature logs and interview with GS #2 and Technical Supervisor (TS), the laboratory failed to ensure QC reagents were stored under the conditions required by the manufacturer since testing began in January of 2023, a period of approximately 32 months. Findings: Review of manufacturer's instructions for BIO-RAD Liquicheck Immunoassay Plus Control Trilevel QC reagent revealed storage requirements of -20C to -70C. During a tour of the laboratory at approximately 3:50 p.m., the surveyor observed BIO-RAD Liquichek Immunoassay Plus Control Trilevel (lot #1003930, expiration date 5/31/27) stored in the white Whirlpool refrigerator/freezer labeled "Uranus." Review of 2023, 2024 and 2025 temperature logs for the "Uranus" freezer revealed temperatures failed to meet the manufacturer's required storage temperatures since testing began in January of 2023. For example; July 2023 - 31 days February 2024 - 29 days January 2025 - 31 days February 2025 - 28 days March 2025 - 31 days May 2025 - 31 days During interview at approximately 4:34 p.m., TS stated all Access reagents and calibrators are stored at 0 to 10 degrees Celsius. During interview at approximately 5:00 p.m., GS #2 and TS confirmed the freezer ranges for Uranus were out of range for the BIO-RAD QC reagent. The TS stated the average freezer temperature range was -10.7C for all freezer items.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of laboratory procedure, review of system user and site planning

	guides, review of manufacturer's instructions, review of 2023, 2024 and 2025 temperature and humidity logs and interview with GS #2, the laboratory failed to establish freezer, humidity, refrigerator and room temperature ranges and failed to ensure ranges were entered in the TempStick Temperature Monitoring System since testing began in January of 2023, a period of approximately 32 months. Findings: Review of the Standard Operating Procedure for TempStick Temperature Monitoring revealed, "...ensure accurate ambient temperature reading...Follow TempStick manufacturer instructions for initial setup, pairing with the wireless network, and configuring alerts/notifications in the online portal..." Review of system user and site planning guides, and manufacturer instructions revealed the following examples of temperature and humidity requirements: 1. SCIEX LCMS 5500 System User Guide, "...room temperature 15C to 30C (59F to 86F)...relative humidity (RH) 20-80%..." 2. API 4000 Site Planning Guide, "...room temperature 15C to 30C (59F to 86F)...RH 20-80%..." 3. Supelco product insert for 17 Beta-Estradiol, Primary Measurement Standard, "...Refrigerator storage (2 to 8 C) conditions..." 4. BIO-Rad manufacturer instructions for the BIO-RAD Liquicheck Immunoassay Plus Control Trilevel revealed storage requirements of -20C to -70C. 5. BECKMAN COULTER ACCESS Immunoassay System Access Testosterone Instructions For Use, "... REAGENTS ... Store upright and refrigerate at 2 to 10C ..." 6. BECKMAN COULTER ACCESS Immunoassay System Access Testosterone Instructions For Use, "... SPECIMEN ... 2. ... Store samples tightly stoppered at room temperature(15 to 30C) for no longer than eight hours. If the assay will not be completed within eight hours, refrigerate the samples at 2 to 8C. If the assay will not be completed within 48 hours, or for shipment of samples, freeze at -20C or colder..." Review of 2023, 2024 and 2025 temperature and humidity logs revealed the following: No defined ranges for room, refrigerator and freezer temperature requirements and no defined ranges for humidity requirements. No system alerts/notifications configured for monitoring if/when temperature and humidity were out of range. During interview at approximately 12:15 p.m., GS #2 confirmed temperature and humidity ranges for the laboratory were not established and no ranges were entered in to the TempStick Temperature Monitoring system. They also confirmed the monitoring system would not alarm if no ranges were entered into the monitoring system.
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 surveyor observation, review of QC reagent package inserts and interview with GS #1, 08/12/25, the laboratory failed to ensure QC reagent was labeled with the expiration date after reconstituting. Findings: At approximately 2:00 p.m. surveyor observed on a shelf in the "Jupiter" laboratory refrigerator the following 4 bottles of QC reagent labeled with a reconstitution date. The 4 bottles of QC reagent failed to be labeled with the expiration date after reconstituting. a. 2 bottles of reconstituted Diatron QC reagent, Lot #331101 and Lot # 331102. b. 2 bottles of reconstituted Medicon QC reagent, Lot #1316 and Lot #1602. Review of package insert for the Diatron QC reagent revealed "Stability and Storage...2. Reconstituted Chemistry

	Control is stable for up to seven (7) days when stored a 2 - 8 C...". Review of package insert for the Medicon QC reagent revealed "STORAGE-STABILITY ... Reconstituted serum is stable for 7 days at 2 - 8 C...". Interview with GS #1 at approximately 2:00 p.m. confirmed the QC reagents were labeled with the reconstitution date but failed to include the new expiration date once reconstituted.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) 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 manufacturer's instructions, review of the laboratory's policies and procedures, review of 2024 and 2025 maintenance records, and interview with GS #1, 8/12/25, the laboratory failed to perform and document maintenance for the Beckman Coulter Access 2 analyzer at the frequency specified by the manufacturer. Findings: Review of the laboratory's "Beckman Coulter Access 2 Operation and Maintenance" procedure revealed "... 8.0 MAINTENANCE 8.1 Daily: Perform the automated 'Daily Cleaning' procedure. Check and manage fluid levels (Substrate, Wash Buffer, Waste). Wipe down the exterior of the instrument with an approved disinfectant. 8.2 Weekly /Monthly: Perform weekly and monthly maintenance tasks as prompted by the system software. Refer to the manufacturer's manual for detailed instructions on these tasks. Document all maintenance activities in the instrument's maintenance log. ... 9.0 RECORDS Maintenance Logs: All daily, weekly, and monthly maintenance must be documented. ...". Review of 2024 and 2025 maintenance records revealed the laboratory routinely failed to perform and document the manufacturer's specified daily and weekly maintenance. Examples: 1. January 2024 - weekly maintenance not documented 2 of 4 weeks (weeks 3 and 4). 2. April 2024 - daily maintenance not documented 5 of 22 days, weekly maintenance not documented 2 of 4 weeks (weeks 1 and 3). 3. August 2024 - weekly maintenance not documented 1 of 4 weeks (week 2). 4. October 2024 - daily maintenance not documented 3 of 23 days, weekly maintenance not documented 5 of 5 weeks. 5. January 2025 - daily maintenance not documented 18 of 22 days, weekly maintenance not documented 4 of 5 weeks (weeks 1, 2, 3 , and 4). 6. May 2025 - daily maintenance not documented 14 of 22 days. During interview at approximately 11:45 a.m., GS #1 stated some days no patient testing was performed, and some days the maintenance was missed.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical

	parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of 2023, 2024 and 2025 QC records, review of calibration records, lack of documentation and interview with GS #1, 08/12/25, the laboratory failed to perform calibration verifications to verify the laboratory's established reportable ranges every 6 months for the testing performed on the Pictus 700 chemistry analyzer since testing began in June of 2023, a period of approximately 27 months in which calibration verifications were not performed. Findings: Review of 2023, 2024 and 2025 QC records revealed the laboratory performs 2 levels of QC each day of patient testing. Review of 2023, 2024, and 2025 calibration records that were retained by the laboratory (See D3031) revealed the laboratory performs 2 point calibrations as required by the manufacturer. Review of laboratory records revealed no documentation the laboratory performed calibration verifications utilizing 3 levels of calibration reagent, a minimal value, a mid-point value, and a maximum value, as least every 6 months to verify the laboratory's established reportable ranges. Interview with GS #1 at approximately 1:30 p.m. confirmed the laboratory failed to perform calibration verifications at least every 6 months for the testing performed on the Pictus 700 analyzer since patient testing began. They stated they were unaware calibration verifications were required.
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 review of patient test reports from 2023, 2024, and 2025, and interview with the GS #2 and TS 08/12/2025, the laboratory test report failed to include the name and physical address where the testing was performed. Findings: Review of patient test reports revealed the absence of the laboratory name and physcial address. Examples: patient #1 - male excel 2023, patient #2 - fem excel December 2024, and patient #3 - male excel July 2025. During interview at approximately 2:01 p.m., GS #2 and TS confirmed the name and physical address of the laboratory was not included on the patient test reports.
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 review of validation records and interviews with GS #1 and LD 08/12/25, the LD failed to ensure verification procedures used by the laboratory were adequate to determine all performance characteristics of testing performed on the Access 2, the LCMS and the Pictus 700 analyzers. Findings: 1. Review of validation records for the Beckman Coulter Access 2 (SN 510140) used for blood spot PSA testing revealed there were no records available to indicate that the laboratory established performance characteristics of sensitivity, specificity (including interfering substances), and reference range. 2. Review of validation records for the two Beckman Coulter Access 2 analyzers (SN 510140 and SN 509151) revealed the records had not been signed and dated by the LD to indicate review and approval for use. 3. Review of validation records for the LCMS analyzer revealed the LD failed to sign his review and approval prior to the performance of patient testing, the documentation was signed on day of survey, 08/12/25. 4. Review of validation records for the Pictus 700 analyzer revealed the LD failed to sign his review and approval prior to the performance of patient testing, the documentation was signed on day of survey, 08/12/25. During interview at approximately 11:15 a.m., GS #1 confirmed that the validation records had not been signed and dated by the previous laboratory director to indicate review and approval.
D6088	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4) (e)(4) Ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed and that-- This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, review of analyzer validation records and interviews with GS #2, 08/12/25, the LD failed to ensure the laboratory was enrolled in a proficiency testing (PT) program prior to reporting patient test results. Findings: Review of laboratory records revealed the laboratory enrolled in PT with Medical Laboratory Evaluation (MLE) on 07/02/25 for all laboratory testing performed. Review of laboratory records revealed no documentation of enrollment in PT prior to 07/02/25. Review of analyzer validation records revealed the following: 1. The laboratory validated and began testing the following analytes on the Pictus 700 analyzer in June of 2023: ALB, TRIG and HDL. 2. The laboratory validated and began testing the following analytes on the Access analyzer in January 2023: blood spot Prostate-Specific Antigen (bsPSA)). 3. The laboratory validated and began testing the following analytes on the Access analyzer in May 2024: Testosterone (TESTO), Free Testosterone (FTESTO), Prostate-Specific Antigen (PSA), Dehydroepiandrosterone sulfate (DHEA), Free Triiodothyronine (FT3), Esterdiol (E3), Progesterone (P4), Insulin (INS) Luteinizing hormone (LH), Follicle-stimulating hormone (FSH) and Sex Hormone Binding Globulin (SHBG). 4. The laboratory validated and began testing the following analytes on the LCMS analyzer in January of 2023: TESTO, DHEA, FTESTO, and E3. 5. The laboratory validated and began testing the following analytes on the LCMS analyzer in May of 2024: Creatinine (CREA), and Vitamin D3 (VITD3). Review of laboratory records revealed no documentation of a verification of accuracy or participation in PT since testing began on the Pictus 700 analyzer in June of 2023, a period of approximately 27 months. Review of laboratory records revealed no documentation of a verification of

	accuracy or participation in PT since testing began on the Access 2 analyzer for bsPSA testing in January of 2023, a period of approximately 32 months. The records also revealed no documentation of a verification of accuracy for the above listed testing on the Access 2 that began in May of 2024, a period of approximately 15 months. Review of laboratory records revealed no documentation of a verification of accuracy or participation in PT since testing began on the LCMS analyzer for the above listed testing that began January of 2023, a period of approximately 32 months. The records also revealed no documentation of a verification of accuracy or participation in PT for the above listed testing on the LCMS that began May 2024, a period of approximately 15 months. Interview with GS #2 at approximately 10:30 a. m. confirmed the laboratory failed to enroll in PT until 07/02/25 for all testing performed. They also confirmed the laboratory had not performed a verification of accuracy since testing began on the Pictus 700, Access and LCMS analyzers.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) (e)(13) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of documentation and interview with LD 08/12/25, the LD failed to ensure policies were established for monitoring the responsibilities delegated to the TS, GS #1 and GS #2. Findings: Review of laboratory policies and procedures revealed no documentation of a policy or procedure for monitoring the responsibilities delegated to the TS, GS #1 and GS #2. Interview with LD at approximately 11:15 a.m. confirmed the laboratory had not established a policy or procedure for monitoring the responsibilities delegated to the TS, GS #1 and GS #2.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) (e)(15) 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 review of laboratory policies and procedures, lack of documentation and interview with LD 08/12/25, the LD failed to specify in writing the procedures (testing) each testing personnel (TP) is authorized to perform. Findings: Review of laboratory policies and procedures revealed no documentation the LD specified in

	writing the testing each TP is authorized to perform. Interview with LD at approximately 11:15 a.m. confirmed they had not specified in writing the testing each TP is authorized to perform.
D6134	CLINICAL CONSULTANT CFR(s): 493.1453 The laboratory must have a clinical consultant who meets the requirements of 493. 1455 of this subpart and provides clinical consultation in accordance with 493.1457 of this subpart. This CONDITION is not met as evidenced by: Based on review of clinical consultant (CC) qualification records, lack of documentation and interview with GS # 2, 08/12/25, the laboratory failed to ensure the CC was licensed to practice medicine in the state of North Carolina. Findings: See D6135.
D6135	CLINICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1455 The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493. 1443(b)(1), (2), or (3) for the subspecialty of oral pathology, 493.1443(b)(5); or (b) Be a doctor of medicine, doctor of osteopathy, doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located. This STANDARD is not met as evidenced by: Based on review of clinical consultant (CC) qualification records, lack of documentation and interview with GS # 2, 08/12/25, the laboratory failed to ensure the CC was licensed to practice medicine in the state of North Carolina. Findings: Review of CC qualification records revealed no documentation of a current license to practice medicine in the state of North Carolina. Interview with GS #2 at approximately 10:30 a.m. confirmed the CC did not have a license to practice medicine in the state of North Carolina. They stated the CC was licensed in other states but had not yet applied for a license in North Carolina.
D6139	CLINICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1457(c) (c) Ensure that reports of test results include pertinent information required for specific patient interpretation; and This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of a random patient test report (patient #3, male excel July 2025), and interview with GS #2 8/12/25, the clinical consultant failed to ensure patient Prostate-Specific Antigen (PSA) test reports included the assay method used by the laboratory. Findings: Review of manufacturer's instructions for the Beckman Coulter Access Hybritech PSA assay revealed

	"WARNING The concentration of PSA in a given specimen determined with assays from different manufacturers can vary due to differences in assay methods and reagent specificity. The results reported by the laboratory to the physician must include the identity of the PSA assay used. Values obtained with different assay methods cannot be used interchangeably. ..." Review of a random patient test report (patient #3, male excel July 2025) revealed the PSA result did not include the assay method used by the laboratory. During interview at approximately 2:05 p.m., GS #2 confirmed patient test reports did not include the PSA assay method used.
D6151	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463(b)(3)(4) (b)(3) Providing orientation to all testing personnel; and (b)(4) Evaluating and documenting the competency of all testing personnel. This STANDARD is not met as evidenced by: Based on review of laboratory director's delegation of duties, review of laboratory policy, review of testing personnel (TP) training and competency records, lack of documentation and interviews with TP #2, 08/12/25, the general supervisor (GS #1) failed to ensure training was documented for TP #2 and also failed to ensure competency was evaluated and documented biannually the first year of testing and annually thereafter for TP #2 since they began testing in January of 2023, a period of approximately 31 months in which competency of TP #2 was not evaluated . Findings: Review of laboratory director's delegation of duties revealed GS #1 was delegated the responsibilities of "...Ensuring all testing personnel receive orientation and training....Evaluating and documenting the competency of all testing personnel annually....". Review of laboratory policy "Laboratory Proficiency and Competency Plan" revealed under section 5.0 "Competency Assessment Program...All testing personnel must have their competency assessed for each test they are authorized to perform...Frequency...Initial...Semi-Annually... Annually...". Review of TP #2 training and competency records revealed no documentation of training or competency assessments. Interview with TP #2 at approximately 10:45 a.m. confirmed they began testing in January of 2023 and there was no training documentation or documentation of competency evaluations since they began in January of 2023.